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Medical Device News and Insights

[FDA Transparency and the Consequences for Medical Device Companies](#)

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The [FDA](#) has been moving forward with its Task Force focused on improving and encouraging transparency across its operational and decision-making apparatus. This particular FDA initiative is tied-in with the Open Government Directive championed by the Obama White House, and in addition to providing the public with more information regarding the FDA's responsibilities and charter, it also speaks to enhancing public disclosure and regulated industry transparency for medical device manufacturers and pharmaceutical companies. retweet

In August, the Journal of Medical Device Regulation [published an article](#) by [MDCI](#)'s own Rosina Robinson entitled "Transparency or Exposure in the USA – It Depends on Which Side of the Window You're On..." In the article, Robinson makes several important points regarding the implications of the FDA Task Force and how it could potentially impact medical device companies across the entire industry.

The key issue brought up by Robinson's article is the concern that an increase in transparency will open up medical equipment manufacturers to a higher level of product liability risk. Part of this increased liability exposure is directly related to the fact that much of the information regarding medical devices that the FDA would like to be made public is at a level which a general audience will not find useful, especially given their lack of familiarity with FDA regulatory requirements surrounding a particular device. Medical device companies will undoubtedly be forced to inflate their legal budgets to handle the potential exposure associated with this FDA initiative, which will in turn further increase the expense of bringing a medical device to market.

The potential for emerging medical technologies to be tried in the court of public opinion instead of being subject exclusively to the rigors of the scientific method could put both the FDA and the medical device industry in an uncomfortable situation. In worst case scenarios, it is not difficult to envision a situation where organizations abandon research into meaningful areas of medicine, due to negative attention from a public that has not been given all of the facts or background required to make a full and objective judgment.

Another area of concern for medical device companies and increased FDA transparency has to do with withdrawn and re-submitted 510(k) or PMA applications, as well as cancelled or postponed clinical trials. It is rare for the general public to be fully informed as to the various reasons why an application may be submitted more than once (or a clinical trial terminated early), as project budgets, changing sponsors, or other non-regulatory reasons for pre-market application cancellation and trial postponement are not always seen with an impartial eye. The danger of associating cancelled applications and trials with unreliable products in the eyes of potential patients is very real.

If the FDA seems to be dedicated to moving forward with a plan that will place significant amounts of information about medical device compliance and regulatory submissions in the hands of the public – especially without the context required to properly analyze this information – it is important for those in the medical equipment industry to prepare themselves for the potential consequences of these actions.

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