Dooling, Bridget C.E.

From: Noe, Paul <Paul_Noe@afandpa.org>
Sent: Wednesday, November 20, 2013 7:38 PM
To: Dooling, Bridget C.E.
Cc: Brenda Aguilar (brenda_aguilar@omg.eop.gov); Malanoski, Margaret A.
Subject: Follow up on Meeting on FDA e-Labeling Rule
Attachments: PPLA & AF&PA Documents to OIRA.pdf

Dear Bridget,

Thank you again for meeting with the representatives from the Pharmaceutical Printed Literature Association (PPLA), Domtar Paper, Twin Rivers Paper, and the American Forest and Paper Association (AF&PA) on Thursday, November 7th. As you recall, we requested the meeting to discuss the implications of a potential proposed rule from the Food and Drug Administration (FDA), entitled "Electronic Distribution of Prescribing information for Human Prescription Drugs Including Biological Products" (RIN: 0910-AG18).

Attached please find a comprehensive, interactive file containing all the documents referenced during our meeting. Included are: a legal analysis regarding FDA's lack of authority to issue such a regulation, along with the Congressional intent and history regarding labeling; the Congressionally-mandated Government Accountability Office (GAO) report from July 2013, which studied the issue of electronic drug labeling; and the 2006 physician labeling rule which touts the benefits of and the importance of labeling accompanying the drug product.

First and foremost, we believe FDA clearly lacks the authority to require the complete replacement of required paper labeling for prescription drug products. Congress has stated that the labeling must be "written, printed, or graphic matter", and "upon the immediate container" (21 USC 321 (k) and (m)). When presented the opportunity to amend these requirements for prescription drug products, Congress has instead reiterated its position. As recently as Monday (November 18, 2013), with the Senate passage of H.R. 3204 (the Drug Quality and Security Act, now awaiting the signature of President Obama), Congress has rejected the inclusion of a provision allowing FDA the authority to make such a change.

The GAO Report, entitled *Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use*, highlights many reasons why electronic labeling is not in the best interest of American patients. The report states, "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." Further, GAO, the official investigative arm of the U.S. Congress, states that disadvantages would offset advantages gained from relying on electronic-only drug labeling.

Lastly, FDA finalized its rule, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* , in 2006 (21 CFR Parts 201, 314, and 601). FDA concluded that, by just making changes to the size, content, and format, and standardizing the drug labeling, health care practitioners would be better informed about drugs they are prescribing to patients, thus improving the effectiveness of treatment and reducing the number of preventable adverse reactions experienced by patients. Accordingly, there is currently no data that we are aware of to suggest that the elimination of paper drug labeling would be beneficial to public health. If the printed labeling for health care practitioners is eliminated and supplied via electronic-only means, we

believe that patient safety would be at risk if the information was compromised, incorrect, or unavailable (as supported by the July 2013 GAO report).

In closing, we believe that FDA is acting outside its authority and is proposing an unsound policy by attempting to eliminate this vital tool for health care professionals. Simply put, this proposed rule should be withdrawn based on all of the considerations we discussed. Otherwise, we are concerned that serious adverse public health effects and other costs would overwhelmingly outweigh any benefits of such a regulation.

Again, thank you for your time on November 7th, and for the opportunity to present our position for our industry, our health care practitioners, and American patients. If you have any questions, please follow up with us at any time.

Best regards,

Paul Noe