AMERICAN ASSOCIATION for JUSTICE

Formerly the Association of Trial Lawyers of America (ATLA®)

April 18, 2013

Mr. Michael Ryan
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave.,
Building 66, Room 1615
Silver Spring, MD 20993–0002

RE: Effective Date of Requirement for Premarket Approval for Two Class III Preamendments Devices (Docket No. FDA–2011–N–0661)

Dear Mr. Ryan:

The American Association for Justice (AAJ), formerly the Association of Trial Lawyers of America (ATLA), hereby submits a response to the Food & Drug Administration's request for comments on the order entitled Effective Date of Requirement for Premarket Approval for Two Class III Preamendments Devices. *See* 77 Fed. Reg. 4094.

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, and protect access to the courts. AAJ submits these comments in support of the FDA's order on metal on metal hips. Requiring premarket approval ensures that these devices go through a more extensive review process then under current standards. However, when a device is approved through the premarket approval process, consumers lose the ability to hold the device manufacturer accountable through the civil justice system.[1] This constitutes a significant loss to the consumer, who then may be personally responsible for any costs, including additional healthcare costs, associated with an unsafe device or those costs are then shifted to the government through Medicare or Medicaid coverage.

Our members have a multitude of clients who have become temporarily and permanently disabled from the work force as a result of the public health debacle of metal on metal hips who desperately need compensation for their loss. Some clients have had their homes go into foreclosure, their cars repossessed and their health insurance terminated due to their loss of employment, and other financial devastations. We have noted that many of our member's clients

[1] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

who required hip replacements at an early age were recommended the metal on metal hip because of their age, needed the replacement precisely because they had physical jobs such as construction, road work and jobs requiring heavy lifting, which caused premature hip failure. They lost months to years of their lives due to the metallosis complications and revisions, and many can never return to the workforce due to the permanent injury to their hips. As a result, AAJ believes that the FDA should affirmatively assert if any of the impacted metal on metal hips are approved via premarket approval or product development protocol, any pending legal claims that were the result of a 510(k) approved device, or claims asserted thereafter involving a prosthesis that was implanted during the 510(k) regime, should not be preempted.

Many thousands of consumers health has been jeopardized by unsafe and ineffective hip devices. More than half a million consumers are thought to have all metal artificial hips. Complaints from consumers regarding unusual side effects or symptoms related to metal on metal hip replacements began to accumulate as early as 2008. First, consumers began experiencing problems and hips began failing earlier than anticipated. Then when surgeons began to replace them, they found effusions of metal tinged fluid representing the body's response to the tiny metal fragments and ions that had sloughed off the device from the wear; causing a soft tissue response resulting in necrosis (death) of tissue, and in some patients even necrosis of muscle, nerves and bone, resulting in permanent damage and a compromised hip resulting all too frequently in problems of dislocation, re-revision and surgical complications such as infection, venous thromboembolism, and sadly in some cases even stroke, heart attack and death.

In addition, metal on metal hips can also cause heavy metal poisoning caused by cobalt and chromium released by the device and absorbed into the patient's blood tissue and organs. In these cases where the hip has failed or is failing, the best case scenario is to undergo an expensive surgical procedure to remediate the hip that has an extensive recovery time and can come with additional complications. However replacing the all metal hips will only help some patients. Others already have such extensive and permanent damage that surgery won't help. Some patients continue to experience hip pain for the rest of their lives.

Many consumers are currently trying to hold the manufacturers accountable for the defective products that they received so that they can be compensated for medical bills, lost wages and pain and suffering. These claims can currently move forward because the metal on metal hips had been cleared through the 510(k) process.[2] It would be absolutely unfair and have a negative financial consequence on the government if these claims all of the sudden were thrown into jeopardy soley because the government determined that the products needed additional safety testing before being marketed to consumers again. While we find it doubtful that any manufacturer will successfully file a PMA seeking approval for any of the impacted all metal hips based on the weight of existing medical literature and joint registry data, in the event that a

[2] *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

manufacturer succeeds, it should not impact any pending legal claims.[3] The FDA's goal here should be to protect consumers from unsafe medical devices, not to further harm those who have already suffered a harm. We can envision a manufacturer seeking to gain retroactive immunity if a device is ultimately approved through a PMA, even though that would be chronologically absurd and terribly wrong. Therefore we request language that makes it explicit that such an argument would have no footing.

AAJ appreciates this opportunity to submit comments in response to the FDA's order on the effective date of requirement for premarket approval for two class III preamendment devices. If you have any questions or comments, please contact Sarah Rooney, AAJ's Regulatory Counsel at (202) 944-2805.

Sincerely,

Mary Alice McLarty

Mary Alice McLarty
President
American Association for Justice