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Ambassador Michael Punke
Deputy United States Trade Representative and U.S. Ambassador and Permanent
Representative to the World Trade Organization
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20503

Dear Ambassador Punke:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide comments on the standards and regulatory components of the U.S.-EU Transatlantic Trade and Investment Partnership (TTIP).

The NAM is the largest manufacturing association in the United States, representing more than 14,000 businesses of all sizes in every industrial sector and in all 50 states. Manufacturing employs more than 12 million women and men across the country, accounting for two-thirds of private sector research and development and contributing over \$2.17 trillion to the U.S. economy annually. Many of those manufacturing companies do business internationally, exporting millions of dollars' worth of products overseas, including to markets in Europe.

A comprehensive, high-standard and market-opening TTIP represents a significant opportunity for manufacturers in the United States. While U.S.-EU trade and investment flows are substantial and U.S. and EU standards are generally high, there remain significant barriers and differences that undermine the competitiveness of manufacturers in the United States in EU markets that a strong TTIP could and should materially address.

As efforts continue to resolve as many outstanding issues as possible by the end of the administration, U.S. and EU negotiators must resist the temptation to conclude any part of the agreement in a way that falls short of the type of ambitious and high-standard outcome envisioned when the talks launched in 2013. Given the current global environment of lower growth and increasing barriers to trade, it is now more important than ever to push for an ambitious TTIP that will meaningfully boost economic growth and opportunity.

Promoting regulatory cooperation and eliminating related barriers to trade have been highlighted by manufacturers and by both U.S. and EU governments as one of the most critical areas on which to make progress. The United States and European Union have been actively negotiating proposals tabled by both sides, including chapters on regulatory cooperation, technical barriers to trade (TBT), food safety and animal and plant health (SPS) and various sector proposals, as well as other regulatory issues that appear in other chapters, such as energy. Improved transparency and stakeholder consultative processes, regulatory cooperation aimed at aligning technical requirements and conformity paths that includes mutual recognition among the

potential options and broader recognition and use of international standards that meet needs in both markets could reduce testing and certification costs in both the United States and European Union. One estimate of even a modest realignment of standards and elimination of non-tariff barriers would increase combined GDP by more than \$106 billion.¹

Yet regulatory cooperation is a perfect example of an area in which the United States should not sacrifice core priorities that would undermine the competitiveness of its manufacturers. Pressure to make such sacrifices comes in the form of a strong EU push to allow greater access for their companies without adjusting any aspects of their own system. This push is embodied in the latest draft proposals tabled by EU negotiators during the April and July rounds of TTIP negotiations, and posted subsequently to a [dedicated webpage for EU proposed texts](#). These proposals raise a number of core questions and concerns for the NAM and its manufacturers, which are summarized in the sections below.

Provisions that Weaken the TBT and Other Strong Horizontal Chapters

The NAM and its members firmly believe that strong horizontal chapters – such as the TBT and SPS chapters – are essential components of successful U.S. trade agreements. Such chapters must include several key components, including transparency – a longstanding challenge for manufacturers in the United States seeking to operate in the European Union.

In the United States, new tools such as the revised Office of Management and Budget Circular A-119 have increased opportunities for all parties, including ones outside the United States, to participate in U.S. regulatory processes. In the European Union, however, transparency remains a challenge for manufacturers in the United States, as companies sometimes learn of relevant regulations just before the regulation is presented for final action at the European Parliament, after it has already been accepted by the European Commission.

The TBT and SPS chapters included in the Trans-Pacific Partnership (TPP), for example, include strong, enforceable provisions on good regulatory practice with respect to transparency and openness during regulatory processes, regular regulatory reviews and interagency coordination. These chapters also reflect a clear recognition of the U.S. approach to private international standards development activities, and contain clear language making them subject to dispute resolution. The SPS chapter contains additional language to ensure rapid responses for shipments delayed at borders due to SPS disputes.

The EU's proposals, however, diverge significantly from that approach. Articles 4 and 5 of the [TBT proposal](#), for example, focus more on adding requirements for each party to consult with the other party on planned regulations than increasing good regulatory practice as part of each party's rulemaking processes. Of even greater concern, however, is the inclusion of TBT-like provisions in various sector-specific annexes that are weaker than the proposed TBT obligations. Such language, which appears in sector annexes of the EU's proposals on [engineering](#) (Article 8), [chemicals](#) (Article 9) and [autos and auto parts](#) (Articles 10 and 12), undermines the strength of the TBT chapter as a whole. Language that undermines horizontal TBT provisions on national treatment for conformity assessment similarly appears in the sector

¹ The Transatlantic Economy 2014: Annual Survey of Jobs, Trade and Investment between the United States and Europe, Daniel S. Hamilton and Joseph P. Quinlan, Center for Transatlantic Relations, Johns Hopkins University Paul H. Nitze School of Advanced International Studies.
http://transatlanticrelations.org/sites/default/files/TE2014_executive_Summary_0.pdf.

annex on engineering, and language on testing and audits appears in annexes on [pharmaceuticals](#) and [cosmetics](#).

The NAM and its members are concerned about any language on transparency and good regulatory practice in sector-specific annexes that would be weaker than the core transparency principles included in the TBT chapter. As such, we urge that any provisions on transparency in sector-specific annexes is accompanied by explicit language saying that those provisions are in addition to, and do not supplant, the core transparency principles included in the TBT chapter. If such language is not included, such sector-specific transparency language would represent a significant step back from the TPP standards that manufacturers in the United States need to compete on a more level playing field globally.

Provisions Calling for One-Sided Market Access Openings to Advantage European Players at the Expense of American Industries

In many of these sector annexes, including the annexes on engineering, [textiles](#), and [chemicals](#), as well as the separate chapter on [energy](#), European negotiators have proposed text designed to gain market access in the United States for their products by altering existing statutory U.S. programs. For example, the EU's position paper on engineering clearly states their desire to sidestep existing third-party conformity assessment requirements, such as the Occupational Safety and Health Administration's Nationally Recognized Testing Laboratory (NRTL) program, to gain access for its products. The EU's proposed energy chapter similarly seems to call for revision of existing U.S. programs for energy efficient products, such as EnergyStar, to more closely align with European norms (Article 7).

While seeking to lessen U.S. standards or subvert well-established U.S. conformity assessment processes, these chapters do not include any language to expand market access for U.S. products. Among the many areas ignored by these proposals that are important for manufacturers in the United States are reducing conformity assessment barriers for U.S. engineering products that enter the EU, allowing national treatment for U.S. conformity assessment bodies, or improving transparency and opportunities for U.S. companies to participate in standard-setting activities.

Provisions for Regulatory Cooperation only through EU-Defined International Standards

Several of the EU's proposals reference the need for greater coordination of regulations between the two parties – a worthwhile goal that overlaps with a U.S. push for mutual recognition and harmonization. Such coordination, however, should involve both bilateral and multilateral engagement to find solutions that fit both regulatory systems. Across the board, the EU's sector-specific proposals call for increased harmonization by the United States and the EU with an emphasis on having both regulatory systems base their work on standards set by a few specified international organizations. This includes a call for standards set by the International Standardization Organization (ISO) and International Electrotechnical Commission (IEC) (engineering, textiles), the United Nations Globally Harmonized System (chemicals), or the International Medical Devices Regulatory Forum (medical devices).

Yet these provisions clearly reflect a top-down, government-led approach to standardization widely seen in the activities of EU standards agencies. In practice, an "international standard" should also be defined to include private-sector standards broadly used around the world, even if they were not developed at the ISO or IEC. The NAM urges the U.S. government to continue

to push back on Europe's attempts to limit the definition of international standards on which joint work should be based only to these bodies.

Provisions that Appear to Target and Block American Industry

Finally, the NAM and its members remain highly concerned about language scattered throughout the EU's proposed text that appears to be aimed at key aspects of the U.S. standards and conformity assessment system and the business model of its key players. For example, several provisions in Articles 7 and 8 of the TBT Chapter seem targeted at industry players, including:

- Article 7.5, which requires the parties to take measures to avoid actual or potential conflicts of interest between conformity assessment bodies (CABs) and standardization bodies by establishing a clear separation of functions;
- Article 7.6, which says CABs testing final products cannot require clients to have components or parts be reassessed by the CABs;
- Article 7.7, which calls for steps to prevent the establishment or abuse of dominant positions by any CAB for the assessment of a specific product or class of risks; and
- Article 8.1, which requires marking to be no more trade-restrictive than necessary and does not take into account needs to protect against counterfeiting.

The NAM also has a number of important questions about provisions in various annexes, such as the definition of "responsible authorities" in the chemicals and cosmetics chapters, concern about the overly broad scope of engineering products and pharmaceutical products in their respective chapters, a need for more information about the process for a "medical devices single audit," and concern about requests to ensure that marketing authorizations for pharmaceuticals are subject to TBT but do not require detailed price data.

Conclusion

The NAM appreciates the strong work of U.S. negotiators to pursue outcomes that will address barriers and improve U.S. competitiveness in the EU, particularly in the regulatory and TBT areas. It is critical that obtaining those strong outcomes drive the pace of the negotiations particularly in the coming weeks. Agreeing to weak regulatory or related provisions would leave in place the most pernicious barriers that manufacturers in the United States face in the EU, damaging the ability of major stakeholders to support such a deal and seriously undermining any chance to conclude a successful TTIP. On behalf of its members, the NAM appreciates the opportunity to engage with U.S. negotiators on these and related TTIP issues, and would be happy to discuss these issues further at your convenience.

Respectfully,

A handwritten signature in black ink, appearing to read "Linda M. Dempsey", is written over a light gray rectangular background.

Linda M. Dempsey