

March 12, 2010

**Via Electronic Submission**

The Honorable Ray LaHood  
Secretary  
U.S. Department of Transportation  
Docket Operations  
M-30, Ground Floor, Room W12-140  
1200 New Jersey Avenue, SE  
Washington, D.C. 20590-0001

**re: Docket Number: PHMSA-2009-0095 (HM-224F)**

Dear Secretary LaHood:

The Medical Device Manufacturers Association ("MDMA") is a national trade association that represents hundreds of small to mid-size medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies. On behalf of our membership, we appreciate the opportunity to comment on the Department of Transportation ("DOT"), Pipeline and Hazardous Materials Safety Administration's ("PHMSA") proposed rule on air shipment of lithium batteries.<sup>1</sup>

The United States is currently the global leader in the development and commercialization of medical devices and represents one of the few manufacturing industries in the United States with a net trade surplus. In addition, the U.S. medical technology industry is responsible for more than 350,000 jobs, including some of the highest paying manufacturing jobs in the country.<sup>2</sup> Most importantly, the medical device industry is comprised mainly of small businesses. In fact, more than 80 percent of medical device companies employ fewer than 50 people.<sup>3</sup> Thus, MDMA is concerned about the proposed rule's impact on both patient access to

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<sup>1</sup> 76 Fed. Reg. 1302 (January 11, 2010)

<sup>2</sup> 2006 "State Impacts of The Medical Technology Industry" The Lewin Group

<sup>3</sup> U.S. Dept. of Commerce, International Trade Administration, Invest in America Initiative, Medical Device Sector, 2007

life-sustaining, life-saving medical technologies and the negative effectives on small, innovative medical device companies.

MDMA is concerned about the unintended consequences that may be caused the proposed rule. Specifically, we are alarmed that the rule will unnecessarily prevent patients from accessing medical devices in a timely manner. Moreover, we are troubled that the rule will unnecessarily burden and increase costs for medical device manufacturers, the majority of which are small businesses. Finally, it is important to note there has been insufficient evidence and data to suggest that lithium batteries in finished medical devices have resulted in any combustible events onboard aircraft.

#### *Exempt Finished Medical Devices from Proposed Rule*

The ability of medical device manufacturers' products to reach patients within an expedited time period is absolutely critical within the practice of modern medicine. Some medical devices, including certain implantable devices, contain small, lithium batteries for the proper power facilitation and function of the device. These devices are developed and manufactured around all parts of the country and are used in hospitals and clinics in every state. Consequently, given the nature and the necessity of the devices in patients, these products, many which contain lithium batteries, are required to be flown within the cargo-holds of both commercial and cargo aircraft. To date, there are no known incidents of these products spontaneously combusting or causing incidents on board aircraft. As you may know, medical devices are strictly regulated by the Food and Drug Administration ("FDA"). Many devices cleared or approved by the FDA undergo rigorous, multi-year clinical trials in order to ensure their safety and effectiveness for patient use. Many of these products are designed to be implanted within the human body or have significant interaction with human physiology. In short, they are tested to withstand the most challenging of elements and conditions.

The proposed rule seeks to change the current standard for products containing batteries with 1.5 grams of lithium 0.or less to be exempted from being classified as Class 9 hazardous materials.<sup>4</sup> Instead of the current standard of 1.5 grams, the proposal seeks to establish the

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<sup>4</sup> Id. at 1311

standard at 0.3 grams of lithium or less for small batteries when packed with or contained in equipment. This proposal would, in effect, force many medical products with internal lithium batteries to be classified as Class 9 hazardous materials. The reality for many medical devices within this spectrum is that their internal lithium batteries would exceed the proposed standard.

MDMA is adamantly opposed to the proposed revision that would require finished products containing small batteries containing 0.3 grams of lithium or less from being exempted from classification as Class 9 hazardous materials. For numerous years, finished medical devices being transported under the existing 1.5 grams of lithium or less standard have been safely transported by both commercial and cargo aircraft. In fact, there are no known incidents on record of medical devices containing lithium batteries spontaneously combusting during flight. These products are designed to be safe, effective and to withstand the most challenging of environmental conditions. For instance, for many finished implantable medical products, they are delivered in hermetically sealed containers that can only be opened by trained professionals utilizing special tools.

#### *Significant Economic Impact*

The impact on small businesses in the medical device industry would also be significant due to the proposed rule. PHMSA speculates that this rule will have an initial cost of implementation of approximately \$9.3 million during the first year and \$70.2 million in 10 years across all industries.<sup>5</sup> MDMA believes that this figure dramatically underestimates the reality of many industries across the spectrum that would be affected by this rule. More specifically, we estimate the economic impact of this rule on the medical device industry alone would far exceed PHMSA's estimate by millions of dollars if companies are forced to ship their products as Class 9 hazardous materials. The reality is that this rule would negatively affect hundreds of small medical device companies that would have to change their entire supply-chain and inventory management systems. For instance, many of our companies rely on Just-In-Time ("JIT") strategies for inventory management to reduce costs and ensure that patients have access to technologies when needed. This rule would compel our member companies to overhaul their entire JIT systems, leading to hundreds of millions of dollars of increased costs to the health care

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<sup>5</sup> Id. at 1314

system. In a time when resources are already limited for small manufacturers, the additional costs associated with compliance will likely lead to less resource allocation towards R&D of future medical innovations and prevent the additional hiring of highly skilled workers. **Therefore, MDMA strongly recommend that the DOT and PHMSA maintain the current standard for products containing batteries with 1.5 grams or less to be exempted from being classified as Class 9 hazardous materials.**

### *Bottlenecking of Product Shipments*

The impact on patient access to life-sustaining and life-saving medical devices containing lithium batteries would also be extremely affected by this proposed rule. In many scenarios, patients often need devices within an extremely limited time-frame. For instance, there may be cases when a hospital or clinic needs to order products directly from either a distributor and within a limited window of time. If the distributor of a particular device doesn't happen to be next door or within a few hours drive of the medical facility, there is the obvious need to have these products transported by air shipment. If the product requires special handling because it is classified as Class 9 hazardous materials, this would only hamper the patient's ability to receive the needed products in time.

The very nature of medical devices by their life-sustaining and life-saving features should afford them to receive priority status in delivery onboard aircraft. If the proposed rule is to be implemented, more products containing lithium batteries under the new standards would be classified as hazardous materials and would be forced to compete with coveted cargo space onboard aircraft. As stated, many medical devices need to have the ability to reach patients in a timely manner which would require their transport on aircraft and not other conventional and slower modes of transportation. It is absolutely critical that patients and physicians can have timely access to these products as needed. **Therefore, medical devices must receive priority status onboard aircraft if the proposed rule is implemented.**

*Delay of Implementation Date for Compliance*

The proposed rule suggests a mandatory compliance date of 75 days after the date of publication of a final rule in the Federal Register.<sup>6</sup> This proposal unfortunately does not recognize the complexity and confusion that this rule would cause in modifying the delivery systems within medical device firms. Companies would be forced to dramatically alter their supply-chain management systems, modify distribution channels and absorb an inordinate amount of costs in order to appropriately comply. Furthermore, there will be a substantial disruption in the delivery of medical devices to patients and the clinics and hospitals that provide them. **Therefore, MDMA recommends that the implementation date for compliance of the rule be extended to a period of 18 months.** This would allow adequate time needed for companies to restructure and modify their supply-chain management and delivery systems. Moreover, it would likely reduce the disruption of product delivery to the patients who need them most.

MDMA appreciate the opportunity to comment on this important rule regarding the air shipment of lithium batteries. We believe that our recommendations outlined in this letter be adopted in order to ensure that patients can receive the life-sustaining and life-saving medical devices when they need them most.

Sincerely,



Thomas C. Novelli  
Director of Federal Affairs  
Medical Device Manufacturers Association

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<sup>6</sup> Id. at 1302