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Transatlantic Trade and Investment Partnership

The Alliance for Healthcare Competitiveness (AHC) is grateful for this opportunity to present comments concerning the proposed Transatlantic Trade and Investment Partnership (TTIP). AHC is a group of 22 leading firms and non-profits involved in American health care, including providers, medical device and pharmaceutical manufacturers, insurers, health IT, hospitals, pharmacy, health-specialized architects, and other participants in America's $2 trillion health sector.

The proposed TTIP is of great interest to our members as the European Union is the site of nearly a third of world health spending, the principal buyer of American exports of health products, and is experimenting with new approaches to health care systems. In these circumstances a successful US-EU trade initiative has great potential to help improve health outcomes for patients, and support growth and employment in the United States and Europe alike.

Below are the principles and positions AHC hopes to see reflected in a US-EU pact.

Introduction – The health sector is the largest single component of the world economy. In 2010, according to the World Bank, health accounted for almost $7 trillion of $63 trillion in global GDP. And over the next two decades, as the world's population grows older, more affluent, and more urban, spending on health care will steadily rise. The health sector will be one of the world's main future drivers of demand, growth, scientific progress and innovation in the decades ahead.

This gives the United States a significant opportunity. The American health sector has the scale and technical excellence to serve a global public. Private-sector health companies employ over 15 million Americans, account for 19 percent of all new job creation, and produce over $2 trillion annually in goods and services. Their technical sophistication is unmatched. Manufacturing industries design new devices and medicines, health IT systems help providers improve care and manage costs and health insurers offer a diverse range of payment options. U.S. players excel in professional care-giving, research and testing labs and in specialized services such as medical architecture.

In all these ways, American health companies are already well placed to meet the world's growing demand for health services and manufactured goods. Moreover, the advance of telecommunications and computer technology means they can offer high-quality care to the entire world, including to poor and isolated people never before able to access care.

But such a future requires the ability to provide goods, services, and care in practice as well as theory. This presents a complex challenge. Each country's health care system is unique, reflecting local history, values, political decisions and social arrangements. Policy cannot change this and should not attempt to try. Thus an ambitious health-sector trade program is not an effort to "export the U.S. health care system," and should not be viewed in those terms.

Rather, as AHC's 2011 White Paper (available at http://www.healthcare-competitiveness.com/documents/ahc.whitepaper.final.pdf) suggests, it is an effort to provide better care, support technological progress, offer new choice and options, and ultimately generate better health outcomes.

These comments describe in greater detail the challenges the U.S. government will need to address if the U.S. health industry is to fully participate in the tremendous opportunities before it. We examine in turn tariffs, non-tariff barriers, government procurement, services, state-owned and state-supported enterprises, investment, and intellectual property rights. As key barriers are addressed through health care sectorial negotiations or in chapters of trade agreements like TTIP, the American health sector can be a significant driver of growth, job creation, and better lives.

U.S. policymakers must view the health sector as an interlinked and interdependent unit in which growth and success in any one part helps the whole of it grow. We know that as hospitals gain rights of establishment abroad, they become natural buyers of American medical devices, natural users of American health IT systems, natural telemedicine customers of U.S.-based hospitals, and natural partners for American doctors and medical schools. Trade negotiations on behalf of the sector as a whole have the potential to unleash powerful synergies.

1. TARIFFS

The simplest barrier to trade in health products is the application of tariffs to health goods like medical devices and medicines. Many tariffs were eliminated through the Uruguay Round of the GATT in 1995, and in WTO accession agreements and Free Trade Agreements since. However, the achievement is not complete, even in wealthy countries.

AHC recommends the following:

(1) Full elimination of tariffs on health goods. In 2006, the U.S. government tabled a proposal for universal tariff elimination on medical goods. This would have eliminated tariffs on goods classified under Harmonized Tariff Schedule 4-digit tariff codes 2844 (radioactive materials used in medical science and treatment), 2933, 2936, 2937, 2939, 2941 (for medicines and precursors), 3001, 3002, 3003, 3004, 3005, and 3006 (pharmaceuticals), 3822 (laboratory reagents), 8419 (medical and laboratory sterilizers), 8543 (nerve stimulation technologies), 8713 and 8714 (carriages for people with disabilities), 9018, 9019, 9021, 9022, and 9025 (medical technologies of all kinds), and 9402 (medical furniture). It should be extended to cover tariffs on medical goods included in HTS section 2935, which includes sulfonamide medicines, surgical preparatory gels and other products.

The 2006 proposal, subsequently updated in 2007 and 2009, remains a sound foundation for policy. Tariff elimination should be a basic element of FTAs and regional agreements, including TTIP.

2. NON-TARIFF BARRIERS

Non-tariff barriers (NTBs) are a larger and more complex topic than tariffs on health products. In most countries, they are the principal barriers to exports of medicines, medical devices, and other health-sector goods. They also are powerful obstacles to many sorts of health-related services, and can force companies to choose to produce via direct investment rather than exports, even when economic logic would suggest exporting from the U.S. as the better choice.

NTBs come in many forms, generally appearing in regulatory policies rather than as formal import bans or quota regimes. Some, particularly in developing countries, are directly meant to favor local producers at the expense of foreign manufacturers, or they reflect imperfect or non-transparent regulatory systems that can bias choices about care. Developed-country regimes less often suffer from these flaws, but can diverge in ways that amount to NTBs by making introduction of valuable and innovative products more complex and expensive than need be.

Some countries have policies that in effect prevent market entry. Turkey, for example, does not recognize the internationally accepted certification of good manufacturing practices (GMP) from other countries unless they have mutual recognition agreements (MRAs) on inspections with Turkey. Neither the United States nor the European Union has such an MRA. In part due to the small number of Turkish inspectors available to review facilities worldwide, the policy serves as a *de facto* ban on imports. The Turkish Government has publicly stated that the purpose of this policy is to promote local Turkish pharmaceutical companies to the disadvantage of foreign companies.

Foreign governments are also increasingly employing a range of strategies to control prices and contain costs related to biopharmaceuticals. Based on a recent analysis, approximately 39 countries proposed or implemented cost containment measures impacting the biopharmaceutical sector in 2010.[i]

In some cases, cost containment measures have disproportionately targeted the research-based biopharmaceutical sector. Such measures often have significant ripple effects in other markets. For example, *ad hoc* price cuts implemented in one country can directly and indirectly impact the price of medicines in many other markets due to international reference pricing, where a government considers the price of a medicine across a set (or "basket") of countries to determine the price of medicine in its own country. This can create a downward spiral in terms of prices for medicines, impact the number of new medicines developed, and result in product shortages for medicines patients need.

AHC recommends a mix of direct bilateral negotiations on particularly onerous NTBs and the inclusion of regulatory measures in future agreements. Capacity building efforts can be helpful in ensuring that regulatory policies fulfill their legitimate purpose of guaranteeing safety and improving care, while encouraging the adoption of innovative new devices and medicines. Trade agreements, including TTIP, should include the following measures:

(1) *General Principles:* Agreements should ensure that national regulatory systems encourage acceptance of international technical standards where they exist; eliminate or at minimum reduce use of price limits; and create transparent regulatory systems, which allow for comment on regulations and appeals procedures, reach decisions within a reasonable time, and ensure that confidential data remains confidential.

(2) *Ensure transparency of pricing and reimbursement:* Regulatory systems should seek to eliminate the use of price controls, and ensure transparency of government pricing and reimbursement systems, including prior comment and rights of appeal.

(3) *Regulatory Harmonization When Widely Accepted International Standards Exist:* The proliferation of regulatory systems adds to costs, often without improving care and patient safety. Trade agreements should encourage, consistent with national responsibilities to guarantee the highest standards of quality and care, participation in groups like the Global Harmonization Task Force (GHTF), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme (PIC/S) and use of the standards set by the International Standards Organization (ISO) to demonstrate compliance with regulatory requirements. Making use of widely

accepted standards can avoid unnecessary divergences and, in countries now developing new health systems, can often raise standards.

(4) *Encourage Country-Specific Innovation:* Regulatory systems should encourage specialized design of products tailored to meet the unique needs of individual countries. Current systems in a number of countries, however, require approval in a "home" country before registration can begin. In practice, this means a product must be approved for use in the United States before it can begin approval procedures elsewhere. This requirement can deter innovative research programs in American labs and research facilities meant to develop products specifically for particular needs in particular countries – e.g., very simple and low-cost devices suited for countries with large low-income populations.

(5) *Capacity-Building in Foreign Inspections:* Countries frequently require their regulatory authority to conduct facility inspections of foreign manufacturers if products are to be sold within their borders. In practice, the authorities in many developing countries lack the manpower or expertise to conduct such inspections. The right approach is a blend of technical support and capacity-building for the ministries in question, coupled with trade agreement commitments that avert the risk that inspection requirements be used as excuses to deny commercialization.

(6) *Certificates for Foreign Governments (CFGs)* – CFGs, issued by the U.S. Food and Drug Administration as reassurance of successful conclusion of dossier review and product approval, should be sufficient for sales in countries using CFGs for purposes of regulatory approval. Additional requirements beyond the FDA's professional judgment – e.g., publication of clinical evidence in peer-reviewed journals – only increase costs and delay access.

(7) *Trade-Balancing Requirements:* Tax penalties for company "trade imbalances" are economically irrational and should not be permitted. These penalties are often especially onerous for citizens in countries with little manufacturing in healthcare products.

3. GOVERNMENT PROCUREMENT

Government procurement is an issue of fundamental importance to the health sector, since the public-sector role in health care is very large in virtually all countries. This includes not only countries in which the public sector as a direct caregiver is very large, but also systems like the one in the United States in which the private sector takes the leading role in provision and financing of care.

Procurement encompasses direct provision of health care services, purchasing of medicines and medical devices, life-sciences research, health-facility construction, financing care for the poor and elderly, and other fields. And with the government role

in health care growing especially rapidly in countries now developing extensive public insurance programs, access to government health contracts will be more important than it is today.

Transparent procurement for publicly funded health services is critical. In cases where the public sector is involved, preferential arrangements with local players, non-transparent requests for proposals and other micro-distortions can keep taxpayers from getting the best deal. Procurements should be based on clinically relevant specifications, with technology neutral procurement policies and regulations to help generate competition and maximize benefits for governments and healthcare consumers alike.

Open procurement systems can reduce the costs of purchase and offer providers and patients the best quality. But despite the importance of procurement to the health sector, the Government Procurement Agreement at the WTO and the procurement features of recent trade agreements have achieved relatively little in health.

The WTO agreement applies only to procurements of 130,000 Special Drawing Rights (about $200,000 at current dollar valuation) and above. FTAs have similar limits. The government procurement rules of the U.S.-Colombia FTA apply only to procurements of $64,876 and above, and those of the U.S.-Panama FTA to procurements of $193,000 and above. Beyond this, the Panama text contains broad exemptions for public health campaigns. These levels are far above those typical of purchasing sophisticated medical devices and medicines for use with patients (i.e., not for resale where WTO rules apply), and therefore of relatively little use.

AHC recommends the following:

(1) *Procurement Chapters Should Cover Health Sector:* Trade agreements should cover health care. Exemptions from government procurement coverage should be minimal, rather than broadly and ambiguously drawn for “health care” or “public health.” Coverage of state-owned enterprises, for procurement and other purposes, should include those specialized in healthcare, except by special dispensation for particular components of products or services unique to the country in question, in which some effect contrary to public good would result from provision by an international provider.

(2) *Significantly Lower Threshold for Coverage:* In any return to a broad-based WTO negotiation, the U.S. government should give priority to reducing the 130,000 SDR “floor” for coverage of tenders for all participants to a level that will allow the American health sector to compete for contracts. The procurement chapters of future FTAs agreements should cover all tenders at 1,000 SDR or above.

4. SERVICES

Healthcare services encompass such areas as architectural and construction services, professional services, health insurance, IT-enabled health services, technical testing, and research and development. As a group, these are the largest providers of private-sector employment in the United States, at 15 million employees in mid-2012. Healthcare service providers pay wages well above the average for the private sector generally and for manufacturing.

An open trading world for these services would create a large new flow of revenue into the United States from foreign operations and from telemedicine. But today's world of health care services is highly restricted and fragmented. This is to some extent unavoidable, as for historical reasons and by virtue of political choice, countries differ widely in regulation of health services, including how to accredit healthcare facilities, certify practitioners, and assess technology. This natural fragmentation is made still more difficult to navigate by market entry barriers and discrimination between domestic and U.S. service providers.

U.S. professionals likewise often find themselves barred not due to quality but restrictions on entry. In France and Germany, for example, healthcare jobs are reserved for nationals of EU countries, of the enlarged European Economic Area, or of Switzerland. In the UK, work permits for healthcare providers can only be granted to non-EU nationals if the applicant's profession appears on a list of "national occupations shortage." Professional standards and licensing requirements intended to ensure the provision of quality health care are natural and reasonable, in the U.S. as in other countries. The goal for policy is not to challenge these quality-based standards, but rather to ensure that professionals able to offer the highest-quality care (e.g., specialist physicians) are able to do so, in particular where their skills are in short supply.

Trade agreements are an opportunity to address these problems; further open healthcare services markets; impose disciplines on regulatory authority, including rules for technical standards and recognition of qualifications; and ensure that trade in health care services will reach its extraordinarily large potential.

AHC recommends the following:

(1) *General:* U.S. negotiators should seek services market access offers on the basis of a negative list. This means the services chapters of TTIP, TPP or any new WTO negotiation should cover all healthcare service sectors unless formally excluded, and that provision of care via new technologies will be allowed, or not allowed, based on objective measures of professional standards and quality of care. U.S. negotiators should seek full market access for specialized service providers, such as medical architectural firms that bid on construction projects, health IT providers, and others.

(2) *Licensing:* Transparent licensing of health care professionals and facilities without unnecessary or discriminatory burdens on U.S. providers. This should enable qualified U.S. professionals and care centers to provide care across borders, by movement of persons or cross-border provision via telemedicine, so long as they meet transparent and fair local standards.

(3) *Mutual Recognition Agreements:* MRAs, when appropriate for licensing and certification of professional services providers, should be included in TTIP and TPP.

(4) *Data transfer:* Commitments allowing cross-border provision and transfer of health information with institutions in other countries, including through telecommunications, and barring forced "localization" of data unless governments can show a clear threat to confidentiality of patient data.

5. STATE-OWNED AND STATE-SUPPORTED ENTERPRISES

Foreign government policy measures favoring state-owned enterprises (SOEs) and state-supported enterprises (SSEs) sponsored as national champions create major competitive distortions in markets around the world when those SOEs and SSEs compete with private sector counterparts. In the health care sector, SOEs and SSEs may take the form of hospitals, medical equipment manufacturers, and insurance providers. No adequate and effective international disciplines now exist to deal with this phenomenon.

Market distortions posed by SOEs and SSEs take many different forms. Regulatory favoritism takes place when government uses policy instruments (such as favorable regulations and subsidies) to change market results. Governments may seek to confer advantages on SOEs because they are state-owned, or otherwise confer advantages on SSEs to create state-sponsored and supported national champions. When government-owned entities compete with private sector businesses, governments should ensure a level playing field for all businesses, irrespective of ownership. They should not offer advantages to SOEs and SSEs at the expense of private capital, including foreign or foreign-invested competitors.

Other forms of market distortions exist, such as preferential purchasing and sales, and provision of financial support on terms not available in the commercial market. SOEs or SSEs are often steered by explicit or implicit government mandates, incentives or informal guidance in their purchasing, sales, technology licensing or other business decisions. Non-market financing or guarantees provided by government policy enables these firms to operate on a noncommercial basis, with an unfair competitive advantage. Preferential market access accorded by and to government enterprises also distorts markets, and adversely affects foreign companies selling to, purchasing from, or competing with these favored businesses.

The rise of SOEs and SSEs and their potential for distorting trade and investment make it imperative to develop new rules ensuring competitive neutrality and based on the fundamental principle of national treatment.

AHC recommends the following:

U.S. negotiators should seek high-standard disciplines on SOEs that enforce competitive neutrality in all trade negotiations whenever those SOEs compete with private sector enterprise.

6. INVESTMENT

Investment policy is closely related to both services trade and to exports of health-care goods. On the services side, investment rights are essential to the ability of hospitals to provide care and of payers to offer finance options. For manufactured goods, the ability of an American-based hospital to operate abroad means the creation of a natural market for devices, medicines, specialized furniture, architectural services and other exports.

However, barriers to U.S. investment in overseas health sectors are numerous. Japan bans foreign operation of hospitals altogether. Some countries impose detailed restrictions like limits on the ability of foreign nationals to work in affiliates or requirements on the nationality of members of a board of directors. Others impose "performance requirements," which require American manufacturers to locate in a country in order to sell medicines and medical devices, which are obvious deterrents to companies preferring to export from the United States.

Certificates of Need are required in many countries as a condition of capital investment, even by private hospital networks. Supported by a view that "innovation drives cost," this requirement has the effect of reducing competition with inefficient state healthcare enterprises. To the extent private insurers are regulated in other areas, such as the services which must be provided, the catchment area they must cover or the minimum number of lives they must insure, regulators can hold up Certificates of Need as leverage to force the requestor to do other things, even though this further warps market-based efficiencies in healthcare delivery.

Fundamentally, health providers and insurers should be able to establish operations abroad in the form of their choice with no artificial limits on their equity ownership (in the same way that the U.S. does not impose such arbitrary ownership restrictions on foreign health care companies doing business in the United States). They should be able to compete fairly with local companies in terms of taxes, regulatory provisions and licenses, and in line with all other non-discriminatory legal and financial requirements. They should, where appropriate, be able to provide services from a base in the United States, or travel when necessary, as in the case of doctors or hospital-managers consulting abroad.

Trade agreements like TTIP are an opportunity to create such a system, with binding legal rules regarding a country's treatment of investments from other countries, and in so doing, promote regulatory transparency and the rule of law.

AHC recommends:

(1) *Ensure Right of Establishment:* Trade agreements should guarantee health services firms the freedom to establish as they choose - i.e., via subsidiary, branch, joint venture, or other format – subject to regulation based on quality and safety, but not to limits based on geography, market share, or similar arbitrary measures.

(2) *Abolish or Liberalize Equity Caps:* Trade agreements and other trade and investment initiatives should ensure that investors are free to determine the percentage of any foreign equity shares in a joint venture.

(3) *Encourage Use of International Norms:* Requirements for minimum capital in health insurance or other payers should follow international norms for products and business models.

(4) *Abolish Performance Requirements:* Manufacturers wishing to sell products in a given country should not be required to locate and produce in that country.

(5) *Transparent Investment Regulation:* Regulations governing investment should be governed by principles of transparency, with opportunity for prior comment on new or revised regulations.

7. INTELLECTUAL PROPERTY

Intellectual property rights are an essential element of the WTO architecture and of free trade agreements. Strong IPR protection is a public good, which encourages research and development of new devices, medicines, and computer programs for health providers. Recent FTAs, notably the KORUS agreement approved in 2011, offer valuable templates for future agreements such as the TPP. They do not, however, offer entirely clear precedent for treatment of biologics. With biotechnology likely to be the most prolific source of new medicines, this is an area in which agreements will need to offer clear and reliable IP protection. An appropriate guide is U.S. domestic law, which ensures full patent protection and 12 years of regulatory data protection for biologics.

AHC recommends the following:

(1) *Robust protection of IPR:* The TTIP, TPP and future FTAs should ensure robust protection of IPR along the lines of the Korea-U.S. Free Trade Agreement. Consistent with American law, this will ensure that intellectual property theft does not vitiate access to markets and that incentives for research remain strong.

(2) 12-year Regulatory Data Protection standard for biologics: U.S. FTAs likewise should ensure 12 years of data protection for biologics, which reflects U.S. law.

[i] IHS Global Insight, analysis for PhRMA, Dec. 2010.