CORR Insights

CORR Insights®: How Do Orthopaedic Devices Change After Their Initial FDA Premarket Approval?

Carlos J. Lavernia MD, Jesus M. Villa MD

Where Are We Now?

In their study, Samuel and colleagues address a key topic pertaining to the safety and effectiveness of implantable orthopaedic devices. The FDA has arguably the most stringent processes to evaluate the safety and effectiveness of high-risk medical devices in the world [3, 4]. Fewer than 100 devices

have undergone the full process or premarket approval (PMA) pathway to get to the marketplace. However, it appears that some device manufacturers have exploited existing FDA rules and regulations. These devices may undergo multiple postmarket modifications—usually without additional supporting clinical data or with substantially fewer evidence requirements than the original PMA. On occasion

after these postmarket modifications, the devices are almost different implants.

Samuel and colleagues showed that between 1982 and 2014, 70 orthopaedic devices were cleared via the FDA PMA pathway. These 70 devices underwent a median of 6.5 postmarket changes during their lifespan or one device change per year. Further, they found that these changes have become more frequent, from fewer than 0.5 device changes per year in 1983 to almost three device changes per year in 2014; of those, 22% have altered the design or the components.

The authors conclude, and we agree, that even though only 70 orthopaedic devices underwent the FDA PMA pathway before reaching the market, surgeons should realize that high-risk medical devices cleared by the FDA may still go through considerable modifications after getting to the market. There are safety concerns when it comes to the PMA supplement pathway [5]. Understanding the consequences of this particular process is of paramount importance for patients, surgeons, and device manufacturers.

This CORR Insights® is a commentary on the article “How Do Orthopaedic Devices Change After Their Initial FDA Premarket Approval?” by Samuel and colleagues available at: DOI: [10.1007/s11999-015-4634-x](https://doi.org/10.1007/s11999-015-4634-x).

One of the authors (CJL) is a consultant and receives royalties from Mako Surgical Corp (Fort Lauderdale, FL, USA) in an amount of USD 100,001 to USD 1,000,000; he also owns stock in Johnson & Johnson (New Brunswick, NJ, USA), Zimmer (Warsaw, IN, USA), Stryker, (Mahwah, NJ, USA), Wright (Arlington, TN, USA), and Symmetry Medical (Warsaw, IN, USA). JMV certifies that he, or any members of his immediate family, have no funding or commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research®* editors and board members are on file with the publication and can be viewed on request.

The opinions expressed are those of the writers, and do not reflect the opinion or policy of *CORR®* or The Association of Bone and Joint Surgeons®.

This *CORR Insights®* comment refers to the article available at DOI: [10.1007/s11999-015-4634-x](https://doi.org/10.1007/s11999-015-4634-x).

C. J. Lavernia MD (✉)
The Center for Advanced Orthopedics at
Larkin Hospital, 7000 SW 62nd Ave,
Suite 600, South Miami, FL 33143, USA
e-mail: c@drclavernia.com

J. M. Villa MD
Arthritis Surgery Research Foundation,
Miami, FL, USA

CORR Insights

Where Do We Need To Go?

Due to the cumulative modifications, the orthopaedic devices ultimately implanted may differ substantially from the original cleared by the PMA. We need to have a process that expedites new innovative technologies but is thorough enough to weed out problem devices. Orthopaedic devices cleared through the postmarket PMA supplement process—or 510(k)—warrant additional scrutiny to limit or minimize the safety risks run by our patients. Modifications to the approval process of existing high-risk orthopaedic devices must balance the need for innovation and improving the state of the art with the need to ensure safety and efficacy.

Lastly, we need a completely independent robust postmarket surveillance process that is not influenced in any way by parties with economic stakes in the devices in order to monitor and effectively remove problem devices earlier with minimal damage to our patients. This process needs to include the American Joint Replacement Registry and a robust national implant retrieval program. This will require major funding and has to be developed by practicing experienced orthopedic surgeons in conjunction with basic scientists.

How Do We Get There?

The current mechanisms in place to identify problem implants and achieve improvements in existing devices are clearly inadequate and do not serve the best interests of patients, surgeons, or even device manufacturers. We have made some progress with the American Joint Replacement Registry, but the mechanics of this registry need to be modified to include carrots and sticks. Currently, fewer than 15% of the country's hospitals participate in it [1, 2]. Financial rewards and penalties should be on the line for all entities and some sort of penalty savings account ultimately benefiting the postmarket surveillance process itself could be created.

The modification of devices with supplements has been radically altered. Changes to a device are often submitted one supplement at a time and end up in an implant system that, in some cases, does not even look like the original PMA cleared device. To solve this challenge, we need to limit the number of changes devices are allowed to undergo before they have to go back to square one. This would have to be done by the US Congress because current regulatory processes have no teeth on this particular issue.

In addition, we need real-time high-quality postrelease implant retrieval information. This information needs to be managed by one or several independent laboratories to monitor actual clinical performance. It seems ironic that the richest country in the world in which more than one million arthroplasties are performed yearly lacks a surveillance system that alerts surgeons and patients on design issues and early failures on a timely basis.

Funding for the American Joint Replacement Registry and a national implant retrieval program must originate from the government to avoid any undue influence by parties with economic interests on these devices. Major funding for these efforts has not been forthcoming due to interests groups that would be economically damaged by such efforts. Postmarket surveillance programs should have the same level of priority and funding, in the like of premarket review evaluations.

We commend the authors of the current study for drawing attention to this present problem. We encourage researchers and scientists, as well as regulators and industry, to work together to avoid another debacle in which 100,000 arthroplasties are recalled.

CORR Insights

References

1. American Hospital Association. Fast facts on US hospitals. Available at: <http://www.aha.org/research/rc/stat-studies/fast-facts.shtml>. Accessed January 5, 2016.
2. American Joint Replacement Registry. Available at: <http://www.ajrr.net/>. Accessed January 5, 2016.
3. U.S. Food and Drug Administration. PMA supplements and amendments. 2015. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm>. Accessed January 4, 2016.
4. U.S. Food and Drug Administration. Premarket approval (PMA). 2015. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/Default.Htm>. Accessed January 4, 2016.
5. Zheng SY, Redberg RF. Premarket approval supplement pathway: Do we know what we are getting? *Ann Intern Med*. 2014;160:798–799.