

**Statement of David Ellison, PhD
Co-founder of LiveAssay & Vice President of Government Relations, LLC
on behalf of Small and Medium Businesses**

**United States International Trade Commission
November 20, 2013**

Honorable Commissioners:

Good Morning, I am Dr. David Ellison representing LiveAssay and Government Relations, LLC. I co-founded LiveAssay during my PhD at Johns Hopkins University. At LiveAssay we make ready-made tests that are faster, more accurate, and less expensive than existing technologies for scientists. Our supply chain starts in Jaipur India, we add significant value in Seattle or Baltimore and then sell to universities in the US and Europe. At Government Relations, LLC I use this experience and passion to help other SMEs expand to global markets.

Thank you for asking for input from Small and Medium-Size Enterprises (SMEs) regarding the Transatlantic Trade and Investment Partnership (TTIP) negotiations. We are encouraged by successful programs such as the National Export Initiative (NEI). Programs such as the NEI give SMEs hope that Washington can indeed influence Main Street. Then, in return, Main Street can strengthen the entire US economy through vigorous expansion of exportation.

Small and medium businesses support the Transatlantic Trade and Investment Partnership:

SMEs agree with the premise of the final report of the US-EU Summit held on November 28, 2011 which then spurred the TTIP negotiations announced on February 13, 2013.¹ Specifically we support the efforts to 1) eliminate barriers to trade and investment 2) enhance regulatory coherence and cooperation and 3) develop new rules in areas such as intellectual property, labor, environment, regulating data flow, facilitation of supply chains, and various other areas. I, and many other businesses, applaud the efforts at trade liberalization, setting global standards, and the strengthening of the bonds between the US and the EU. With the US-EU trade accounting for 30% of global trade and investments of roughly \$3.7 trillion in each other's economies,² it is hard to underestimate the importance of increasing trade on the mutual economies.

Market liberalization is a shared value in our partnership; it is my strong urging that the TTIP negotiations be changed to a "living" agreement so that other trading partners wishing to join in our common values may do so easily. This is all the more important because many have concerns as to the commitment of the White House to our partners in Europe. The rebalancing policy as set forth in the President's speech before the Australian Parliament in 2011, reconfirmed by the National Security Advisor's speech at the Asia Society in March of this year, and then solidified in the President's Fiscal Year 2014 Budget demonstrates this policy. SMEs, such as the businesses I represent, also wish to see our trade partners in Asia opened up. However, as this Commission must already be aware, these tensions put a great deal of pressure on the TTIP negotiations to be aggressive and far-reaching. Falling short of this, by perhaps only eliminating the already low tariffs and not aggressively progressing on the harmonization of regulations, will be seen as a failure and a sign that the Administration did not place enough political capital behind the European agenda. On behalf of all SMEs we ask for an ambitious plan on regulation harmonization.

Onerous regulations are the key barrier to SME exports:

Why did I, as a SME, target regulatory harmonization in all the topics to be discussed at TTIP? That is because excessive regulations present a key unfair disadvantage to SME trade. The reason is simple: regulatory compliance is largely a fixed cost. A SME simply has fewer "widgets" (e.g. products, service hours) in which to recover those fixed

costs before making a profit. This is the largest factor stopping SME trade with the EU of which the US government directly controls. Every regulatory hurdle that falls, allows more SMEs to enter the market simply because they have a fair chance to do so.

I will give an example of some of the regulations which cause concern. This is by no means, even remotely, is close to a comprehensive list. I could only wish that it was possible to briefly name the regulations slowing trade between our countries.

SMEs support harmonized medical device regulation:

Medical devices are critical to delivering fast and safe treatment opinions for patients, and yet face significant harmonization barriers. In general, European patients have access to new medical devices earlier than American patients. The European system has been reported to be better for patient care³ and unnecessarily sends jobs out of the USA⁴. I would prefer to see a harmonized system in which the US learns from the European model and relaxes onerous regulations. However realistically, I see these four objectives being met at minimum: 1) Mutual recognition of ISO 13485 (the standard for quality management in the design and manufacture of medical devices), 2) A single audit process 3) Harmonized format for product registration submission, and 4) A common way to trace products through a single unique device identification (UDI) process with interoperable databases - all of which recommendations are accordance with the suggestions of AdvaMed⁵.

Dangers of REACH annexes on nanomaterials and other advanced materials:

I cannot think of very many businesses happy with the EU's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation of 2006. In particular however, nanomaterials were at least not explicitly mentioned by this regulation. This is changing as the consultation on the modification of the REACH Annexes on Nanomaterials was closed September 13, 2013.⁶ Please include harmonization of these forthcoming regulations into the TTIP negotiations. We cannot afford that this critical segment of trade be crushed by new regulation coming out moments after the TTIP deal is signed.

More trade equals a safer, freer world:

Thank you for your attention to these matters. I, and the companies I represent, are more than willing to help assist the Commission in helping small businesses export. Why? Because I know that exportation policy is an area in which the government itself can have a great affect for good on small businesses. When small businesses export that puts money in the pockets of our friends, families, and neighbors. More exports equal a stronger US economy. More trade equals a safer, freer world. Thank you.

References:

¹ The White House. "Statement from United States President Barack Obama, European Council President Herman Van Rompuy and European Commission President José Manuel Barroso." Press Release. February 13, 2013.

² Cooper WH. "EU-U.S. Economic Ties: Framework, Scope, and Magnitude." CRS Report RL30608.

³ Gottlieb S. "How the FDA could cost you your life." Wall Street Journal. October 3, 2011:A17.

⁴ Ferman J. "Medical devices industry assessment: report of the Office of Health and Consumer Goods Health Team International Trade Administration." International Trade Administration. July 12, 2010.

⁵ Moebius A. "Medical Technology Industry Calls for Regulatory Convergence In US-EU Trade Deal." Press Release. April 11, 2013.

⁶ European Commission. "Nanomaterials: Case by case safety approach for breakthrough technology." Press Release. October 3, 2012.