August 25, 2014

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

Comments of the Patient, Consumer and Public Health Coalition on the Draft Guidance for Industry on
As members of the Patient, Consumer and Public Health Coalition, we strongly urge the Food and Drug Administration (FDA) to withdraw its draft guidance proposing to allow pharmaceutical firms to distribute to health care providers and facilities scientific medical literature suggesting that the risk information for prescription drugs and biological products are less than what is stated in the FDA-approved product labeling. The guidance has the potential to cause confusion and greatly harm patients. It would undermine the public health mission of the FDA by allowing companies to provide potentially invalid and misleading information that patients and their physicians would use as the basis for medical decisions.

The guidance would allow the distribution of risk information prior to FDA approval of formal changes to label information. While proposed changes to FDA-approved labels that involve removal or mitigation of previously stated risk information must be reviewed and approved by the FDA in accordance with existing regulatory requirements, the publications that would be distributed in accordance with this proposed guidance would not be reviewed by the FDA. Thus, there will be no safeguards to ensure that the “new risk information” is unbiased or accurate.

The draft guidance states that it “is not intended to apply to information about a newly identified risk (not previously included in the approved labeling) or new information that indicates that a risk already identified in approved labeling is more serious [italics ours] than is reflected in that labeling.” The guidance states that, “the term new risk information refers to information that becomes available after a drug is marketed that rebuts or mitigates information about a risk already identified in the approved labeling.” This limited definition of “new risk information” essentially facilitates more rapid communication of reduced risk alone, but neglects greater risk. Moreover, there would be no safeguards to ensure that the “new risk information” is unbiased or accurate.

The FDA recommends that the scientific and medical data should be from independent, peer-reviewed journals, and be “at least as persuasive as the data sources that underlie the existing risk assessment…as reflected in approved labeling.” However, it is widely recognized that peer-reviewed scientific journals vary significantly in their data requirements and review standards for publication. Moreover, many peer reviewed articles are ghostwritten by industry staff and consultants.1 There is no assurance that the peer-reviewed journal processes would approach the comprehensiveness and scrutiny of an FDA pre-market review. Moreover, journals of varying standards would be entrusted to review critical risk data that could have dire health implications for patients. The FDA acknowledges the potential for harm, stating that “if the new information is unreliable or presented without the appropriate context, it could influence prescribing decisions or patient monitoring in a way that could harm patients.” Yet, the FDA guidance would allow such biased information to undermine the integrity of risk information provided to physicians (and indirectly, to patients).
The FDA guidance suggests a cover sheet to accompany such literature, which would include several pertinent statements, including a reminder that the FDA has not reviewed the data, and disclosing any financial interests or affiliations between the study authors and the company. This cover sheet would not be sufficient to counterbalance biased or questionable information in the articles. Moreover, guidance documents are non-binding, and no enforcement strategies have been outlined. Companies would therefore be under no obligation to comply with these suggested restrictions.

Obviously, companies would not be likely to distribute scientific or medical articles that indicate an increased risk of their own products, but they might want to distribute scientific or medical articles that indicate an increased risk of their competitors’ products. Such information could certainly be biased or inaccurate, but not more so than the information provided by companies regarding their own products. So, why would the FDA allow one type of communication and not the other? We believe distribution of either type of risk information by drug company reps is unacceptable.

In addition to the problematic public health implications of this guidance, we strongly question its scientific rationale. The draft guidance notes the value of post-market information, stating that premarket risk information may be limited in assessing a drug’s safety profile “by the nature of the supporting data and the size of the population exposed.” However, if a rare safety signal is detected in small pre-market studies, finding a reduced risk in a larger post-market study would be unexpected, and would deserve careful unbiased scrutiny from FDA scientists before that information could be used to influence physicians’ prescribing habits. Moreover, a larger or more generalizable post-market study that confirms or identifies rare safety events would be much more likely. Yet this guidance intentionally does not address this situation.

In summary, this guidance is misguided and dangerous. It would undermine the already limited efficacy of risk information provided in FDA-approved labels by allowing the distribution of competing risk information not subject to the same scientific rigor and neutrality which are the whole rationale for the existence of the FDA review process. We strongly urge the FDA to withdraw this poorly conceived guidance, which would allow potentially unsubstantiated safety information to be communicated without the safeguards patients need and the public health deserves.

American Medical Student Association
American Medical Women’s Association
Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Community Catalyst
Connecticut Center for Patient Safety
Consumer Reports
Jacobs Institute of Women’s Health
MISSD
National Center for Health Research
The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at pb@center4research.org