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August 18, 2017

**SUBMITTED ELECTRONICALLY**

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Re: Docket No. FDA-2014-N-0345: Data To Support Drug Product Communications as Used by the Food and Drug Administration**

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments on the U.S. Food and Drug Administration's (FDA or the Agency) Paperwork Reduction Act (PRA) notice, "Data To Support Drug Product Communications as Used by the Food and Drug Administration" (PRA Notice or the Notice).[1]

PhRMA represents the country's leading innovative biopharmaceutical research and manufacturing companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than half a trillion dollars in the search for new treatments and cures, including an estimated $65.5 billion in 2016 alone.

The PRA Notice concerns studies that FDA plans to conduct regarding communications on regulated drug products. In the PRA Notice, FDA states, in relevant part:

> FDA will use [] methods to test and help refine messages and other communications but will generally conduct further research before making important decisions. FDA will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products,

[1] 82 Fed. Reg. 27840 (June 19, 2017) ("Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration"); Docket No. FDA-2014-N-0345.

> and consumer and professional education. Annually, FDA projects about 45 communication studies using the variety of test methods listed in this document.[2]

Although it is not entirely clear, FDA seems to have in mind studies regarding communications the Agency itself might make and possibly communications that drug manufacturers or others might make about a regulated medicine.

PhRMA recognizes the importance of FDA conducting communication studies on appropriate topics. At the same time, the Agency apparently plans to undertake a large number of such studies per year, and it will be important to ensure that the planned studies are properly conceptualized and fit together into a sensible and coherent overall work plan. We thus request that FDA annually publish a list of proposed communication studies and the specific subject matter of such studies. While FDA does list broad topic categories (e.g., patient labeling, emerging risk communications) in the PRA Notice, this very general listing does not provide adequate notice to the public about FDA's plans and does not permit interested stakeholders to assess whether these studies are "necessary for the proper performance of FDA's functions."[3] Even if FDA subsequently publishes more detail before proceeding with an individual study, FDA should provide transparent public notice about its overall plans in this important area, as FDA does when it publishes items such as the semi-annual Unified Agenda of Regulatory and Deregulatory Actions or the annual CDER Guidance Agenda.

Thank you for considering these comments. Please do not hesitate to contact us if you have any questions.

Sincerely,

_____/s/_____
Kelly Goldberg,
Vice President, Law/Senior Counsel for Biopharmaceutical Regulation

_____/s/_____
Ryan Kaat
Senior Director, Law

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[2] *Id*. at 27841.

[3] *Id*.