

## ALERTS

### Food, Drug & Device Law Alert - FDA Issues Plan Of Action On Recommendations For Medical Device Reviews

June 16, 2014 | [Atlanta](#) | [Chicago](#) | [Columbus](#) | [Delaware](#) | [Elkhart](#) | [Fort Wayne](#) | [Grand Rapids](#) | [Indianapolis](#) | [Los Angeles](#) | [Minneapolis](#) | [South Bend](#)

As reported in a [previous alert](#), one of the things the medical device industry obtained in exchange for agreeing to higher user fees in 2012 was an independent review and analysis of FDA's medical device review procedures. A preliminary report was issued in December 2013, and the final report was just issued. In response, the FDA's Center for Devices and Radiological Health (CDRH) has issued a Plan of Action.

The Plan of Action is organized around the following four recommendations from the independent review:

- Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process
- Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews
- Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes
- Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews

The good news is that the Plan of Action is only nine pages long and a quick read. The bad news is that it is written in an outline, summary fashion and thus is not amenable to further summarization. It is also general and not particularly informative. The independent management review is 147 pages and considerably more detailed and may provide insight into likely changes.

A pdf copy of the Plan of Action is [available here](#)

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or [lynn.tyler@btlaw.com](mailto:lynn.tyler@btlaw.com); and Hae Park-Suk at (202) 408-6919 or [hae.park.suk@btlaw.com](mailto:hae.park.suk@btlaw.com).

©2014 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, is proprietary and the property of Barnes & Thornburg LLP. It may not be reproduced, in any form, without the express written consent of Barnes & Thornburg LLP.

This Barnes & Thornburg LLP publication should not be construed as legal advice or legal opinion on any specific facts or circumstances. The

## RELATED PEOPLE



**Lynn C. Tyler, M.S.**

Partner  
Indianapolis

P 317-231-7392  
F 317-231-7433  
[lynn.tyler@btlaw.com](mailto:lynn.tyler@btlaw.com)

## RELATED PRACTICE AREAS

Food, Drug and Device Law

*contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.*

Visit us online at [www.btlaw.com](http://www.btlaw.com) and follow us on Twitter [@BTLawNews](https://twitter.com/BTLawNews).