



November 20, 2015

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

**Comments of members of the Patient, Consumer, and Public Health Coalition on
the Establishment of the Patient Engagement Advisory Committee
[Docket No. FDA-2015-N-3166]**

As members of the Patient, Consumer, and Public Health Coalition we are concerned about the establishment of a stand-alone Patient Engagement Advisory Committee for medical devices. It is not clear whether this committee will isolate rather than integrate the voices of patients into CDRH decision-making.

We believe that CDRH would greatly benefit from more input from patients who are independent of financial ties to industry. We believe that is more likely to happen if CDRH shows greater respect for patients in all their public meetings.

We support both patient representatives and consumer representatives becoming voting members on the current medical device advisory committee with its 18 panels.

The main goal the Patient Engagement AC is “to increase the integration of patient perspectives into the regulatory process for medical devices.”¹ That is achievable by allowing patients to be full participants in the current medical device advisory panels, and by treating patients with respect when they speak during the public comments portions of advisory committees. For example, at the September 2015 Advisory Committee meeting on Essure, patients were segregated behind a red tape that separated the sponsor, FDA staff, and the Advisory Committee from them. While sponsors and FDA speakers spoke at length at a lectern with functioning PowerPoint, the many patient speakers (most of whom had been injured by the device and many who suffered from chronic pain) were given only 3 minutes to speak and had to stand in the audience without a lectern, with only a very small low table that was not high enough to use for their written comments. Several had PowerPoint presentations that could not be shown because of IT problems, and yet there was no apparent consideration that perhaps they could speak at the lectern instead.

Moreover, the patient representative on the Advisory Committee showed no interest in the patients’ remarks, asked them no questions, and said very little during the public meeting. When panel members asked questions about the patients’ experience with the device, such as why there was a problem with insurance coverage, the FDA deflected the questions away from the patients who wanted to answer the questions, instead asking the sponsor to answer, or other FDA officials. Ironically, in many instances the FDA officials and the sponsor did not know the answers, whereas the patients did.

Key topics that the FDA states that the Patient Engagement AC would discuss include benefit-risk determinations, device labeling, available alternatives and patient reported outcomes.¹ Patients should be included in the public meetings of the 18 medical device advisory committee panels in sufficient numbers to address those issues, which will vary according to the device under consideration. Another duty that the FDA asks the Patient Engagement AC panel to conduct is “promoting innovation.” That should not be the responsibility of patient representatives, whose main concerns are that devices work effectively and provide benefits to them. Although everyone likes innovation, there is a question of what that means; for patients, innovation without benefit is not useful.

We are also concerned that the Patient Engagement AC will be unduly influenced by the medical device industry. It is not unusual for patient groups to be heavily funded by industry, and those companies provide resources and information that is biased to support their interests. It will be difficult for CDRH to create a patient AC that doesn’t represent companies’ perspectives more than patients.’

For the above reasons, we urge the CDRH to show more respect for patients at every public meeting, rather than segregate patients into a separate committee. Although we do not oppose the new AC, if patient representatives were treated with respect on the current advisory panels they serve on, and patients who choose to participate in public FDA meetings during open comment periods were given more time to share their experiences, express their views, and answer questions regarding the safety and effectiveness of medical devices, that would benefit patients much more than the Patient Engagement AC.

Annie Appleseed Project
ASHES (Advocating Safety in Healthcare E-Sisters)
Connecticut Center for Patient Safety
Consumers Union Safe Patient Project
Mothers Against Medical Error
MRSA Survivors Network
National Center for Health Research
National Consumers League
National Organization for Women
National Physicians Alliance
The TMJ Association
WAPS (Washington Advocates for Patient Safety)
WoodMatters

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202)223-4000 or at pb@center4research.org

¹ Federal Register (September 21, 2015). Food and Drug Administration: Establishment of the Patient Engagement Advisory Committee; Establishment of a Public Docket; Request for Comments.