Medtronic News

Medtronic Responds to Star Tribune Article Regarding INFUSE Bone Graft

MINNEAPOLIS - April 10, 2016 - This weekend, an article was published in the Minneapolis Star Tribune that criticized Medtronic's handling of data collected during a retrospective chart review (RCR) of INFUSE Bone Graft between 2006-2008. The article makes insinuations that are false, and fails to include important information regarding the RCR and Medtronic's actions.

Medtronic provided the Star Tribune an extensive account of what transpired around the RCR, both in person and in writing, which was largely omitted from the article.

Medtronic has acknowledged that at the time the RCR was discontinued back in 2008, it was not properly archived and the information collected was not fully assessed for reportability to the FDA. We have taken a number of steps to update our clinical policies and our training to enhance our reporting practices. That said:

- When the RCR data was identified in 2013, the company took immediate and rigorous actions to assess and report the information.
- We reported the information to all appropriate regulatory bodies.
- The reported adverse events do not change the safety and efficacy profile of INFUSE.
- We have fully lived up to our principles of transparency and disclosure.

Despite these facts the article suggests Medtronic attempted to conceal information about the RCR, including information about adverse events reported in the data. This suggestion is false, and we want to set the record straight by sharing details that were provided to the Star Tribune but omitted from the article.

- First, as Medtronic repeatedly informed the reporters but the article fails to report, the information from the RCR had not been assessed for reportability during the 2006-2008 period. Since the company did not complete an analysis of adverse events in the accumulated records, there is no basis for the paper's implication that Medtronic intentionally failed to report information in 2008.
- Second, in 2013 when the RCR was discovered by Medtronic and properly assessed, Medtronic personnel from our regulatory and clinical safety groups concluded that the adverse event data identified in the RCR were consistent with those already known across a wide body of literature and clinical study. This conclusion was validated by an independent physician. The information contained no new types or unusual numbers of adverse events that had not been previously reported in clinical trials, MDR reports, or medical literature.
- Third, Medtronic submitted the adverse event data to FDA more than two years ago. The data was submitted after consultation with, and guidance from, the FDA by means of a summary report. While the Star Tribune insinuates that this was not a detailed accounting, it is wrong. Rather, the submission included a line-by-line description of 1,039 reported events, including specific codes associated with the conditions reported. The report reflected a wide range of conditions, including events such as diarrhea and hypertension. While the Agency did not require the company to submit individual MDR's for all these conditions, it did require a detailed summary of the reported events. The submitted summary report provided the required adverse event information in a 76-page table accompanying the report. This level of detail allowed the FDA to conclude that the adverse events in the RCR were consistent with the known history of INFUSE.

The FDA is the leading regulatory authority on device safety and efficacy. Their highly-trained medical and clinical experts have access to all device information, including both public and proprietary information.

Information collected during the RCR in no way changed the safety profile of INFUSE , nor has the FDA required any labeling changes to the product since Medtronic provided RCR information to the Agency more than two years ago. It is further notable that this past December, with this information on file, the FDA approved additional spine surgery indications for INFUSE Bone Graft, providing its use with new implants and new procedures.

- Fourth, the Star Tribune mischaracterizes the use of adverse event data by Yale in their systematic review, despite our consistent explanations to them and statements provided to them by Yale to the contrary. In their meta-analysis, Yale only included adverse event data collected during clinical trials. That was true for all individual MDR's filed prior to the systematic reviews completed in 2012, and is consistent with why Yale would not include the RCR adverse events in 2013

- they were outside the scope of the Yale's study.
- Fifth, the Star Tribune attributes certain statements to James Kirwin, a former Medtronic employee. Mr. Kirwin had extremely limited involvement with the RCR process and the reporting of its findings to regulatory authorities during his brief time at Medtronic. As the company shared with the Star Tribune, Mr. Kirwin went so far as to nominate the Medtronic Clinical and Regulatory team involved in the Yale Open Data Access (YODA) Third Party Data Transparency project for the Medtronic Global Clinical Research Excellence Award in August 2013 - after he was made aware of the identification of the chart review information and before he left the company. On the nomination form, Mr. Kirwin stated: "I am proud to be associated with such dedicated and un-compromising individuals and the company the [sic] supports these types of efforts."

Patient safety is our primary concern with all of our products, and we continue to stand by the safe and effective use of INFUSE Bone Graft in its approved indications. INFUSE is an important option for physicians treating patients requiring spinal surgery in FDA-approved indications for use. With its decade of clinical application, BMP has become one of the most extensively researched biologic agents commercially available today, and has been used to treat more than one million patients.

We are committed to, and have led the industry in, transparency - transparency regarding our business, our interactions with physicians, and the disclosure of clinical evidence related to our therapies - in particular with INFUSE.

The INFUSE device continues to benefit thousands of patients around the world.

Patients should consult their physician and have a meaningful, fact-based discussion on whether INFUSE is a viable treatment option for them. For more information, please visit www.infusebonegraft.com.

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