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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:
Subject: Public Comment from Stuart Portnoy, MD

- Public Comment [Executive Order 12866] - Stuart Portnoy, MD.doc

Re: Public Comment to OMB's Proposed Bulletin Executive Order 12866
Peer Review and Information Quality

I am responding to OMB's Proposed Bulletin under Executive Order 12866 in which OMB proposes to issue a new guidance to obtain the benefits of meaningful peer review of the most important science disseminated by the federal government regarding regulatory topics.

I worked for 8 years as a Medical Officer in FDA's Division of Cardiovascular Devices [1994 - 2002]. At FDA, I worked as a physician and manager responsible for determining if a manufacturer provided sufficient safety and effectiveness data to support market approval of new and often life-sustaining medical technologies. These devices included pacemakers, defibrillators, artificial hearts, and drug-coated stents.

With device clinical trials typically ranging in size from 100 to 300 patients, we at FDA often had to make safety and effectiveness determinations based on limited device experience and clinical data. Despite these limitations, there is ample evidence that the current process at FDA works very well. Most would agree that Americans enjoy a level of public health that is second to none regarding the safety and effectiveness of commercially-available drugs, devices, and biotechnology therapies.

If FDA and other regulatory agencies were required to obtain peer review for these and other high profile science decisions prior to commercial release, I am deeply concerned that the approval process would suffer unnecessary delays over differences of opinion. I can foresee that peer review scientists would likely get bogged down in disagreements regarding whether new products have been adequately demonstrated to be safe and effective.

There is no way to achieve scientific certainty about many of the issues that FDA deals with in evaluating new therapies. The FDA has learned how to balance competing internal views to make judgments concerning the public health. There is already a formal panel review process to obtain outside expert opinion when the FDA does not feel it has sufficient internal clinical resources or expertise to make the judgment.

Please don't try to fix something that's not broken. Especially when the FDA approval process happens to work amazingly well in protecting and promoting the public health.

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