UNFOLD THE BENEFITS OF TTIP

The EU – U.S. Transatlantic Trade and Investment Partnership (TTIP):

Towards better health outcomes for patients and economic growth

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European Federation of Pharmaceutical Industries and Associations

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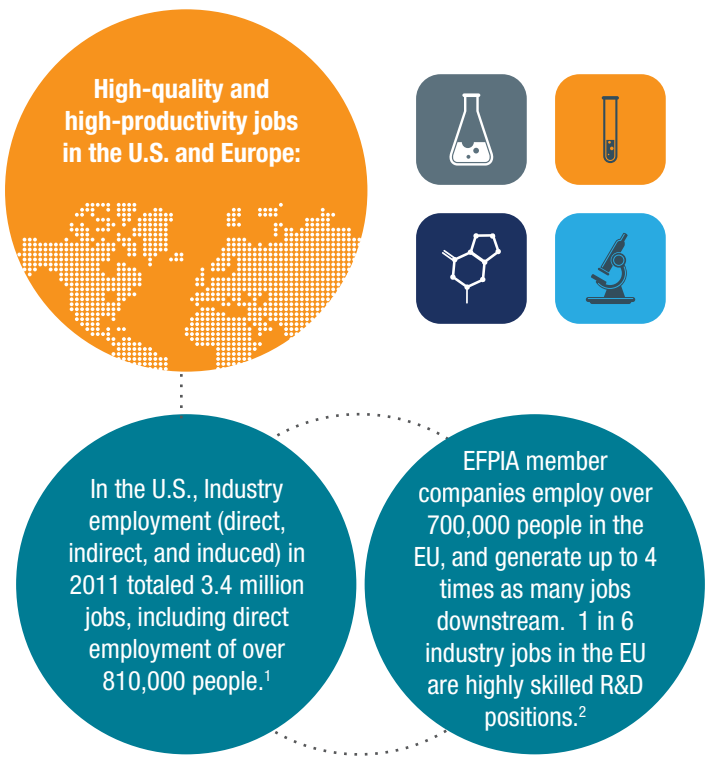
RESEARCH • PROGRESS • HOPE

WHY TTIP IS IMPORTANT

A TTIP agreement has the potential to benefit patients and economies across both sides of the Atlantic. In short, it could lead to speeding up patients' access to medicines. Expanding the world's most dynamic trading relationship will also address a broad range of trade and investment policies and stimulate growth.

ABOUT THE TRANSATLANTIC INDUSTRY

PhRMA and EFPIA represent the world's leading research-based biopharmaceutical companies that are devoted to new discoveries allowing patients to live longer, healthier, and more productive lives. Our member companies are important drivers of the economy and patient health.



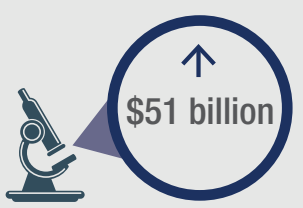
EU POSITIVE TRADE BALANCE: HIGHEST AMONG HIGH-TECH SECTORS AT

€55.6 BILLION[3]

U.S. EXPORTS:
$52 billion in biopharmaceuticals exports in 2013.[4]

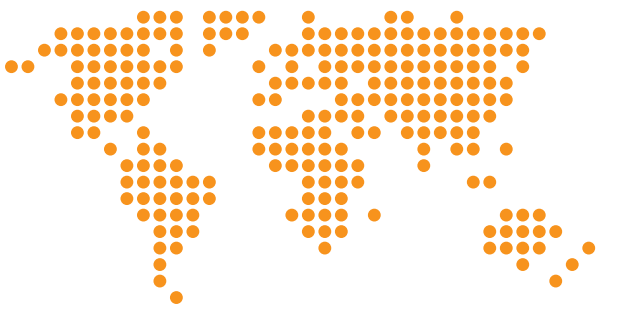
RESEARCH & DEVELOPMENT (R&D) INVESTMENTS AND ACHIEVEMENTS:

PhRMA member companies invested over $51 billion in R&D globally in 2013.[5]



In 2012, EFPIA member companies invested over €30 billion in R&D in Europe.[6]

There are more than 5,000 medicines in development globally,[7] and 70% of those in clinical development are potential first-in-class medicines.[8]



CONTRIBUTIONS TO GLOBAL HEALTH:

$9.2 BILLION

The innovative industry provided over $9.2 billion in direct assistance to healthcare for the developing world in the last decade, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor.[9]

$527 MILLION

Research-based pharmaceutical companies comprise the second-largest group of funders of global R&D for neglected diseases, investing more than $527 million in 2012 alone – ahead of all countries but the U.S.[10]

1. Battelle Technology Partnership Practice, The Economic Impact of the U.S. Biopharmaceutical Industry (July 2013). Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America.
2. EFPIA – The pharmaceutical industry in figures, edition 2014.
3. Id. / 4. PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration. "TradeStats Express™: National Trade Data." Export.gov. At http://tse.export.gov/TSE/TSEhome.aspx. / 5. Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2013). / 6. EFPIA – The pharmaceutical industry in figures, edition 2014. / 7. G. Long and J. Works. "Innovation in the Biopharmaceutical Pipeline: A Multidimensional View." Boston, MA: Analysis Group, Inc., January 2013. Available at www.analysisgroup.com/uploadedFiles/Publishing/Articles/2012_Innovation_in_the_Biopharmaceutical_Pipeline.pdf. / 8. Id.
9. IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science. / 10. Policy Cures 2013 G-FINDER Report.

ECONOMIC BENEFITS OF TTIP

The innovative biopharmaceutical industry is just one of many that could potentially gain from a strong TTIP agreement. A European Commission study[11] estimates:

	UNITED STATES	EUROPEAN UNION
Potential economic gains	$131 billion or €95 billion	$165 billion or €120 billion
Increase in GDP by 2027	0.4%	0.5%
Increase in bilateral exports	$219 billion or €159 billion	$257 billion or €187 billion
Increase in global exports	8%; $110 billion or €80 billion	6%; $45 billion or €33 billion
Increase in wages (skilled and unskilled)	0.5%	0.5%

11. "Transatlantic Trade and Investment Partnership: The Economic Analysis Explained," European Commission, (Sept. 2013), available at http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf.

OUR PERSPECTIVE

The innovative biopharmaceutical industry supports a comprehensive and ambitious agreement that promotes regulatory compatibility, strengthens intellectual property protections, and enhances patient access to innovative biopharmaceuticals. In addition, many of these elements, such as regulatory compatibility, can be expected to not only benefit bigger companies, but have a particularly positive impact on smaller companies and collaborations that are central to the broader life sciences ecosystem. In turn, we strongly believe that all these elements will help accelerate global development of medicines and enhance patient access to much-needed innovative medicines.

REGULATORY COMPATIBILITY

Addressing regulatory differences and duplicative requirements can help to enhance efficiency of drug development. TTIP is an opportunity to develop even greater streamlined processes and procedures that can lead to expedited patient access to new, innovative, life-saving medicines:

Reduce redundant testing and optimize deployment of limited regulatory agency resources while preserving patient protections and encouraging expedited patient access, including recognition of each other's Good Manufacturing Practices (GMP) inspections.

Address regulatory differences and duplicative requirements that hinder efficiency in global drug development. For example, the EU and U.S. should work together to standardize the content, scope and timing of pediatric plans, harmonize clinical trials data fields results, and develop a common approach to post-approval variation submissions for manufacturing changes.

INTELLECTUAL PROPERTY PROTECTION AND ENFORCEMENT

The ability of the innovative biopharmaceutical industry to invest in researching and developing life-saving and -enhancing medicines relies on strong intellectual property (IP) rights protection and enforcement. Recognizing that IP is the lifeblood of innovation, the U.S. and EU provide strong standards of IP protection and enforcement to innovative biopharmaceuticals. Any agreement between the U.S. and the EU must not dilute these standards and should:

Reinforce EU and U.S. shared commitment to high-level standards for IP protection and enforcement.

Advance effective patent enforcement mechanisms.

Affirm high-standard IP principles to be promoted by the U.S. and the EU in their respective trade agendas that can help enhance global access to tomorrow's cures and treatments.

PREDICTABLE AND TRANSPARENT MARKET ACCESS

To promote development of innovative medicines and thereby ensure patient access to medicines, it is critical that government pricing and reimbursement policies appropriately recognize and reward the value of medicines in reducing more costly medical interventions and in improving the lives of patients. TTIP should include a Pharmaceuticals Annex similar to that included in the EU and United States' free trade agreements with Korea to:

Ensure transparent, timely and predictable pricing and reimbursement processes that provide applicants with meaningful due process.

Respect the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need.

Underline the importance of ethical business practices.