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

Re: Food and Drug Administration's Draft Strategic Priorities for 2014–2018 (Docket No. FDA-2014-N-0833)

These comments are submitted on behalf of the Medical Information Working Group (MIWG) in response to FDA's July 1, 2014 notice (79 Fed. Reg. 37332) inviting comments on the Agency's Draft Strategic Priorities for 2014–2018 (Draft Strategic Priorities).[1]

The MIWG is pleased that FDA's Draft Strategic Priorities document (pp. 5, 30) identifies "promot[ing] better informed decisions about the use of FDA-regulated products" as one of the Agency's four "core mission goals and objectives." Since 2008, and consistently with its core mission, the MIWG has made submissions to FDA advancing various requests intended to improve the regulatory and enforcement climate for manufacturer dissemination of science-based, accurate information about medical products. The MIWG's requests have the same objective as that set forth by FDA in the Draft Strategic Priorities document—protecting and promoting the public health by facilitating well-informed decisions about the use of drugs and medical devices by making high-quality information available to patients and their caregivers, health care practitioners, payors, and other stakeholders.

FDA's Draft Strategic Priorities document correctly observes that, "[a]s consumers, patients, health professionals, and purchasers gain access to relevant information about . . . medical products . . . , they are better able to make informed decisions about whether or how to use these products."[2] Giving stakeholders full access to truthful, non-misleading information bearing on health care decisions is vital to the public health. The MIWG and its members therefore support FDA's identification of this goal among the Agency's four core objectives for the next five years. We also appreciate FDA's commitment to "continue to work in collaboration with partners inside and outside of the Federal government to determine innovative and effective ways to provide better information to the public and to develop outreach and other tools that can assist in better decision-making."[3] We are eager to continue working

[1] The MIWG is a coalition of medical product manufacturers formed to consider issues relating to the federal government's regulation of truthful, non-misleading, scientifically substantiated manufacturer communications about new uses of approved drugs and approved/cleared medical devices. The members of the MIWG are: Allergan, Inc.; Amgen Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceuticals Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US.

[2] Draft Strategic Priorities at 30.

[3] Id.

with FDA to further its goal of promoting better informed decision-making and believe manufacturers of medical products can be an important source of information for physicians, patients, payors, and others making health care decisions.

Part I outlines the informational needs of participants in the health care system and highlights manufacturers' ability to advance FDA's goal of meeting those needs. Part II examines how allowing manufacturers greater ability to provide information about their products serves FDA's broad aim of updating its regulatory policies in light of dramatic shifts in society, today's health care system, and the judicial landscape.

I. Drug and Device Manufacturers Have Unparalleled Access to Information about Their Own Products and Can Play an Integral Role in Providing the Information Stakeholders Need to Make Informed Decisions.

The MIWG and its members fully support FDA's aims to "[e]nhance communication of FDA's benefit-risk assessment for approved products" and to "[d]isseminate FDA product information through partnerships with stakeholders and outreach at national meetings and conferences."[4] We interpret these objectives as involving better communication of product risks and benefits as described in FDA-approved product labeling. Once FDA authorizes the marketing of a medical product, it must be accompanied by labeling that provides important information about the product's approved uses. Product labeling thus is a key source of information about drugs and devices, and we believe enhanced access to information in approved labeling plays a beneficial role in shaping health care decisions.

Participants in the modern health care system have other informational needs as well—requiring a great deal of information that does not, or cannot, appear in product labeling. Labeling is not a comprehensive source of clinically relevant information. As FDA recognized almost forty years ago, "the labeling of a marketed drug does not always contain all the most current information available to physicians relating to the proper use of the drug in good medical practice. Advances in medical knowledge and practice inevitably precede labeling revision."[5] Clinical decisions are based not only on information adjudicated by FDA in labeling, but also on the prescriber's own judgment, informed by a range of other sources of information unrelated to approved labeling and not reviewed by FDA, such as anecdotal evidence, peer experience, and medical and scientific literature. Patient preferences (e.g., tolerance for risk) and other key values, and payor-driven considerations (e.g., formulary status) also influence therapy selection.

Approved product labeling necessarily excludes medical and scientific information that is highly relevant to health care decision-making. Statements in approved labeling must meet regulatory standards, and therefore often must be supported by data from randomized controlled trials (RCTs). Health care practitioners, patients and their caregivers, and payors, however, have different informational needs, and information that would not qualify for inclusion in approved labeling may nonetheless be of considerable value to them. Real-world evidence, data from observational studies, meta-analyses, retrospective analyses, and other non-RCT sources of information provide useful information and are commonly considered in clinical and payor decisions. Studies comparing the effectiveness of one product or intervention to another also may shape decision-making, and this comparative effectiveness

[4] Id. at 32.
[5] 40 Fed. Reg. 15392, 15394 (Apr. 7, 1975).

research (CER) usually does not involve the head-to-head clinical trials required to support statements in approved labeling.

Manufacturers have access to a trove of information about biopharmaceutical and medical technology products, giving them a unique ability to assist FDA in promoting informed decision-making about the use of these products.[6] And FDA has set out a number of safe harbors aimed at enabling manufacturers to communicate important information to those who need it. Presently, however, the boundaries of these safe harbors often are not clearly defined, and new safe harbors are needed to allow manufacturers to communicate information important to the choices many decision-makers face. Thus, truly engaging manufacturers in meeting stakeholders' informational needs will require clarification of existing safe harbors and development of new safe harbors to encompass the full range of appropriate manufacturer communications about medical products.

In past submissions to FDA,[7] the MIWG and its members have outlined specific proposals to enable manufacturers to provide product information that is critical to informed decision-making. We believe the changes we have proposed will assist FDA in achieving its goal of promoting better informed decision-making, and we look forward to continuing our work with FDA to advance this important aim.

II. The Goal of Promoting Informed Decision-Making Provides an Opportunity for FDA to Adapt its Policies to the Changing Landscape.

Allowing manufacturers to communicate accurate, up-to-date, and complete information to participants in the health care system would not only enable stakeholders to make better informed decisions, but also help FDA achieve its broader aim of updating its regulatory policies. Senior FDA officials have indicated that the Agency is reevaluating its policies in light of changes in societal expectations, the health care delivery system, and applicable law. Speaking at the Food and Drug Law Institute's (FDLI's) Annual Conference in

[6] Wyeth v. Levine, 129 S. Ct. 1187, 1202 (2009) ("Manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.").

[7] The MIWG and its members have made these submissions to the Agency since 2008: (1) Comments, Draft Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, Docket No. FDA-2008-D-0053 (Apr. 18, 2008); (2) Amended Comments, FDA Transparency Task Force, Docket No. FDA-2009-N-0247 (Apr. 15, 2010); (3) Citizen Petition, Docket No. FDA-2011-P-0512 (July 5, 2011); (4) Comments re: Scientific Exchange and Responses to Unsolicited Requests, Docket Nos. FDA-2011-N-0912 and FDA-2011-D-0868 (Mar. 27, 2012); (5) Comments, Docket Nos. FDA-2011-P-0512 and FDA-2011-D-0868 (Mar. 1, 2013); (6) Comments, CDER Medical Policy Council, Docket No. FDA-2013-N-0206 (July 16, 2013); (7) Citizen Petition, Docket No. FDA-2013-P-1079 (Sept. 3, 2013); (8) Comments, Food and Drug Administration Safety and Innovation Act Section 907 Report (Nov. 20, 2013); (9) Comments, Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, Docket No. FDA-2013-N-1430 (Apr. 14, 2014); and (10) Comments, Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses-Recommended Practices, Docket No. FDA-2008-D-0053 (May 2, 2014). The MIWG has also participated as amicus curiae in litigation relating to the role of manufacturers in distributing information containing information about new uses. See Brief Amicus Curiae for MIWG, United States v. Caronia, No. 09-5006-CR, 703 F.3d 149 (2d Cir. 2012).

April 2014, Center for Drug Evaluation and Research (CDER) Director Janet Woodcock observed that FDA is "aware of the outside world," including recent court rulings.[8] Dr. Woodcock further noted that "[t]here is a paradigm that has existed for quite a long time," but that "[c]ommunication has changed, attitudes have changed, health care has changed."[9] Also speaking at the FDLI Annual Conference, FDA Chief Counsel Elizabeth Dickinson noted, "[i]ndustry challenges along with the agency's own evolving scientific and medical policy views and changes in how information is conveyed and healthcare is delivered are driving a new commitment at the highest levels of the agency . . . to realign FDA's regulatory posture" as it relates to speech about medical products.[10]

Enabling freer manufacturer communication would help FDA better serve the needs of participants in the health care system, which has seen sweeping changes in recent years. In the past, physicians were rewarded for the quantity of services they performed. More and more, however, the health care system emphasizes the quality of services performed, increasing the focus on efficiently achieving positive health outcomes. As a consequence, physicians and payors increasingly demand access to the best information regarding the most effective treatment options. This can include CER or other information that is not reflected in product labeling. At the same time, the health care system is increasingly encouraging patients to participate in their own care, driving patients' needs for current and comprehensive information about the full range of treatment options. In addition, technological advances, particularly the Internet, have given patients unprecedented access to health care information, much of it delivered in real time. Patients expect information bearing on their decisions to be available to them instantly and without restrictions. Because of their superior access to information about their own products, manufacturers can play a key role in responding to these growing informational needs and expectations.

For constitutional reasons described in greater detail in earlier MIWG submissions, it is important for the Agency to make clear that all speakers—including manufacturers—are able to disseminate truthful, non-misleading information about medical products. The proposals of the MIWG and its members in past submissions to FDA provide several suggestions for allowing appropriate manufacturer communications within FDA's regulatory scheme. We recognize that the systematic analysis of the regulatory and enforcement environment that FDA has committed to undertake raises a host of complex issues, implicating not only legal and regulatory issues but also the Agency's ability to advance its public health mission. We remain committed to constructively engaging with FDA to identify concrete steps the Agency can take to improve the regulatory system consistent with effective enforcement and reinforcing FDA's important role in conducting review and approval of medical products—a function that itself facilitates better informed decision-making.

We appreciate the opportunity to comment.

[8] Michael McCaughan, Acknowledging Caronia: FDA Takes The First Step To Rethinking Off-Label Policy, The RPM Report, May 1, 2014 (quoting Janet Woodcock).
[9] Id.
[10] Remarks by Elizabeth Dickinson, Chief Counsel, FDA at the FDLI Annual Conference (Apr. 24, 2014).

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