Testimony before the Joint Economic Committee of Congress
April 30, 2014
Shaye R. Mandle, EVP & COO, LifeScience Alley

Vice-Chair Klobuchar, Chairman Brady, Members of the Committee - thank you for the opportunity to testify before you this morning. My name is Shaye Mandle and, tomorrow, I will take over as President & CEO of LifeScience Alley, the nation's largest regional life science association. This year, LifeScience Alley celebrates our 30th anniversary of leading Minnesota's Medical Alley – the most densely concentrated medical technology cluster in the world and home to some of history's greatest therapeutic and healthcare innovations. Our members include 3M, Medtronic, Boston Scientific, St. Jude Medical, Covidien, Endo/AMS, Mayo Clinic and hundreds of small companies that will bring new innovation to the healthcare marketplace. Before we get started, I would like to personally thank Senator Klobuchar for her leadership and advocacy on behalf of patients and our companies who serve them, especially for those of us who call Minnesota home.

Today, this committee is interested in taking the first step to cutting red tape through better analysis. We agree that better analysis is needed and that a regulatory environment that is smarter and more collaborative would serve patients and the U.S. healthcare system well. It is also important for broad-based analysis of the entire ecosystem, including tax and regulatory policy. It is critical for Congress to address repeal of the medical device tax if we want to keep our jobs and competitive advantage, as well as providing a permanent fix to the FDA user fees and sequestration issue, to ensure that FDA has access to the funds committed by industry.

In 1957, Earl Bakken and Medtronic introduced the first battery operated external pacemaker. In 1976, the Federal Food, Drug and Cosmetics Act was amended to include the regulation of medical devices. At the beginning, innovation came from doctors and engineers working together to save lives. For the first 25 years of medical technology innovation there was no FDA oversight.

Is it our position that medical devices shouldn't be regulated? Quite the contrary. When medical devices were added to the FDA's regulatory responsibility, something unique happened. An agency with no expertise in the field connected with the patients, doctors, and innovators to form a collaborative relationship. If you talk to anyone from industry or the FDA from the early years of regulation, they will amaze you with stories of working together to accomplish a shared goal – delivering the safest and most effective therapies in the world to the patients whose lives depended on them.

Both the medical device industry and the FDA want the same outcome – safe and effective devices, invented in the U.S., and available in the U.S. first. For a couple of decades, this is exactly what we got. Over the past decade or so, this dynamic has changed and an adversarial relationship emerged.

As a result, patients outside of the U.S. frequently gain access to innovation and technology before American patients do. In fact, Eucomed claims that European patients get innovative technologies 3-5 years earlier than U.S. patients. They even have a website called "Don't Lose the 3," as in the 3 years of therapeutic advantage that European patients have over their U.S. counterparts.

But, things are improving. Passage of FDASIA in 2012 was a welcome update to our regulatory environment and MDUFA III should promote a more collaborative and effective pathway to approval. This legislation, if fully implemented as intended, will be a real benefit for patients, innovation and our economy. The FDA is working hard to collaborate with industry and is focusing on practical priorities, including 1) improving efficiency in clinical trials 2) balancing the premarket and post market process, and 3) identifying ways to shorten the lag between product approval by the FDA and reimbursement approval by CMS and/or private payers.

Dynamic public-private solutions are also happening. Since 2011, LifeScience Alley has worked closely with CDRH Director Jeff Shuren to find a solution that would re-engage the agency and industry in a conversation of collaboration and cooperation. As a result, we created the Medical Device Innovation Consortium, a public-private partnership that still has its roots in Minnesota, but now includes a national consortium from industry and key members from government, including CMS and the NIH. Through the MDIC, we are working to identify opportunities for technical collaboration in the pre-competitive space, where industry and the FDA can work together to share knowledge and improve the regulatory environment.

Better analysis means constant improvement. As one the few U.S. industries with a positive trade balance and an average wage of more than $70,000 annually, the medical device industry is a U.S. success story. Regulation is vital. Smart regulation is even more vital. We look forward to working with this committee to ensure that the U.S. regulatory environment represents the safest and smartest in the world. Thank you!