AdvaMed Position on ICIJ Medical Device Stories

November 28, 2018

“We have been following the series of articles led by the International Consortium of Investigative Journalists (ICIJ), published over the course of this week. AdvaMed and its member companies have been engaged with various ICIJ reporters over the past several weeks leading up to these stories, and it has been clear from our interactions that ICIJ had a clear bias against the industry. In a sector like healthcare, providing the true and complete picture is imperative when it comes to patients. These stories miss the bigger picture of an industry that produces hundreds of millions of medical devices annually that safely and effectively do exactly what they were designed to do. As an industry association, we want patients to continue having positive experiences and not lose faith in the innovations that are aimed to make the quality of their lives, better.

These stories paint a very one-sided view of an industry which has always been committed to providing safe medical devices that help save and improve people’s lives. Patient safety has always been, and always will be, the #1 priority of the medical device industry. We recognize why we developed these technologies in the first place: to address the critical, debilitating, and often life-threatening needs of patients who are desperate for solutions. Our member companies seek to address this need and ensure, all patients have access to life-changing medical technologies that extend and improve lives. These companies invest immensely in research and development and training of healthcare professionals in India to ensure improved/predictable clinical outcomes and enhanced patient safety.

Having said that; unfortunately, any medical intervention includes some element of risk. But when you consider the hundreds of millions of medical devices successfully implanted or interacted with annually, it proves we have a strong track record of safety. We take seriously all reports of patient impact, and though the medical community can never completely eliminate risk, we always strive to improve our technologies and care delivery. A medical device constantly evolves and is improved, with an aim to better patient care and patient safety, as feedback is gathered from real-world use by physicians, patients and other sources. Device safety does not stop once a product is in the market – it is a never-ending process and our most important commitment.

While these stories have a uniformly negative tone, they do bring to light certain gaps that exist in the healthcare system prevalent in a country like India. In addition to the conversations AdvaMed has been building on the need to fill these gaps, the recent articles further present an opportunity to take the conversation ahead, for the sake of patient well-being. As medical devices may be a small cog in the wheel of healthcare sector, some changes need to be holistic to resolve problems highlighted based on the following:

- **Medical devices and Drugs** – Medical devices and pharmaceuticals are vastly different in their development, evolution, manufacture, method of delivery and impact on patients. Hence, it does not make sense for them to be evaluated the same way. There is a clear segregation between the two and therefore the need for a separate regulatory framework for medical devices.

- **Quality benchmarking** - We seek and support regulations that enable all companies (global or domestic) to follow patient safety measures for better clinical outcomes. In India, the medical technology industry supports further development of a medical device regulatory framework unique from the one used for drugs, and that goes beyond BIS standards compliance, to help further demonstrate and ensure safety and effectiveness. Globally, there is a harmonised process of checking the quality of the devices and the global medical device companies follow FDA's rigorous premarket requirements which are considered global “gold standard” for
product safety. Domestic companies however, may, follow BIS which only requires conformance with standards. While standards are important, they represent only part of the pre and post market regulatory requirements of U.S. and European regulatory authorities. Conformance with standards is not commensurate with an FDA clearance or approval or CE mark in Europe and all of the requirements that flow from marketing these devices such as clinical evaluation, risk assessment, establishment registration and product listing, recall requirements and adverse event reporting requirements.

- **Transparency** – We truly believe in being transparent and the importance of Adverse Events (AE) reporting. AE reporting is viewed as a positive because it provides a dedicated mechanism for manufacturers, healthcare providers and patients to report potential device-related problems. Through this reporting structure, device manufacturers are able to promptly respond to potential issues by taking corrective measures. Global companies have Adverse Reporting mechanisms which transparently brings issues of any, to the fore, to resolve. It might be worthwhile for Indian regulators to adopt a similar mechanism for imported and domestic medical devices alike. The intent is to ensure the highest possible levels of safety and outcomes for the well-being of the patients and develop the next generation of a product.

As an association representing the medical device industry committed to help improve patient lives by ensuring safety, effectiveness and quality for all devices, we have been working constructively with the government on meaningful reforms that will truly benefit patients across the spectrum. With patient safety as paramount, we will continue to work with and support the government even in future.”