

FDA BALKS AT MEDICAL DEVICE SHAKEUP by Andrew Seaman

I heard about the Institute of Medicine report at a House committee hearing on medical devices in July. The IOM was asked to determine what – if anything – should be done to fix the 510(k) process, which allows medical devices to get to market faster than the cumbersome premarket approval process.

I approached the topic with trepidation. While I've worked with many government agencies, this was the first time I had to interact with the Food and Drug Administration.

The report was not slated to be released for a few more days, which gave me enough time to digest a lot of research on the topic. With a few exceptions, Democrats say the 510(k) process does not do enough to protect Americans from malfunctions or poorly designed devices. Republicans say even the fast track process is too cumbersome for the medical device industry.

Like most reports, Reuters received an embargoed copy ahead of the public release. Surprisingly the IOM's committee of experts recommended the 510(k) process should be thrown out. I talked to a lot of people before the report's release, and no one knew what the IOM was going to decide.

What was most interesting, from my perspective, was that the FDA's response became the big news of the day. The FDA basically said thanks, but no thanks to the IOM. As one person told me, people have been telling the FDA for years that the 510(k) process is dangerous, but this is the first time the agency paid someone to tell them that.

The FDA's rejection of the IOM report seemed to align them more with industry, and that's what everyone picked up on. The events were really interesting to watch and report on.

<http://www.reuters.com/article/2011/07/29/us-fda-devices-idUSTRE76S5GW20110729>

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