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October 22, 2014

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Burwell:

The purpose of this letter is to urge that you order the Food and Drug Administration (FDA) to withdraw a dangerous proposed pharmaceutical industry Guidance because it undermines the agency's drug safety laws and regulations.

The following concern highlights the dangers to patients of this proposal:

What if pharmaceutical companies could give your doctor information that claims the medications it markets are less risky than FDA-approved labels say they are?

On June 11, the FDA proposed a draft "Guidance for Industry on Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products — Recommended Practices."¹

The Guidance would allow pharmaceutical companies that believe FDA-approved safety labeling information for a drug overstates the medication's risks to tell doctors that the risks are lower than those described in the FDA-approved labeling. Company salespeople could inform physicians of the purportedly lower risks by distributing peer-reviewed articles assessing a drug's risks and discussing with doctors the information about the "lower" risks, without the FDA reviewing the articles, analyzing the data, or approving distribution of that information.

The FDA acknowledged its awareness of the danger of this proposed Guidance in its June 6, 2014, response to two petitions from the drug and medical device industry seeking authority to engage in the distribution and communication of information regarding off-label uses of marketed drugs and devices. The FDA stated, "Information that emphasizes the drugs' claimed benefits, while minimizing the drugs' limitations and adverse effects, may inappropriately

¹ Food and Drug Administration. Guidance for Industry Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400104.pdf>. Accessed October 17, 2014.

influence a physician's prescribing decisions in a manner that is not in the patient's best interest."²

After the proposed Guidance was published, I wrote an article objecting to it that was published in the *Journal of the American Medical Association's JAMA Internal Medicine* (enclosed) and submitted this article to the docket for the proposed Guidance,³ along with my recommendation that the Guidance be withdrawn.⁴

If a company believes that new information concerning a drug supports a reduction in risk, the company should inform the FDA and provide the evidence, as is required under current regulations; if the agency's objective evaluation confirms that the labeling overstates the risk, the label can then be changed with agency approval. Just as FDA review and approval of the warnings is wisely required when a drug first comes on the market, FDA review and approval should be maintained before a company can change — orally or on the labeling — approved warnings and other descriptions of risk information.

Allowing off-label statements asserting reduced risk is the wrong approach.

As of today, there have been 1,781 comments submitted to the docket for this proposed Guidance, but, close to two months since the docket was closed for comments (August 25), the text of only one comment has been posted. I have just requested from the FDA, under the Freedom of Information Act, the full text of all of the comments.

I hope you will order the FDA to retract this ill-conceived Guidance.

Sincerely,

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Enclosure

² Regulations.gov. Citizen Petition Approval Response from FDA CDER to Ropes & Gray LLP and Sidley Austin LLP. <http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-1079-0004>. Accessed October 17, 2014. Pages 5-6.

³ Regulations.gov. Comment form. <http://www.regulations.gov/#!submitComment;D=FDA-2014-D-0758-0002>. Accessed October 17, 2014.

⁴ Public Citizen. Public Citizen Opposes FDA Guidance for Distribution of Risk Information. <http://www.citizen.org/hrg2215>. Accessed October 17, 2014.