TRANSATLANTIC
BUSINESS COUNCIL

COMMENTS OF THE TRANSATLANTIC BUSINESS COUNCIL CONCERNING THE PROPOSED TRANSATLANTIC TRADE AND INVESTMENT AGREEMENT

Submitted to Office of the United States Trade Representative

May 10, 2013

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May 10, 2013

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RE: FEDERAL REGISTER NOTICE OF APRIL 13, 2013-REQUEST FOR COMMENTS CONCERNING PROPOSED TRANSATLANTIC TRADE AND INVESTMENT AGREEMENT

Mr. Bell:

The comments and recommendations contained herein reflect the considered input from the member companies of the Transatlantic Business Council (TBC). The TBC is a cross-sectorial business association representing companies headquartered in the US and Canada and in the EU and EFTA countries. The organization's mission is to (1) promote a barrier-free transatlantic market that contributes to economic growth, innovation, and security; (2) foster discussion and the exchange of ideas among business and government leaders; and (3) serve as a platform for engaging others in the global economy.

TBC's members have long supported negotiation of an expansive free trade agreement between the European Union and the United States and warmly welcomed the February 13, 2013 announcements by EU leaders and President Obama of their intentions to initiate the internal procedures necessary for the eventual launching of formal negotiation of the Transatlantic Trade and Investment Partnership (TTIP). In response to the above referenced Federal Register notice, the TBC requests consideration of the comments and recommendations contained herein in order to assist the US and EU negotiators in their effort to complete a successful agreement as expeditiously as possible. Although the TBC is not submitting recommendations on every issue addressed in the Final Report of the US-EU High Level Working Group on Jobs and Growth, our membership firmly supports an agreement as expansive and comprehensive as possible.

I. MARKET ACCESS-GENERAL

- Immediate elimination of tariffs should be applied to as many tariff lines as possible. Staged tariff elimination on all remaining products should be achieved in reasonable timeframes.
- No *a priori* exclusions of any product or tariff lines from the scope of any provisions and chapters of the trade agreement
- No export quantitative restrictions on raw materials or agricultural products.

II. REGULATORY PRACTICES

Regulatory Convergence

- The TBC believes that regulatory differences, including with respect to the role of science and evidence in developing regulatory measures, in some sectors are acting as a major brake on transatlantic trade and economic growth. Lack of regulatory convergence increases costs across the range of industrial and service sectors and undermines competitiveness among actors in the value chain, ultimately leading to a poorer deal for European and US consumers.
- Significant differences often exist in regulatory philosophy and the prescribed test procedures and requirements between US and EU regulations, although the intended environmental and safety outcomes can be very similar.
- The transatlantic trade agreement presents an opportunity to implement a regime that effectively breaks down regulatory barriers across industrial sectors, while respecting US and EU sovereignty and without sacrificing safety or environmental standards for consumers. In this vein, the agreement presents both an opportunity to overcome existing barriers to trade in goods and services between our respective markets and to strengthen ongoing work under the US – EU High Level Regulatory Cooperation Forum (HLRCF) in order to prevent barriers from being established in new and emerging technology.
- We recommend that the US and the EU begin with areas where mutually beneficial change can be made quickly in order to build an appropriate amount of momentum going forward. It is essential that adequate resources be devoted to ensuring that any new tools or governing processes established under the initiative will be adequately supported, and a mechanism is established to facilitate regular engagement with the private sector.

Key Principles

We suggest the following as principles, which should underpin the regulatory convergence process with a clear recognition that if the US and EU can agree on common standards, they can become global standards to the benefit of our companies on both sides of the Atlantic:

- As negotiators address issues across legal, regulatory, and policy frameworks, they must consider how to best coordinate approaches on both sides of the Atlantic to maximize the potential for trade opportunities, reduce unnecessary costs and administrative burdens, and enhance economic growth and societal benefit. In some cases, harmonization may be among the best approaches where it results in a compromise of positions that achieve the objectives set forth above. However, the parties recognize that harmonization may be a longer-term project. We also recognize the benefits of regulatory approaches converging where they can embrace the best practices of facilitating trade and investment. At a minimum, there should be coherence across regulatory approaches so as not to create impediments to trade. Finally, one of the most practical approaches to bridging divides across legal, regulatory and policy frameworks is interoperability. We should be clear that this is not interoperability in the technical sense, but is rather policy interoperability, or the ability of policies to work together. This type of policy interoperability often

affords shorter-term solutions to enable trade and business across regions where there is incomplete legal, policy or regulatory coherence.

- With respect to existing technical regulations and standards, the TTIP should encourage harmonization and consider the potential for mutual recognition frameworks, if doing so meets legitimate business objectives and enables regulators to meet the legitimate objectives of the regulation. Regulators should be encouraged to look for sectoral opportunities where the concept, "tested once, accepted in both markets" can be pursued. The future agreement should build upon WTO TBT principles, including preserving regulators' decision making authority.
- The TBC believes that the process of reviewing sectors where additional regulatory convergence and standards harmonization should continue or commence under the High Level Regulatory Cooperation Forum (HLRCF) during TTIP negotiations between the EU and US. We note that the auto industry is proposing the immediate commencement of a review process with a defined timeline to mutually recognize a list of specific regulations with regulators making public their findings on specific regulations.
- In order to minimize regulatory impediments and avoid unintended consequences, the TTIP should include the following provisions for trade-impacting regulations:
    - regulations should be limited to specific and legitimate public policy objectives consistent with international treaties;
    - regulations should be established pursuant to transparent procedures allowing comment by all interested parties;
    - regulations should not constitute unnecessary barriers to trade in services such as impediments to integrated services and complex supply chains; and
    - parties should review and eliminate regulations, or forbear from their application, in situations where competitive market forces are present; and
    - technical regulations, if and when justified, should be performance-based and only in the rarest of circumstances should they be prescriptive (i.e., mandates requiring specific technologies or product characteristics), in which case the enacting government should have the burden of proving why they are justified and other alternatives are not feasible.
- **New Regulations** – For emerging regulations, the EU and the US should implement a joint regulatory harmonization or interoperability process that promotes and facilitates the development and adoption of common future new regulations. Both sides should agree on the use of science-based, risk-based, transparent regulatory approaches. For those sectors where international regulatory bodies already exist, the EU and US should continue using those forums to develop new regulations.
- **Standards** – To enhance innovation and transatlantic trade both the EU and US should ensure that regulatory convergence mechanisms allow companies and consumers the ability to choose international standards from multiple sources following the definition of international standards embodied in WTO TBT Committee Decision, and the actual qualities, attributes, and relevance of the standards. Harmonization of EU and US standards should also be encouraged on emerging technologies, where there are no legacy issues, such as but not limited to, Internet-based products and services. As we consider global technical frameworks related to the Internet and Cloud, we highlight the importance of mapping to internationally accepted standards.

- **Electro Mobility** - In developing this joint approach, the lessons and experience of the recent US-EU collaboration in developing an electric vehicle plug standard should be used. We strongly support this effort and encourage using this as a model for regulatory convergence and compatibility and by expanding this approach to other new regulations being considered by the United States and the European Union.
- **Regulatory Cooperation Forum** - Strengthen the US-EU High Level Regulatory Cooperation Forum of key US and EU regulators to develop common approaches to regulation, with an overarching Framework Regulatory Accord, that would embody many of the principles of transparency embodied in the US Administrative Procedures Act.
- **Sector Task Forces** - Consider establishment of sector-specific task forces to continue to work towards recognition frameworks following the conclusion of the trade pact negotiations. The automotive industry is proposing a task force to meet at least twice a year to consider industry proposals for further regulatory convergence of existing regulations. The task force would be coordinated by the Office of the United States Trade Representative (USTR) and the Office of Information and Regulatory Affairs (OIRA) for the United States and Directorate General for Trade and the Office of the Secretary General for the European Commission.
- **Transparency** – There should be a transatlantic impact assessment with clear criteria for evidence and cost-benefit analysis for all regulations over a certain economic impact, providing notice to either side along with an opportunity to comment. The decisions of regulators on specific regulations should be made public. For example, the proposed auto sector task force would release annual reports to the public on its regulatory convergence efforts and if the US and/or EU officials reject a proposal, the supporting performance outcome data should be published.

III. INTELLECTUAL PROPERTY

- **Intellectual property remains essential to economic expansion, business and societal innovation and national competitiveness for both the US and EU**. IP-intensive industries are linked to 35% of US GDP and nearly 30% of all US employment. The EU is no less reliant on its many IP-based industries, including health, aerospace and green technologies along with many others. And as internet-enabled innovation increasingly drives productivity and growth on both sides of the Atlantic, the importance of intellectual property to creating new jobs and growing exports will only increase.
- **We believe strongly that any eventual transatlantic trade agreement should reflect this shared reliance on intellectual property.** Both markets share a deep commitment to protecting intellectual property and a recognition that strong intellectual property regimes are an indispensable element of successful economies and to create and maintain innovation and technology-driven exports, competitive opportunities, and jobs. This shared consensus should serve as the starting point for discussion.
- **Inclusion of provisions on intellectual property in any transatlantic agreement is especially important as a means to foster strengthening of intellectual property standards globally.** More than half of our exports originate from IP-intensive industries. Expanding the transatlantic economy is thus directly contingent on strong protections for US and European intellectual property in foreign markets. But many of our trading partners -- in particular emerging economies -- are moving in the opposite direction,

toward an erosion of intellectual property rights, often intended to advance protectionist industrial policies or otherwise ill-advised agendas. Examples of this erosion include:

- **"Domestic innovation" policies.** These policies take many forms, such as procurement policies that discriminate against "foreign" IP or impose local content requirements; measures to force technology transfer, including through liberal use of compulsory licenses targeted at foreign patent holders; restrictions on the use of trademarks; and preferences for products that implement domestic standards. While approaches differ, all of these measures serve as non-tariff trade barriers, reducing the ability to compete in foreign markets.
- **"State-sponsored IP theft."** Evidence is building that some governments have supported and even sponsored the theft of proprietary information from innovators in third countries. This "state sponsored IP theft" is often focused on the highest value and most innovative sectors in a country's economy.
- **"Calls for greater IP "flexibilities."** Emerging markets now routinely take the position in multilateral fora that intellectual property rights are a barrier to economic and societal (i.e., the public interest) advancement, despite overwhelming evidence to the contrary. These claims -- made in the UNFCCC, WIPO, WTO and WHO -- often reflect the claimants' short-term political and industrial policy aims, and not a desire to advance broader economic development or access objectives. Weighing a number of considerations is of course essential to any workable multilateral intellectual property framework -- but this is precisely what the TRIPS Agreement, as well as a range of existing EU and US bilateral and regional trade agreements already do; dismantling or destabilizing that framework should not be our aim.

- **A transatlantic trade agreement presents a unique opportunity for both the US and EU to demonstrate global leadership on intellectual property.** The parties have already acknowledged that an EU-US agreement will go beyond existing trade agreements in both substance and scope; and that it is intended to be a deep, comprehensive and 21st Century trade and investment agreement. The world's two most important markets have a rare opportunity to establish high standards for intellectual property protection in a trade agreement that will govern trade and influence other negotiations for decades to come. Positive commitments regarding patents, trade secrets, and other forms of intellectual property rights are essential elements in this regard. Failure to include intellectual property, in contrast, would send the wrong message to third countries and would substantially undermine the value of any agreement, leading them to believe violation of IP rights can be done with impunity.
- **Any transatlantic agreement should reflect a shared commitment to robust protection of all forms of IP, including patents, trademarks, copyright and trade secrets.** Examples of possible IP-based commitments that the US and EU could undertake include:
  - **Expanding current commitments to align US and EU positions in multilateral dialogues, to encourage robust third country protection of intellectual property**. The EU and US already collaborate towards this objective, in commitments made in the Transatlantic IPR Working Group's Action Strategy,

and in the Transatlantic Economic Council. These commitments could be further bolstered by the inclusion of similar mechanisms in a transatlantic agreement.

- **Harmonizing and improving protections for trade secrets**. Although trade secrets often represent a company's most valuable knowledge, these intellectual property rights are often subject to the weakest regulatory protections. A transatlantic agreement should seek to remedy this gap.
- **Improving the quality and effectiveness of the patent system.** The Transatlantic Economic Council framework already highlights the importance of cooperation to enhance the effectiveness of the patent system. While important steps have already been taken towards this goal, even greater cooperation and harmonization is achievable, including through measures to expedite the patent examination and prosecution process.
- **Maintaining a strong trademark system as incentive to innovation and creativity.** Trademarks are key to indicate the source and origin of goods and services and to assure consumers of the quality of these. Trademarks are also crucial to enable competition and innovation for companies. There are growing instances of public policy debates suggesting interventions which could damage normal use of trademarks, impact consumers' choice, lead to trade discrimination and increase counterfeiting activity. Efforts should be made to keep a balance and proportionate system ensuring continuing business confidence.

IV. INNOVATION

In the economy of the 21st Century, innovation is the principal driver of economic growth, employment and competitiveness. One of the most significant contributions that a comprehensive Transatlantic Trade and Investment Partnership (TTIP) can make to mutual economic development is to remove unnecessary impediments to transatlantic research and development and other cooperation in innovation. While many TTIP chapters will contain provisions supportive of innovation (such as strengthened protections for intellectual property, and regulatory coherence), negotiators should consider also including a separate chapter on innovation to emphasize its importance and facilitate development of a comprehensive, coherent set of measures to create a transatlantic zone in which innovation can flourish. The potential for transatlantic cross-fertilization is particularly strong in mobile/communications, bio-pharmaceuticals, recycling, smart grid, renewable energies, automotives, and nanotechnologies.
A comprehensive innovation chapter should address impediments to the freest possible exchange of ideas, capital, goods, services, and people, and create common frameworks between the US and EU for programs to encourage both basic research and development and also the commercialization of new technologies. For illustration, such measures should include:

- removal of statutory impediments to collaboration between public and private sectors thereby allowing for optimal research cooperation;
- procedures and processes for the treatment of flows of controlled technology for collaborative, transatlantic research and development projects that recognize the particular needs for such exchanges;
- provisions to facilitate the transatlantic mobility of researchers and technologists engaged in collaborative projects;

- support for policies that promote investment in innovation-centric sectors;
- provisions for the cross-border flow of information that facilitate research into new and innovative processes and products, as well as technological developments such as the industrial internet; and
- elimination of "localization requirements" for the application of technology whose development is supported by public funds.

These recommendations are based on our experience as global businesses, and reflect some of the areas that have the greatest potential to accelerate innovation. They also are based on observations about the process of innovation in the transatlantic market.

Much of the world's scientific and technical innovation takes place within and between the US and EU. Working together, we have the opportunity to revitalize languishing industries, accelerate the development of advanced technologies, develop new products and services, create good paying quality jobs and enhance the ability of the transatlantic market to compete with the rest of the world. Moreover, transatlantic leadership to foster innovation would set the example for other countries struggling to develop and implement appropriate policies that support and accelerate innovation.

V. INVESTMENT

We believe that the EU and the United States are well-positioned to set the highest level of standards for investment protection. In order to promote the 2012 agreed-upon Shared Principles for International Investment, we call on both parties to:

- Negotiate a liberal investment agreement that includes broad provisions for (a) reducing, or wherever possible, eliminating exceptions to national treatment principle, (b) robust disciplines to protect investments against expropriation, (c) fair compensation for expropriation in all sectors, including IP, and (d) meaningful procedures for resolving investment disputes.
- Ensure the fullest measure of transparency in the dispute settlement mechanism, to the extent consistent with the need to protect information that is classified or business confidential.
- Establish a mechanism for acceptance of amicus curiae submissions from businesses, unions, and nongovernmental organizations.
- Use robust mechanisms to resolve disputes between an investor and a government.
- Adopt procedures to ensure the efficient selection of arbitrators and the expeditious disposition of claims.
- Provide for an appellate body/review mechanism to provide coherence to the interpretations of investment provisions in trade agreements; and
- Base regulatory measures which limit or reduce investment protection provisions on sound science and objective evidence.
- Remove obstacles to cross-border venture capital.
- End transatlantic foreign ownership restrictions.

VI. PROCUREMENT

While the US and EU both are members of the WTO Government Procurement Agreement, TTIP provides a good opportunity further to improve market access between the two parties. We propose that TTIP include a robust chapter on procurement that contains the following:

- agreement that neither party will adopt new measures restricting market access in procurement beyond measures already in place, regardless whether they may be consistent with obligations under the WTO GPA or other provisions of TTIP;
- increased coverage of central government procurement, based on a negative list approach;
- increased coverage of sub-central entities, including coverage of procurement using financial assistance and other funds flowing from central governments to sub-central entities; and
- measures to guarantee transparency in procurement, including a requirement that procuring entities maintain effective anti-solicitation compliance programs.

VII. SERVICES

Many statistical data and studies demonstrate the vital importance of trade and investment in services for the transatlantic economies. The volume of EU-US bilateral trade in services, with a total of $338 billion in 2010, is by very far the highest in the world. The figures demonstrate the importance of the US market to European services companies and vice versa, highlighting the importance of services in the TTIP negotiations.

In particular it is important to consider in the negotiations the key role of services for the global value chain. Services are a critical but often overlooked part of it. They play an on-going essential role in the transformation of international trade and investment patterns, both through enabling the development of value chains and through the creation of value chains in their own right. The global value chain includes the full range of activities that firms undertake to bring a product or service from its conception to its end-use by final consumers. These activities include design, production, marketing and support.

The competitiveness of EU and US manufacturing is increasingly dependent on services. Logistics, maintenance, ICT business services, consulting, financing, electronic communications and data processing are integral part of any competitive offering in technology, machinery, processing and consumer businesses. Efficient services consumed by the manufacturing companies in their daily operations are also an integral part of their competitiveness. Manufacturing firms increasingly buy, produce, sell and export services as integrated or accompanying parts of their primary offer. This concept is also called *servicification*.

The large potential for further growth in services trade is hampered by regulatory restrictions on both sides of the Atlantic. TBC calls upon the European Commission and the US Administration to ensure that the importance of trade and investment in services, including services that can be delivered through cross border data flows, is duly reflected in the negotiations. While the transatlantic services market is already very much integrated, there is a need to go further. TTIP

should cover market access negotiations at all possible levels, including NTBs and other forms of de facto barriers to compete.

We believe that to create a real transatlantic services market, the EU and US need to establish meaningful and outcome-driven regulatory cooperation in key services sectors involving not only regulators at EU and US federal level, but also regulators at sub-federal level and EU Member states level, i.e. wherever the regulators are.

The TTIP agreement should also comprise a comprehensive market access to public procurement for services, with low thresholds and substantive coverage of all public institutions and entities. The agreement also should include high level investment protection with efficient investor-to-state dispute settlement.

VIII. CUSTOMS/ TRADE FACILITATION

Government and non-government organizations ranging from the WTO to the UN have emphasized that overly complex customs and trade procedures, requirements and practices can hugely disrupt supply chain logistics, creating costly obstacles that harm companies, consumers and, by extension, global economies. Major burdens, delays, and costs can emanate from slow customs clearance procedures; excessive requirements for customs entry documents and data; non-automated processes for the import/export/transit of goods; vague or inconsistently applied customs requirements; and rules that do not take account of risk management or reasonable penalty mitigation procedures. By disrupting global supply chains, these impediments and expenses can stifle easy market access and increase the cost of goods. In a report entitled *Enabling Trade — Valuing Growth Opportunities,* the World Economic Forum noted that "Reducing supply chain barriers to trade could increase GDP up to six times more than removing tariffs." Further, World Trade Organization (WTO) Director-General Pascal Lamy has stated that "removing barriers to trade and cutting red tape in half… could stimulate the US$22 trillion world economy by more than $1 trillion."

While customs and trade officials within the US and EU have made trade facilitation a high priority over the years, numerous TTIP commitments could be undertaken to further improve trade procedures and practices between the two parties and to set a global standard. In particular, TBC recommends commitments to the following actions in the agreement:

- A single window within the territory of each TTIP party that enables traders to electronically transmit all customs or other data required by a government for the import, export or transit of goods.
- Submission and processing of import-related information (including security data) to enable pre-clearance of goods before their arrival at a port of entry.
- Separating the release of goods in customs custody from the payment of duties or other import charges.
- A unitary import clearance process which ensures that the inspection requirements of all government agencies with border-related responsibilities are met in the conduct of a single cargo release. In addition, clearance procedures across EU member states should be harmonized.

- Robust deployment of automated systems and procedures that expedite release of goods and processing of customs information, ensure system interoperability and compatibility, and avoid redundancy via use of common data elements and related processes for the import, export and transit of goods.
- A US/EU mutual recognition agreement that streamlines criteria and procedures for trusted trader programs through such means as: uniformity between the EU Economic Operator and US Customs-Trade Partnership Against Terrorism programs; a common web-based application process for participation in trusted trader programs between the EU and the US and among EU member states; assurance that program participants are "first-in-queue" when inspections are required; and enabling program participants to provide import documents to authorities after release of goods.
- Capability for the export documentation/declaration of one party to be used as the import documentation/declaration of the other party, while ensuring harmonization of data requirements.
- Commitment to an administratively easy and time-limited process for issuance of advance rulings.
- Establishment of an enduring transatlantic trade facilitation forum involving government and business stakeholders from both parties to ensure that progress is made on ongoing facilitation measures and that new facilitation efforts are pursued as warranted.
- Commitment to reasonable border compliance and enforcement practices, including consistent interpretation and enforcement of import laws and regulations, elimination of vague requirements, and use of penalty mitigation guidelines that take account of an importer's compliance record and internal procedures.
- Better coordination between CBP and other federal agencies (i.e., FDA, USDA, etc.) in order to streamline the process.

IX. WORKFORCE

We request inclusion of measures to promote short term skilled labor mobility within the scope of the Transatlantic Trade and Investment Partnership (TTIP) negotiations or other relevant discussions between the two trading partners. Labor mobility is not only a necessary component in the provision of many cross-border services. Mobility and the corresponding ability to utilize the skills and competence of employees deployed outside of their regular country of residence are critical elements of the global talent sourcing practices increasingly common within companies on both sides of the Atlantic.

Speed and predictability are key aspects of a skills mobility policy which should include a broad and comprehensive definition of skilled workers employed by EU and US companies. A preliminary sample list of objectives for TTIP negotiations should entail:

- Establish a fast track approach for expeditious processing of visa/work permit applications.
    - Expand this expedited, Consulate-only process to all employees—not just "professionals"—in other words, allow technicians to automatically qualify for blanket L-1B process.
    - Recognize "degree equivalency" for accredited universities (currently, some

degrees awarded in Europe are not recognized as "equivalent" to US degrees).
    - Exempt EU and US employees from prevailing wage standards for all visa types since they are already presumably being compensated at commensurate levels.
- Exempt EU nationals from H-1B cap or create a separate quota for them and allow them to apply directly at the Consular post rather than going through USCIS similar to H-1B1s for Chile and Singapore or the E-3 Certain Specialty Occupation Professionals visa which applies to nationals of Australia.
- In any instances where local labor market or volume quotas tests exist, such tests will not be applied to intra-corporate transferees.
- In the context of intra-corporate transferees, a simple notification should be required prior to beginning work in the US for EU nationals or in the EU for US nationals rather than submission of a visa application for prior approval (based upon for instance listing of trusted companies).
- In the context of intra-corporate transferees, the benefits of the provisions of a TTIP agreement should apply to employees of US or EU enterprises regardless of the nationality of the individual concerned.
    - There should be no home residency requirements (just like a TN can work even if subject).
    - Make the visas be valid for at least 3 years initially but NOT subject to a cap, as in the TN context.
    - Employees of acquired companies will immediately qualify for this visa—no need to wait for one year of L eligibility, for example, even if not a successor in interest.
- Harmonize and widen the scope of "allowable activities" under business visitor status and have more flexible treatment for duration of stay under short term business visas.
    - Visas and authorized stay should be for maximum validity allowed under that visa category.
    - The agreement should authorize in-country visa revalidation for these individuals.
    - Visas should allow for multiple entries within the validity of the visa.
- More liberal family reunification rights should be accorded in order to accommodate non-married spouses, children above the age of 18 as well as parents. Integration should be encouraged through provisions providing access to the host country job market for spouses and working age dependents.
    - Spouses should be able to work incident to status without an Employment Authorization Document.
    - Children of work-eligible age should be allowed to work incident to status.
    - Domestic partners should be issued derivative visas and periods of stay coterminous with that of the principal, as well as the ability to legally study and to work incident to status.
    - Children of domestic partners should be issued derivative visas and periods of stay coterminous with that of the principal, as well as the ability to legally study and to work incident to status if of work age.
    - Children over the age of majority eligible for derivative status should be

accorded derivative status if still dependent on the principal and that status should be considered "dual intent".
    - Dependent visa or visa for family reunification should be processed along with the main applicant's visa.
- Current rights available under Mode 4 in the GATS agreement should be expanded to include additional skilled job categories such as researchers and technicians.
- A stand still clause should be imposed with respect to any new potential restrictive migration measures.
- Harmonizes the provisions of bilateral social security tantalization agreements between individual EU member states and the US.
- Global Entry: For frequent travelers from the EU to the US and also from the US to the EU an expansion of the American Global Entry System and the setup of the European Registered Traveler Programme would be very helpful to reduce waiting times at the point of entering the respective country. The system should be expanded to also include non-immigrant visa holders and also frequent travelers from visa waiver countries.
- US Immigration Preclearance: Consideration should be given to the expansion of the system of US immigration preclearance at the airport of departure. Currently, the US system of immigration preclearance is largely limited to airports in Canada and the Caribbean.

X. COMPETITION

Competition law should be applied in an open, transparent manner that provides procedural fairness to all parties. Moreover, governments must assure that state-owned enterprises ("SOEs") compete in the marketplace on a level playing field, not displace private company efforts, and do not enjoy unfair advantages over their private-sector competitors, whether in the form of direct aid or disparate treatment in regulatory or other matters. We propose that TTIP contain a chapter on competition to address these issues, including:

- adherence to transparency and due process obligations in competition enforcement matters encompassing both conduct and merger review, with possible reference to OECD and ICN best practices; and
- disciplines on financial subsidies and other public support to SOE's;
- disciplines on indirect government support of SOE's, such as preferential access to public services or preferential treatment in regulatory matters;
- disciplines on conduct by SOE's that if taken by governments directly would be inconsistent with obligations under TTIP or multilateral agreements, including actions not taken in accordance with normal commercial considerations; and
- an obligation for SOE's to adopt effective anticorruption compliance programs and direct accountability of governments for damages to competitors caused by illicit practices undertaken by SOE's.

SECTORS

A. AUTOMOBILES

The potential gains to be derived from regulatory convergence are particularly pronounced for the automotive sector (as highlighted in section II above). We understand that the industry is making detailed proposals for mutual recognition of existing regulations, establishing a process to improve harmonisation for new regulations and setting out a clear timetable concrete next steps. TBC supports the joint ACEA/AAPC submission to USTR.

B. AVIATION

Aircraft Wet Leasing: Aircraft wet leasing involves the provision of an aircraft with crew to another airline, where the lessor maintains operational control over the aircraft and the lessee markets the aircraft as if it were its own. Wet leasing provides critical flexibility to all aspects of the airline industry and for that reason has become an important, beneficial and universal component of the aviation system. It contributes to global economic growth, substantially enhances operating efficiencies and produces significant consumer benefits. It has allowed international air carriers to serve new markets effectively and efficiently and expand their capacity and global reach, without having to develop new protocols to operate a new aircraft type, hire additional employees and invest in extraordinarily expensive new assets.

Under regulation EC No. 1008/2008, Article 13, wet leasing by carriers from third countries to EU carriers is not permitted unless the EU carrier justifies the leasing on the basis of a demonstration (i) of "exceptional circumstances", in which case the lease is limited to only seven months, subject to one seven month renewal, or (ii) that the leasing is needed to satisfy "seasonal capacity need which cannot be satisfied through leasing aircraft registered with the" EU, or, (iii) that the leasing is needed to overcome operational difficulties and "it is not possible or reasonable to lease aircraft registered" in the EU. These restrictions serve no purpose other than to exclude non-EU service providers. The US has no such restrictions. Although the United States requires prior approval of wet leases of more than 60 days duration from foreign carriers to US carriers, the basis for US review is very narrow: to determine if there is adequate reciprocity between the wet lessor's homeland and the US

There is a significant imbalance in treatment of wet leasing by the US and EU. EU carriers enjoy opportunities that US carriers do not. We request that both parties find a solution that will harmonize regulatory treatment and permit carriers from the US and EU the same unrestricted ability to engage in wet leasing.

Air Cargo Security: Although there was a June 1, 2012 air cargo security agreement between the US and EU, it could be enhanced. The agreement recognizes the validity of each jurisdiction's program, but does not harmonize the regulations or establish harmonized definitions across the board.

We suggest that the US and EU develop a harmonized approach to air cargo security regulations and procedures. We suggest a threat-based, risk management layered approach to aircraft

security, including known shipper programs and supply chain security programs. 100% screening of cargo on all cargo aircraft is unworkable, ineffective and will not enhance security. In the absence of radical technology advancements, which currently do not exist, screening of all or even a large percentage of cargo is simply not possible due to the immense volume of cargo and the complexity of the supply chain.

With respect to cargo information, there are currently numerous advance cargo information pilot programs underway in the EU in Belgium, France, Germany, and in the UK. The US has the ACAS (Air Cargo Advance Screening) pilot program. To prevent diverging transatlantic requirements, it would serve both the US and the EU, and the goals of the TTIP, to have a common approach through harmonized requirements for data, protocols in communication with carriers/forwarders, and risk criteria. The negotiation of such harmonized cargo security provisions could be conducted either in the traditional context of sector-specific bilateral aviation talks or in the context of the TTIP, which share the common goal of harmonizing customs, regulatory, and technical barriers to trade.

C. CHEMICALS

We support the recommendations contained in the submission of the American Chemistry Council (and supported by CEFIC, the European Chemical Industry Council).

D. ENERGY

- **Energy Efficiency:** The TBC advocates the harmonization of standards and metrics with regard to accounting treatment for energy efficiency investments.
- **Oil and Gas Exports and Market Liberalization:** TBC advocates a policy of free trade on the part of the United States and Europe with respect to the exports of liquefied natural gas (LNG) and crude oil. TBC rejects any efforts on the part of US or European governments to prevent or restrict the export of natural resources. Such intervention would diminish the credibility of the US and EU as advocates of free trade and as critics of other countries that seek to impose restrictions for commercial or political advantage. Informed by the same principle of market-based allocation of resources, the TBC advocates for the removal of regional and national barriers with respect to the shipment of crude oil and natural gas, including the liberalization of the European gas market and the repeal of the Jones Act in the United States.
- **Climate Policy:** TBC believes that any meaningful effort on greenhouse gas emissions will be most effective through coordinated global policies and climate targets. As two of the world's leading energy consumers, the US and the EU should seek to align their policies on climate action in support of technology-neutral, market-based approaches.
- **Transparency in Extractive Industries:** The US and the EU have adopted statutory requirements for listed companies to report certain information regarding concessions paid to foreign governments for the development of resources. Such legislation should be harmonized on both sides of the Atlantic to avoid unnecessary double reporting, especially for the companies listed both in the EU and the United States.
- **Fuel Quality Directive (FQD):** In conjunction with its support of a non-discriminatory, market-based mechanism to address the challenge of green-house gas reduction, the TBC

rejects the differentiation between different kinds of fossil fuels based on arbitrary taxonomy. For this reason, and because of its potentially negative impact on US exports to the EU, TBC opposes the categorization in the EU's Fuel Quality Directive of oil sands as a separate feedstock. Instead it advocates for the evaluation of all crude oil with respect to the FQD on the basis of their lifecycle carbon intensity, irrespective of region of origin or geologic feedstock.

E. FINANCIAL SERVICES

The Transatlantic Business Council supports a deeper integration of the EU and US economies through trade, investment and regulatory. We support the ongoing effort on both sides to identify those issue areas in which further cooperation would bring substantial gains to both sides.

Financial services is such an issue area and should be part of negotiations going forward that involve traditional trade and investment provisions pertaining to the General Agreement on Trade in Services, horizontal issues that are of general importance to a broad range of industrial or services providers and regulatory issues which might have market access implications. The latter is of particular importance in order to avoid regulatory fragmentation of EU and US financial services markets, which would frustrate efforts of international bodies such as the Financial Stability Board that have been charged by the G20 to find ways to make national financial regulatory systems more consistent and harmonious.

The process of up-grading the framework for financial regulation is well under way in G20 countries and beyond. The G20 reform effort effectively addresses shortcomings in financial regulations and market infrastructures and products. In the process of legislation and rule-making on those issues, regulatory cooperation between the EU and the US should play a significant role in the process of setting international standards and best practices related to financial markets regulation and oversight. It is essential that the EU and the US continue to coordinate and collaborate on finding the best approaches to financial markets regulation in order to drive down regulatory duplication costs for companies operating on both sides of the Atlantic. A framework for regulatory cooperation within existing forms of dialogue that take place on both a transatlantic and global basis should be the most effective way forward and should add transparency to regulatory differences and commonalities.

As well as the existing dialogue, the broader EU-US negotiation on a trade agreement would also be a useful avenue for pursuing deeper transatlantic cooperation in financial services regulation.

An effort should be made to improve upon the current institutional, regulatory and policy status quo on financial services, which after all represents a services sector that already displays high volumes of cross-border activity, in the form of both commercial presence and cross-border services trade. Improving dialogue to enhance compatibility between the EU and US financial regulatory environment would help decrease the opportunities for regulatory arbitrage and reduce the cost of duplicative regulation as well as provide legal clarity on prudential, market infrastructure and product issues for financial market participants on both sides of the Atlantic. It would also enhance the ability of financial supervisors to effectively monitor cross-border financial markets activities.

The Financial Markets Regulatory Dialogue (FMRD) works to pursue these goals and the importance of its work is increasing, as legislation and rule-making in implementing G20 principles in the EU and in the US have in some cases increased barriers to trade in the transatlantic financial market. Often times when this happens, explicit legislative or other official action is necessary to facilitate barrier-free access to each other's financial market. Also, there is no explicit mandate on either side to strive for such an objective.

Therefore, we propose consideration of legislative mandates for agencies of financial regulation on both sides of the Atlantic to explicitly strive for EU-US regulatory cooperation, based on the working assumption that common standards, equivalence or mutual recognition should be reached. In clearly limited circumstances, in which, due to profound differences in constitutional, institutional or legal contexts, neither objective seems attainable, a comply-or-explain approach might be pursued to explicitly lay down why neither of both seems feasible.

Adding a specific mandate would encourage regulators on both sides of the Atlantic to consider the impact on the transatlantic financial market at every step of rulemaking process in line with the general recommendations of the HLWG quoted above.

We recognize that there may be issues for which regulatory harmony cannot be reached and that some topics would be more effectively dealt with as part of trade negotiations. That said, this should not prevent trying to achieve negotiations on other issues where agreement can be reached. We would suggest categorizing financial services issues by means of four boxes. The first two boxes would represent trade domains and need not necessarily be dealt with within the framework of the FMRD, whereas the third and fourth box issues would be dealt with in that framework. For example:

(1) The first box would include traditional trade and investment provisions consistent with the four modes of delivery in the GATS.

- The EU and the US should work towards strengthening the national treatment of financial institutions, a binding of current levels of market access and removing remaining restrictions to trade at either the EU or federal US level, or at the EU member state level and, respectively, at the US state level (cross-border supply).
- The EU and the US should also work towards establishing and binding free access via foreign direct investment of EU- and US-domiciled financial institutions across the Atlantic (commercial presence) and as well as strong investment protection rules.
- The EU and the US should also improve current practical arrangements on the temporary movement of qualified persons by improving the status of qualified persons not only but also in financial services, by reducing administrative burdens and by providing mechanisms similar to the APEC Card for business visitors or by broadening the US Visa Waiver Program.

(2) The second box would include horizontal business issues that are of importance to financial services firms. These include cross-border, intra-corporate use of data and the

interoperability of legislation pertaining to data protection and security, cyber security and also consumer protection issues.

(3) The third box would include some financial regulatory issues which create difficulties in mutual market access and are, in principle, for legal, political and economic reasons, viable areas for on-going regulatory cooperation (for example, rule-making on derivatives). All of these topics are presumably at issue in the FMRD which would be the right body to address these topics. In addressing these topics, the FMRD should use the following principles as a guide:

- Undertaking consultation in advance of proposing and adopting legislation or regulation;
- Avoiding to the greatest extent possible the imposition of extraterritorial requirements, and wherever possible, recognizing the equivalence of regulatory regimes that share objectives but differ in approach;
- Adopting international standards and global best practices, and promoting the development of high quality international standards by global bodies; and
- Supporting closer coordination among regulators in the oversight of entities regulated in both markets to enhance oversight while avoiding overlap and duplication.

(4) The fourth box would include jointly agreed prudential carve-outs of such provisions that cannot be subject to considerations of mutually assured market access. These issues must mostly be those clearly dominated by financial stability, investor and/or client protection considerations and which, due to insurmountable differences in constitutional or legal provision on either or both sides of the Atlantic, cannot be bridged in the foreseeable future by either common standards, mutual recognition, "substituted compliance", "equivalence decisions" or similar legal methods. While accepting the pre-eminence of supervisory concerns on both sides of the Atlantic, even in these cases there is scope for progress to be made in further talks improving supervisory conditions and practices across the Atlantic, in particular with respect to an efficient division of labour between host and home regulators. In addition, there should be some consideration paid to the issue of proportionality of financial supervisory and market access considerations. The FMRD should pursue measures that would limit to the extent possible negative spill-over impacts of regulation.

While the first box should not contain particularly controversial issues but may well lead to demanding legal drafting of GATS-consistent provisions, the second box would potentially require legislative changes on both sides of the Atlantic of those horizontal sets of rules which present or threaten to present barriers to market access.

While issues in the first two boxes may not require continuous consultation with financial services firms once brought into force, on-going regulatory cooperation may well have to be based on a more elaborate consultation process involving industry input, a structured legislators' dialogue as to determine whether general financial services legislation rather than financial regulation and rule-making are at issue and high-level political oversight. Also, enhanced

transparency of efforts to align regulatory approaches would be welcome, both in terms of work-streams, schedules, objectives (in broad categories as described above) and progress to reduce the potential for regulatory fragmentation.

Concerning the third and fourth box, governments and regulatory agencies on both sides of the Atlantic should establish a working programme to identify which types of issues should be put into which type of treatment, and how market access issues arising from inconsistent legislation or implementation can be rectified. The default, in all of these questions, should be that issues be treated in the third box with a view to achieving mutually agreed and compatible regimes.

Rather than describing the numerous issues of partly inconsistent or conflicting rule-making in the EU and the US in the field of banking and securities (see Report of the EU-US Coalition on Financial Regulation on "Inter-jurisdictional Regulatory Recognition", June 2012, attached) or in other sectors of financial services, we would like to highlight only the most important areas requiring additional efforts of aligning regulation on both sides with the aim of maintaining an integrated transatlantic financial market while deepening it in the medium-term.

F. INFORMATION and COMMUNICATIONS TECHNOLOGIES (ICT)

1. Technological Innovation.

a. Information and Communication Technologies (ICT) can enable and facilitate the development of new business models and services that drive economic growth and societal benefits. These technologies include the Internet of Things, Cloud Computing, Big Data, M2M/Mobility among others. As governments develop frameworks and policies that address innovation and these technologies, care should be taken to assure that the innovative capacity of these technologies and the business models and services that use them are enabled and that the potential for burdens and unintended consequences are minimized.

b. In this digital age, companies in international markets constantly use Internet-based services, broadband networks and related ICT products to move data for their own internal operations and in serving their customers. The Transatlantic Trade and Investment Partnership (TTIP) should facilitate trade in innovative information and communication technology services by encouraging public policy regimes that promote transatlantic and global competition across the value chain and minimize regulatory impediments to such services.

   In general, when competitors are subject to differing regulatory obligations, parties should seek to facilitate trade by applying the least burdensome regulatory obligations to all such competitors. The TTIP negotiations are an opportunity for the EU and the US to develop a common vision for the sector that would promote a flexible and investment-friendly environment with less focus on the use of legacy networks through regulated access and more emphasis on dynamic outcomes such as investment and innovation.

c. Prevention of forced localization. The US and the EU should endeavor to prevent the development of forced localization and other trade and market distorting policies that are based on the requirements to force localization of facilities, manufacture and/or use of locally developed intellectual property. The parties should also use their best efforts to promote policies that prohibit such forced localization in bilateral trade discussions and international fora. Thus, market access for ICT goods and services covered under this chapter shall not be conditioned on requirements to (i) invest in, develop, or use local R&D, intellectual property, ICT manufacturing or assembly capabilities; (ii) store, process, or manage data locally; (iii) transfer technology to another party involuntarily; or (iv) disclose unnecessary proprietary information as defined in Section III on IPR.

d. Principles and practices which support innovation also include:

   i. A broad freedom for individuals, firms and electronic systems operators to utilize global information networks to transfer, process and store information necessary for the performance of legitimate activities taking into account existing privacy rules.

   ii. Promoting interoperable, technology neutral policies that are based on voluntary, industry driven, market-based, internationally recognized, standards and are flexible, risk-based, and context appropriate in implementation.

   iii. Coordinated and collaborative action to address emerging international information security threats, including through joint research.

   iv. Facilitating growth in innovative ICT services by encouraging public policies that minimize regulatory impediments to such services, in order to permit the flexibility best suited for rapidly evolving and sectorally integrated services. Such measures may include removal of, or forbearance from, economic regulations for ICT services except where required to remedy demonstrated harm to competition or consumer protection. Moreover, regulations should not constitute unnecessary barriers to trade in services.

   v. Expanding opportunities for ICT government procurement. Government services should be able to tap the most advanced ICT services, including from the other trading party's providers. TTIP should expand market access opportunities for ICT goods, services, and suppliers to the government procurement markets of the EU, the US and their Member States.

   vi. Eliminating regulations that act as barriers to entry or disincentives to investment in broadband and next generation communications networks and support market-based broadband communications policies, including non-discriminating spectrum policies that enable efficient, technology-neutral spectrum allocation to effectively access high-bandwidth broadband networks. That includes the immediate allocation to commercial mobile services or applications of inefficiently-used or unused spectrum currently designated to government agencies.

e. The EU-US ICT Principles agreed under the TEC in 2011 should be reviewed and updated/improved if necessary. A formal plan should be agreed between the US and EU for their advocacy in multinational fora and in bilateral dialogues e.g. the BRIC nations. Such a principles-based approach might be considered for application to other key areas with an expectation that both parties might advocate them with other nations e.g. cybersecurity, transborder data flows, cloud and privacy.

f. Recent years have shown an increase in both the quantity and the severity of malicious cyber attacks. To date, countries and regions have approached cybersecurity in a disconnected manner. Through TTIP, the US and EU have an opportunity to embrace emerging common cybersecurity standards, incentives and principles that minimize both security threats and any trade-distorting impacts. Specifically, the TTIP should incorporate by reference, and update when necessary, the principles embodied in the "Global ICT Industry Statement: Recommended Government Approaches to Cybersecurity," issued in June 2012, by the Information Technology and Industry Council, Digital Europe, and the Japan Electronics & Information Technology Industries Association. These principles provide all governments with a common foundation for policymaking in the area of cybersecurity. The 12 cybersecurity recommendations represent a cooperative approach between government and industry that meets security needs while preserving interoperability, openness, and industry's capability to innovate and compete. We also urge the Parties to use the TTIP to promote this cybersecurity approach globally.

2. Privacy / Data Protection

Strong and complementary regulatory ecosystems in the US and EU which drive innovation and treat data privacy as paramount is our common goal. Privacy laws are important national imperatives that embody domestic legal and cultural priorities. Seamless flows of data are the oxygen of our modern economies in the US and the EU. This is founded on the trust that the data we use is handled in an ethical and transparent and legally compliant manner. Privacy regulation must strike a balance between enhancing citizens' data rights and minimizing barriers to innovation (e.g. compliance costs) for companies, while not advantaging or disadvantaging companies competing in the global value chain. These domestic legal and cultural priorities often result in divergent approaches to privacy which should not be regarded as trade barriers. Almost all approaches to privacy embody the founding principles of privacy – the US Fair Information Principles, the OECD Privacy Guidelines and the principles of the Council of Europe Treaty 108. The commonality of foundation principles means that basic interoperability exists across the global approaches to privacy at the principle level, but significant divergence can exist in the more detailed texts and implementation methodologies.

A shared objective of both the US and the EU is to promote maximum interoperability across our approaches to enable the global information flows that support the digital economy and information society. That objective should not be seen as an attempt to weaken privacy, but rather a requirement for credible privacy enforcement that addresses all of the main components of privacy requirements in the totality of the circumstances, without a

rigid requirement to see exact language duplication. The importance of encouraging innovative new business models and approaches should also be recognized.

An example of such a beneficial and cooperative approach is the current work being undertaken in APEC to map Binding Corporate Rules (BCRs) and Cross Border Privacy Rules (CBPRs). This mapping is undertaken under the interoperability work-stream of APEC. It seeks to find the common elements between BCRs and CBPRs and further find a way to "give credit" for the valid work of complying with one standard when demonstrating compliance with the other standard. This mapping and interoperability will reduce much of the duplicative effort required to comply with a regulation without necessarily diminishing the standard upon which the regulation is founded.

The Transatlantic Business Councils recommends that TTIP negotiators commit to a joint work program on the following topics with respect to privacy:

1. Promote work on both sides of the Atlantic to minimize the potential burdens and unintended consequences of developing and implementing credible privacy policy frameworks and regulation. In particular, we should work towards ensuring Data Protection regulations do not impose such significant costs on businesses as to result in an unfair competitive disadvantage for the EU or the US.

2. Explore flexible and "totality of the circumstances" ways of recognizing credible approaches to privacy based on common principles to further the digital economy and information society.

3. Support and expand the mapping of new and existing regulations and policy frameworks to allow global organizations to leverage existing compliance procedures to the extent they satisfy the compliance requirements of other regulations.

4. Continue to honor existing international agreements and explore new mechanisms to enable data flows.

5. Commit to strive for legal frameworks recognizing high levels of individual protection, consumer empowerment and prosperity of new technologies, business models and data flows while taking into account the essential role of privacy in supporting the trust in these data flows, and commit best efforts on both sides of the Atlantic to optimize the combined benefits of both of these objectives.

G. LIFE SCIENCES and HEALTH

Life Sciences and the sectors it comprises account for a significant share of trade and innovation on both sides of the Atlantic. TBC would like to express strong support for an environment that allows the US and the EU to succeed in the global race for R&D, to spur both academic and private research, and to support innovation, job growth and the development of innovative products to improve health. In order to achieve this, the US and the EU must reward innovation and encourage open market access, investment (research funding, taxation), regulatory

harmonization and mutual recognition, as well as strengthened intellectual property rights, and the removal of tariffs.

Market Access:
Pharmaceuticals face unique market access challenges, most notably due to strict regulatory approval standards, as well the dependence on obtaining positive pricing and reimbursement decisions from governments and other authorities. TBC urges the adoption of measures that respond to these challenges, emphasizing that procedures and decisions in this field must be governed by transparent, verifiable and enforceable rules, and guided by science-based decision making.

- TBC recommends the inclusion of a Pharmaceuticals Annex as with KORUS and EU-Korea FTA. This would include provisions ensuring that all aspects of pricing and reimbursement processes for pharmaceutical products should be transparent, timely and predictable, and should adequately recognize the value of the product, and reward innovation. This would include, *inter alia*:

    - Recognizing that International Reference Pricing (IRP) should only be applied between countries with similar socio-economic levels, populations, disease burdens and health care systems; furthermore, there should never be reference to countries subject to economic crisis measures (e.g. IMF intervention) and countries that mandate cost containment measures such as price cuts or price freezes.
    - Acknowledging innovation by never allowing the government price for an innovative product be set by reference to prices for generic products.
    - Safeguarding the independence of Health Technology Assessment (HTA) bodies and the active involvement of all interested parties, as well as mechanisms to ensure that HTA is conducted in an objective, fair and transparent manner, and consistently uses international best practices, with effective means to challenge decisions and make available adequate remedies to all interested parties.
    - Recognizing the value that pharmaceuticals can have in reducing other more costly medical expenditures and improving the lives of patients (consistent with Article 5.1(b) of KORUS).
    - Respecting the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need.

Dissemination of Information to Patients and Health Care Professionals:
In order to make informed decisions, health care professionals and patients need to have access to information concerning their health care options. This includes understanding the benefits and risks associated with a medicine deemed to be medically appropriate by a patient's physician or health care provider. Given this, TBC proposes:

- That the proposed agreement between the United States and the European Union include language permitting manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites based, of course, on such information being truthful, not misleading and balanced, and limited to indications for which the relevant regulatory authority has granted market approval for that medicine.

Regulatory issues:
Unnecessary differences between the regulatory processes of the FDA and EMA complicate the expedited access of patients to innovative medicines, reduce efficiency for regulatory authorities, and create more costs to manufacturers. Therefore, TBC offers the following recommendations:

- Mutually recognize production site (GMP) inspections.
- Have more flexibility in FDA/EMA parallel scientific advice: expand its applicability to all medicines; and grant sponsors the right to receive upon request.
- Have greater compatibility in scope content and timing of submission of pediatric plans.
- Apply framework and methodology for benefit-risk assessment to drug/biologic development.
- Establish a procedure for collaborative development of scientific and other regulatory guidelines for specific therapeutic areas.
- Urge EMA and FDA collaboration on the submission of the dossier review and establish a procedure for collaborative development of post-approval risk management plans.
- Strive to achieve more consistent regulatory requirements for trial data for drug approval, including but not limited to: trial endpoints, patient population, size of study, and size of databases.
- Regarding Over-the-Counter (OTC) medicines, require both the approval of an Rx-to-OTC switch by the EMA and FDA, and the acceptability of foreign trial data by the EMA and FDA in support of an Rx-to OTC switch.
- Consider allowing open access to over-the-counter medicines, and allowing the placement of them "in front of the counter" at pharmacies.
- Implement common EMA and FDA practices on the clearance and acceptance of drug names, since a lack of harmonization may risk major hindrances for recognition of globally recognized brands.
- Aim for closer collaboration and common recognition of standards.
- Work collaboratively to eliminate counterfeit and substandard medicines.

Clinical data transparency and public disclosure of data contained in marketing authorization dossiers for medical products by the competent regulatory authority:
Pharmaceutical companies have recently challenged the EMA's recent decisions at the EU's General Court, because they grant public access to raw clinical data submitted by pharmaceutical companies in support of their applications for marketing authorization, without the possibility to exempt confidential commercial information from disclosure. TBC believes responsible data sharing arrangements must protect (i) patient privacy; (ii) the integrity of regulatory systems worldwide; and (iii) incentives to invest in biomedical research and develop innovative medicines for patients. Inappropriate disclosure, such as proactive, indiscriminate disclosure of companies' non-public data submitted in clinical and pre-clinical dossiers and patient-level data sets, risks undermining these important goals. Therefore, TBC recommends:

- Wide consultation with appropriate stakeholders to ensure that any future policies balance the desire for meaningful sharing of clinical trial data with the need to reward and incentivize investments in medical research.

Intellectual Property Rights:
IPR is a fundamental element of the life sciences sector. Effective protection and enforcement of IPR are essential for the continued development of innovative pharmaceuticals. However, certain policies conflict with the IPR of companies, e.g. the restrictions on the use of trademarks. Therefore, TBC recommends:

- Improve upon existing intellectual property standards and further harmonize and strengthen intellectual property protection.
- Recognize that both parties must ensure the availability of strong IPR and effective mechanisms for IPR enforcement.
- The EU and US should seek to harmonize and align intellectual property protection and enforcement measures, e.g. by increasing Data Exclusivity (DE) for biologics in the EU to 12 years, and to 10+1 years data exclusivity for small molecules in the US.
- Provide for enforcement mechanisms to prevent patent-infringing products from entering a market while a patent-infringement dispute is ongoing. In such cases, the innovative manufacturer, even if successful in that dispute, is rarely restored to the position that it would have been in but for the launch of the patent-infringing product. It is essential, therefore, that TTIP provide for the adoption of patent enforcement systems (or a unified system) that allow for the early resolution of patent disputes before an infringing product is launched on the market.
- Avoid imposing restrictions on the use of trademarks by not requiring that only generic names be listed on the packaging of a pharmaceutical and that, on such material, generic names are given more prominence than proprietary drug names or that use of generic names in prescriptions is given preference over the use of the proprietary drug names.
- Ensure incentives for the development of pediatric medicines, orphan medicines, Rx-to-OTC switches (3 year data protection) and other specific needs.
- Avoid interference with markets stemming from rules and provisions in EU (and EU member states') law that give privilege or even exclusivity to generic names over proprietary names.
- Allow for greater flexibility in umbrella branding i.e. multi APIs under a single brand

Taxation:
The life science sector relies on a business environment that is supportive of R&D to generate innovations and create jobs. Tax incentives are an important tool to increase R&D and can take a variety of forms, including: R&D tax credits, R&D allowances, accelerated depreciation of capital used for R&D, reduction in R&D workers' wage taxes and social security contributions. Tax incentives will advance the US and EU ability to successfully develop innovative medicines to treat or cure diseases. Furthermore, VAT disparity exists between the US and countries within the EU that levy VAT on pharmaceuticals. While countries within the EU have implemented mechanisms to control pharmaceutical pricing, government levied taxes increase the overall cost of pharmaceuticals. Therefore, TBC recommends:

- Coordinate and introduce growth-orientated tax incentives for R&D to boost US/EU innovation, competitiveness, job creation and long-term prosperity. Tax incentives will increase GDP as well as the number of filed patents, and can be expected to produce net revenues to the respective governments in the long-run.

- Harmonize the VAT on pharmaceuticals and earmark tax revenues for healthcare and R&D; this would allow funding to be available for innovative medicines and R&D funding.
- Goods manufactured in multiple EU countries are subject to VAT even if said goods are not ultimately consumed in the EU. Provide non-VAT registered US purchasers with certificate to exempt these goods from VAT.

Customs and Tariffs:

Tariffs and duties can cause burdensome administrative hurdles and additional costs, limiting the ability to conduct necessary research across countries. Tariffs can affect the ability to export/import within the US. Although most finished pharmaceutical products are imported duty-free under the Pharmaceutical Appendix to the Harmonized Tariff Code in the US, the process for adding additional items to the Appendix is time-consuming and uncertain. However, some medical technology products (medical devices and medical equipment) still incur import tariffs which should be eliminated immediately. In addition, research and development compounds are generally subject to duties. This can influence the decision of whether to import into the US or to perform research or development activities elsewhere. Lastly, the tariff codes are not sufficiently harmonized between the US and the EU, and thus there are potential conflicts in classifying goods that are traded between the two areas. It is not possible to determine an average tariff on exports/imports due to the volume and complexity of the items imported. Therefore the group makes the following recommendations:

- Harmonize tariff codes between the EU and the US.
- Harmonize the EU and US country of origin marketing rules for pharmaceutical products.
- Reduce and harmonize export and re-export control complexities for "medicine" products.

Research:

- Strengthen EU/US university and industry access to research grants generated in the US and the EU.
- Promote cooperation on specific regulatory reforms that could benefit research into potential innovations delivered through information networks to address emerging social phenomena. These could include:

  eHealth - We commend the EU and US Health IT government leadership for developing the newly released Transatlantic eHealth/Health IT Cooperation Roadmap. The roadmap follows the Memorandum of Understanding (MOU) between the United States Department of Health and Human Services and the European Commission on Cooperation Surrounding Health Related Information and Communication Technologies signed in December 2010, to demonstrate the shared dedication to cooperation addressing the challenges of international interoperability of electronic health records. The two entities have demonstrated a commitment to standards and workforce development to ensure the accurate, timely and comprehensive exchange of medical health records across borders while protecting the security and privacy of these records. The 18-month roadmap is a concrete action plan that will use eHealth science and technology to empower individuals, support care, improve clinical outcomes, enhance patient safety and improve the health of populations.

While we are extremely pleased to see the roadmap for cooperation, we would recommend that the exchange of records include not only the electronic clinical records, but also the patient generated data which is becoming more and more critical to assessing an individual's health status. This information is typically provided by mobile or home based devices and monitors[i] often networked to electronic record systems or health care providers. We have great confidence that the US and EU working together will improve the data capture, relevancy and accuracy of this important source of patient data and request that this objective be added to the current roadmap. Additionally we recommend that the 2010 MOU between the US Department of HHS and the EU become part of the official TTIP Agreement.

[1] These sensors and monitors provide real time patient biometric data including blood pressure, glucose readings, pulse oximeter readings, stethoscopes, weight scales and more.

H. MEDICAL PRODUCTS

- The European and American industry associations for medical technology have put forward the following joint priorities for the TTIP: 1) maintain harmonization between ISO 13485 and FDA's Quality System Regulation (QSR), 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. The TBC supports these recommendations.
- Clarify and harmonize the application of export controls to medical devices to (1) more closely reflect the aims and policy of the Wassenauer Agreement; (2) avoid unnecessary complexity of classification of goods for medical and humanitarian use; and (3) provide consistency of treatment of medical devices, equipment and related software and accessories across the EU and between the EU and US.