



CENTER FOR MEDICAL CONSUMERS



November 19, 2009

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

**Comments of the Patient and Consumer Coalition  
on the proposed rule for  
“Medical Device Reporting: Electronic Submission Requirements”  
[Docket No. FDA-2008-N-0393 and/or RIN number 0910-AF86]**

Members of the Patient and Consumer Coalition support the FDA’s proposed rule to amend its postmarket medical device reporting regulation to require that medical device reports (MDRs) be submitted in an electronic format.

We agree with the agency that “The major benefit of this proposed rule would be to public health because the agency would have quicker access to the medical device adverse event reports information...” Under the old paper system it can take more than 6 months before an MDR would be available for analysis in the Manufacturer and User Device Experience database (MAUDE), but with the standard electronic format, MDRs would be available for analysis much more quickly. If the FDA identifies problems and acts upon them sooner, we anticipate that fewer patients and consumers will be harmed by medical device problems.

Once a medical device is cleared or approved by the FDA, the device is used by a larger and more diverse population than it was tested on, so it is important to gather new

information from the MDRs as quickly as possible in order to accurately measure the real world benefits and risks of the products.

In addition, electronic MDRs will eliminate transcription errors and save the FDA about \$1.25 million annually in data entry costs. Electronic records will also save industry (manufacturers, importers, and user facilities) time and money by making MDRs easier to file.

For the above reasons, the Patient and Consumer Coalition strongly supports the FDA's proposed rule for electronic medical device reporting.

Sincerely,

Breast Cancer Action  
Community Access National Network  
Center for Medical Consumers  
Consumers Union  
Government Accountability Project (GAP)  
National Research Center for Women & Families  
National Women's Health Network  
Our Bodies Ourselves  
THE TMJ Association  
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*For additional information, contact Paul Brown at the National Research Center for Women & Families, 202-223-4000 or at [pb@center4research.org](mailto:pb@center4research.org)*