Comment of the National Center for Health Research Regarding the

510(k) Third Party Review Program:

Draft Guidance for Industry, FDA Staff, and Third Party Review Organizations.

OMB Control Number 0910-0375

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We appreciate the opportunity to comment on this draft guidance. We note that this draft guidance applies to low-to-medium risk medical devices, which concerns us because many Class II devices are permanent implants that have the potential to cause permanent harm to patients. In fact, our research indicates that even Class I devices have been subjected to high-risk recalls by the FDA due to the potential for causing death or permanent harm.[i] [ii] [iii]

We have several serious concerns about the draft guidance. First, Original Equipment Manufacturers (OEM) are accountable for the efficacy and safety of their medical devices. FDA standards require that devices manufactured by OEM's comply with relevant regulatory standards. OEMs are required to track, monitor, and report product issues to FDA. Overseeing the OEMs and their reporting are FDA's responsibility to ensure patient safety.

Second, in the past FDA has had the opportunity to review the work of any third party reviewer, and reject it if deemed inadequate or shoddy. In fact, the agency has often found problems with the third party reviews. The proposed guidance would sharply reduce the agency's oversight of third party reviews, which will clearly compromise safety. Even if certified as qualified, third party review companies have an inherent conflict of interest: If their standards are too high, no device company will hire them and they will go out of business. The system is similar to the EU regulation of medical devices, which has resulted in very harmful decisions, such as the clearance of the PIP breast implants that were found to use non-medical grade silicone.[iv] In addition, investigative reporters recently obtained CE clearance for a "surgical" mesh that was made out of a plastic mesh bag used for oranges.

Transparency is also a crucial factor. Currently, third party review companies are not required to clearly label an OEM device indicating that a critical repair has been completed by someone other than the OEM. Once that repair is made, the device is no longer the same device that was approved or cleared by FDA. It is important that this chain of accountability is not broken or interrupted.

While we understand the desire of FDA officials to reduce medical device review times and reduce the burden on FDA staff and industry, the 510(k) program already is a quick way to get devices to market and the device industry has clearly benefitted from it. The 510(k) pathway has been widely criticized by the Institute of Medicine, physicians, patients, and the media for its lack of clinical trials and lack of scientific evidence.[v] Despite its weaknesses, the 510(k) pathway is considered superior to the EU regulatory system, however. By reducing the "burden" for FDA staff and industry, the proposed guidance increases the burden on patients and doctors to figure out which devices are safe and which are not. This would clearly put U.S. patients at greater risk.

FDA has not demonstrated that its proposed changes to the third party review pathway of Class I and Class II devices will benefit patients. By definition, 510(k) devices only rarely are substantially superior to recent predicates. Speeding up the process of clearance is not demonstrated to benefit patients. Moreover, with registries, NEST, and other planned efforts to improve post-market surveillance still far from effectively implemented, any loosening of 510(k) regulations is very premature.

Finally, we note that Commissioner Gottlieb responded to recent media criticism of CDRH regulations by promising improvements to the 510(k) pathway to ensure patient safety. The third party review program clearly moves in the opposite direction, reducing patient safety, rather than protecting patients from potentially harmful devices. We strongly oppose it for that reason.

Footnotes

[i] Zuckerman, D.M., Brown, P, and Nissen, S.E. (2011) Medical Device Recalls and the FDA Approval Process, Archives of Internal Medicine, 117, 1006-11.

Zuckerman D.M., Brown P., Nissen S.E. (2011). In Reply, Archives of Internal Medicine, 171(11), 1045.

[iii] Zuckerman D.M., Brown P., Nissen S.E. (2011). In Reply, Archives of Internal Medicine, 171(21), 1963.

[iv] Zuckerman, D., Booker, N, and Nagda, S. (2012) Public Health Implications of Difference in US and European Union Regulatory Policies for Breast Implants, Reproductive Health Matters, 20 (40),102-111.

[v] Zuckerman D.M., Brown P. & Das A. (2014) Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices, JAMA Internal Medicine, 174(11): 1781-1787.