



September 16, 2014

Re: FDA-2014-D-0447-0001

The National Physicians Alliance (NPA) welcomes this opportunity to comment on the U.S. Food and Drug Administration's (FDA) draft guidance "**Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices.**" The NPA represents physicians across more than 40 medical specialties who share a commitment to patient-centered health care, evidence-based health policy, and professional integrity. The organization strictly refuses funding from pharmaceutical or medical device companies and supports the scientific advancement of knowledge through empirical research that is conducted free of financial conflict of interest; subjected to professional peer-review; and transparent in process. These comments were prepared by the NPA's FDA Task Force.

The draft guidance **Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices** only applies to companies who "voluntarily choose" to correct misinformation that appears on the Internet or through social media platforms from third party entities. We believe companies should be held responsible for the accuracy and balance of all information about their product that appears to be promotional, not just for sources they voluntarily choose to correct.

Because this guidance is voluntary in nature and there are no enforcement mechanisms in place, it will not do enough to protect individual patients or the public's health more generally. Only a strict requirement to correct misinformation would ensure that patients are not misled. Information in blogs, patient Web sites, Wikipedia and other "independent" third party sources are often bought and paid for, directly or indirectly, by the companies whose products are being praised (or whose competitors' products are being criticized). Without any enforcement mechanism, it is impossible for us as physicians or for our patients to determine the true source and accuracy of such information.

We thank the FDA for developing a new user-friendly app for reporting adverse drug reactions or problems with medical devices:

<http://www.fda.gov/MedicalDevices/Safety/ReportProblem/ucm385880.htm>

We suggest that the FDA could add to this app by reporting on incomplete or misinformation found on the internet or social media. In addition, the FDA needs to do a better job of promoting this app to providers; most are unaware it exists.

To further help minimize the misuse of social media and internet promotions, we believe penalties should be imposed on companies that pay for any promotional materials that are biased or inaccurate.

The draft guidance states that all corrective information provided by the drug or device companies should be "consistent with FDA-required labeling for the product." The FDA should also insist on complete labeling information, to include information about risks and side effects.

In addition, the draft guidance does not address the issue of information on off-label usage of medical products. It is essential that the FDA stipulate that companies must also identify when information refers to indications not approved by the FDA and inform consumers that the accuracy of such statements has not been reviewed by the FDA.

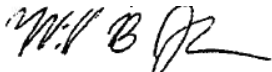
In conclusion, the Internet and social media are often the first source of information that health professionals and patients use to find out about risks and benefits of medical products. Information found on-line can directly impact our treatment decisions and clinical outcomes for our patients. The FDA needs to make sure that the information available on the Internet is as accurate and balanced as possible, and should not rely on companies who make the medical products to voluntarily correct promotional material about the products they are selling. The FDA should require companies to correct this information to the greatest extent possible in order to ensure that patients are not influenced by misinformation that may harm their health.

We further urge you to expand on your excellent new app for reporting drug and device problems to include corrections of any misinformation located on the internet and social media.

Respectfully,



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