CIVIL JUSTICE & NATIONAL ADVOCACY

Center for Justice & Democracy's
Public Policy Clinic
New York Law School
185 West Broadway
New York, NY 10013

April 2, 2021

Janet Woodcock, MD, Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Re: Revival of Generic Labeling Rule

My name is Megan Galloway. I am a student intern for the Center of Justice & Democracy, at New York Law School. I am writing on behalf of our clinic to urge the FDA to consider reviving its former proposed rule to allow ANDA holders to submit CBE-o supplements for generic drug labeling that differs from the labeling RLD. This rule would allow generic manufacturers to change warning labels and packaging they know to be unsafe, just as brand name manufacturers are currently able to do.

As you may know, the agency originally proposed this rule during the Obama administration on November 13, 2013,[1] but withdrew it during the Trump administration on December 2018.[2] When the FDA originally proposed this rule, it undertook an extensive period of notice and comment, including a public hearings during which the agency heard from numerous generic drug victims who testified in favor of the rule.[3] The agency finally withdrew it after heavy lobbying by the generic drug industry.[4] We believe this was a mistake. This proposed rule would greatly benefit consumer safety, and any issues raised by the industry far outweigh any alleged risks.

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[1] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, *Pages 67985 – 67999* [FR DOC # 2013-26799] https://www.federalregister.gov/documents/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products

[2]FDA Withdraws Proposed Rule on Generic Label Changes https://www.raps.org/news-and-articles/news-articles/2018/12/fda-withdraws-proposed-rule-on-generic-label-chang

[3] FOOD & DRUG ADMINISTRATION (FDA) CENTER FOR DRUG EVALUATION AND RESEARCH Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products Public Meeting https://www.regulations.gov/document/FDA-2013-N-0500-0112

[4]FDA Withdraws Proposed Rule on Generic Label Changes https://www.raps.org/news-and-articles/news-articles/2018/12/fda-withdraws-proposed-rule-on-generic-label-chang

Consumers depend on the safety of the drugs they are given, most of which are generic. At the time the rule was proposed, 80% of the general public took generic drugs, while pharmacies filled 90% of prescriptions with generic drug brands. Additionally, most Americans' insurance plans only cover generic brand name prescriptions. Therefore, it is imperative these generic companies have the ability to promptly change their labels so they may reflect currently known adverse effects of their drugs and consumers may gain protection and confidence in a drug's safety that does not currently exist.

Moreover, the rule was proposed response to the Supreme Court's ruling in *PLIVA, Inc v. Mensing*. There, the Court decided that Mensing could not recover damages for debilitating injuries she received from a drug with an inadequate warning label because her prescription was filled with a generic version rather than a brand-name version.[5] The *Mensing* decision created an arbitrary distinction, where an injured consumer's ability to obtain relief turns solely on whether their prescriptions is filled with a brand-name or a generic drugs. The ruling also grants immunity to the generic drug industry for marketing drugs with labels the companies knows are unsafe.

Those opposing the rule say that healthcare professionals would be confused by differing labels, thus causing a risk to consumer safety, and that the costs of generic drugs would increase due to litigation.[6] They are wrong. Healthcare professionals already encounter differing labels among brand name and generic drugs based on the current FDA rules. The current proposed rule would not be adding any additional obstacles for healthcare professionals. As far as costs, generic drug companies have only had immunity since 2011. For decades before that, the industry encountered lawsuits and litigation. Yet drug costs stayed low. There is no reason to believe they would not remain low if this rule were changed.

Until generic drug manufacturers are given a mechanism to provide correct and appropriate warnings on their labels, patients and consumers will always be at the mercy of these companies. Patient and consumer safety has fueled this rule and we cannot forget what is at stake by failing to adequately protect them. We urge the FDA to reintroduce this rule so that consumers are protected and the generic drug industry can no longer escape accountability for harm.

Thank you for your time and consideration.

Sincerely,

Megan Galloway

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[5] *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011)

[6] FOOD & DRUG ADMINISTRATION (FDA) CENTER FOR DRUG EVALUATION AND RESEARCH Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products Public Meeting https://www.regulations.gov/document/FDA-2013-N-0500-0112