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US International Trade Commission
500 E Street SW
Washington, DC 20436

Dear Sir or Madam,

Please find below the UACT written statement prepared for the January 13, 2016 hearing on Investigation no. TPA-105-001, regarding the likely impact of the Trans-Pacific Partnership Agreement on the US economy.

I am here on behalf of the Union for Affordable Cancer Treatment (UACT). The Union for Affordable Cancer Treatment (UACT) is an international network of people who share the conviction that cancer treatment and care should be available everywhere for everyone, regardless of gender, age, nationality, or financial resources. Our web page is <http://cancerunion.org>. UACT is a volunteer organization of people affected by cancer, their family members and friends, people who take care of people with cancer, health care professionals and cancer researchers committed to increasing access to effective cancer treatment and care. UACT believes that research and development of new cancer drugs requires a mixture of financing approaches, including both push and pull mechanisms, including innovation inducement prizes and direct government funding for research, from basic research through late stage clinical trials.

I myself am a stage IV HER2 positive breast cancer patient in active treatment since May 2010, and am extremely fortunate to have access to the most advanced cancer treatment available today. My cancer, as for many cancer patients, has become a chronic disease. It is costly and will be more and more costly for all of us as the price of insurance increases to cover the many cancer patients living for longer and longer time.

Like many patients, caregivers, doctors, insurers and policymakers, we are extremely concerned about the rapidly escalating cost of cancer medications. Because we believe the Trans-Pacific Partnership Agreement will increase the cost of cancer treatments, we are worried about its impact on the US economy and on patients in the United States, and also on cancer patients living outside the United States who will be affected by the provisions of the TPP.

The Trans-Pacific Partnership is an important trade deal that includes 12 diverse nations, and will initially regulate about 40 percent of the world's economy, while aspiring to set standards that will affect nations that join later, and even non-TPP member countries.

While we recognize that the TPP is seen by some as a compromise between the commercial interests of pharmaceutical industry and those of health systems and patients, everyone must acknowledge that the TPP advances the goal of increasing the price of medicines and thus making them less accessible for increasing numbers of patients.

Our concerns about high prices for medicines are also addressed in the USITC hearing on the "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedure, and I am attaching the 5 page testimony from that proceeding¹ to be included in the record of this hearing.

I will make these specific points about the TPP.

In general, the provisions in the TPP on pharmaceutical patents and other intellectual property rights, as well as provisions on drug registration and reimbursements, are designed to make drugs, vaccines, diagnostic tests and other medical technologies more expensive, by (a) creating, broadening and extending the obligations to grant legal monopolies conferred by intellectual property rights, beyond those found in the WTO TRIPS Agreement (so called TRIPS+ provisions), (b) by undermining state efforts to curb excessive prices for pharmaceutical products, and (c) by giving pharmaceutical companies the right of arbitration over allegations that state actions constitute "indirect expropriation" when a "government action interferes with distinct, reasonable investment-backed expectations."

In some cases these measures are consistent with U.S. law, but are designed to lock the United States into policies that should be reformed. In other cases, the TPP requires changes in U.S. law. For non-U.S. countries, the TPP provisions will often require new obligations and changes in laws, including in particular for the countries with the lowest incomes which runs counter to the WTO Doha Declaration on TRIPS and Public Health.

¹ Testimony of Manon Ress on behalf of the Union for Affordable Cancer Treatment (UACT) United States International Trade Commission (USITC) hearing on "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedure, 2016 Report. Inv. No.: 332555 November 17, 2015.

Note also that for the intellectual property rights provisions, drug and medical device companies can bring ISDS actions against governments, even when they have no legal claims in the national courts.

We expect that the TPP will also be used to impose changes to intellectual property laws in the several developing countries that have indicated an interest in joining the TPP as new parties, as well as to legitimize the TPP standards as global or regional standards, even for non-TPP countries.

We recognize there are a number of annexes and transition provisions that mitigate or delay the negative impact of the intellectual property provisions on some countries, as well as certain safeguards related to health² and the public interest. While these safeguards are important, and welcome, they do not eliminate the harms or risks that the TPP creates. On balance and taken as a whole, the TPP has to be seen as a series of measures designed to increase the prices of medicines and other medical technologies.

1. Patents.

The TPP diverts from the WTO standard for patents, by mandating that patents are granted for new uses or methods of using known products³. The Agreement also requires an effective extension of the patent term beyond the 20 years required by the WTO both for delays in granting patent⁴ and in granting marketing approvals of products.⁵

² For example, the safeguards in Article 18.3: Principles, and Article 18.6: Understandings Regarding Certain Public Health Measures.

³ Article 18.37(2) Patentable Subject Matter [...]

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.

⁴ Article 18.46: Patent Term Adjustment for Patent Office Delays

3. If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for such delays.[36]

4. For the purposes of this Article, an unreasonable delay at least shall include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later. A Party may exclude, from the determination of such delays, periods of time that do not occur during the processing[37] of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable[38] to the granting authority; as well as periods of time that are attributable to the patent applicant.[39] Footnotes Omitted.

⁵ Article 18.48(2) : Patent Term Adjustment for Unreasonable Curtailment [...]

2. With respect to a pharmaceutical product [45] that is subject to a patent, each Party shall make available an adjustment [46] of the patent term to compensate the patent owner for unreasonable

In Article 18.41, the TPP helpfully protects the right of countries to grant compulsory licenses⁶ under the standards set out in Article 31 of the TRIPS agreement. However, the TPP gives drug and medical device companies new rights to challenge such actions under the ISDS provisions of the TPP (more on this later), and also appears to limit the flexibility of governments to limit the remedies for infringement -- which is a different approach to allowing non-voluntary use of medical patents. The data exclusivity requirements of the TPP create monopolies in countries without patents and further hamper the effective use of compulsory licensing and risk making article 18.41 an empty gesture in cases where rights in test data presents a barrier to registration of the affordable generic or biosimilar products.

The limitation on injunctions and damages for ongoing infringement of patents is currently the most important legal mechanism for judicially ordered compulsory licensing of patents in the United States, particularly for medical devices including diagnostic tests.

The United States also uses limitations on liability for infringement in cases of non-voluntary use of patents "by and for" the federal government.

Some experts want to vastly expand the use of liability rules in the United States, as part of patent reforms, creating systems whereby patents are no longer an exclusive right, but a right to be compensated.⁷ In such regimes, it is important that damages be reasonable, and designed to allow rather than deter infringements.

The TPP creates a TRIPS-plus standard for damages for infringement of patents⁸, including a requirement that judicial authorities "shall have the authority to consider, any legitimate measure of value the right holder submits." This may include "the value of the infringed goods or services measured by the market price, or the suggested retail price," which in the case of a cancer drug,

curtailment of the effective patent term as a result of the marketing approval process.[47],[48].

Footnotes omitted.

⁶ Article 18.41: Other Use Without Authorisation of the Right Holder

The Parties understand that nothing in this Chapter limits a Party's rights and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the Parties accept.

⁷ See: Arti Rai, Jerome Reichman, Paul Uhlir, and Colin Crossman, Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery. *Yale Journal Of Health Policy, Law, And Ethics* VIII:1 (2008). Mark Lemley, Phil Weiser, "Should Property or Liability Rules Govern Information?" *Texas Law Review*, Vol. 85, p. 783, 2007

⁸ Article 18.74: Civil and Administrative Procedures and Remedies

. . . .
4. In determining the amount of damages . . . each Party's judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

can be a very large number, and indeed, one that is completely unaffordable to patients or third party payers, including public programs.

UACT supports certain reforms in the financing of medical R&D that would eliminate the exclusive rights of patents in favor of different reward systems for inventors and developers of drugs and medical devices that delink R&D costs from product prices. Some of the implementation proposals involve the use of limitations on the damages for infringing patents. Such limitations on remedies already exist in U.S. law, in certain specific circumstances, including, for example, for patents on biologic drugs, when the patent landscape is not constructively disclosed to biosimilar competitors⁹, or when patents are infringed by a “medical practitioner or against a related health care entity” with respect to “the performance of a medical or surgical procedure on a body.”¹⁰

To the extent that the TPP conflicts with existing U.S. law, or prevents the Congress from expanding such statutory limitations on damages to accommodate desired reforms, such as the proposal in 2015 by Senator Bernard Sanders as regard non-voluntary use of patented medical inventions for the purposes providing treatments to veterans, the TPP undermines access to medicines.¹¹ We note that Senator Sander’s 2015 proposal was stimulated by concerns over lack of access to excessively priced drugs to treat the hepatitis C virus, a virus that can create severe health problems, including in some cases liver cancer.

2. Pharmaceutical test data protection

The TPP provides certain *sui generis* rights in the data that pharmaceutical companies submit as part of their marketing approval applications, particularly data from clinical trials intended to demonstrate the safety and efficacy of their products. For non-biologic drugs, the minimum term of protection of the data is five years for “a new pharmaceutical product” and three years for “a new indication, new formulation or new method of administration” of an older product.¹² For biologic products, the term is longer, perhaps eight years, depending upon how one parses the complex and somewhat confusing language in Article 18.52 of the TPP.¹³

⁹ 35 USC 271(e)(6)(B-C)

¹⁰ 35 USC 287(c).

¹¹ Senator Bernie Sanders proposal to expand Veterans access to patented medical inventions <http://keionline.org/node/2324> September 19, 2015.

¹² Article 18.50: Protection of Undisclosed Test or Other Data. Also, nuanced obligations as regards fixed dose combinations.

¹³ Article 18.52: Biologics.

Many cancer patients are treated with biologics drugs. Some of these these drugs are not only efficient in stopping or slowing the growth of cancer, but also allow cancer patients to have a better quality of life with fewer side effects than the products that preceded them.

Significantly, the terms begin after “the date of marketing approval . . . in the territory of the Party,” rather than the date of the first registration anywhere in the world. If a product registration is delayed for years, as is often the case in developing countries where companies are not as diligent in seeking marketing approval for new drugs, the effective term of the test data rights is longer, from the point of view of patients needing the drug.

In the absence of the exceptions, the test data rights can create huge barriers for the entry of affordable generic or biosimilar products. Clinical trials for some drugs are expensive, can take several years, and violate ethical restrictions on the duplicative testing of products on animal¹⁴ or human subjects¹⁵.

The TPP does have language on “measures to protect public health” in paragraph 3 of the Article 18.50 on test data, but confusingly “in accordance with” the WTO Doha Declaration on TRIPS and Public Health,” which addresses patents, and not test data. It would be useful for the USTR to make it clear that Article 18.50 or some other provision in the TPP allow its members to create exceptions to the exclusive rights in order to address abuses of rights, such as excessive prices, drug shortages (docetaxel, Fabrazyme, etc), ethical concerns, such as duplicative testing, or other public interest concerns.

3. Reimbursement Policies

The TPP has an Annex 26-A, oddly named “Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices.” This Annex provides special rights to companies selling drugs or medical devices to have access to information about the decision making on product pricing or reimbursements, and to challenge such decisions in a review process that provides “at a minimum, a substantive reconsideration of the application.”

This annex applies:

“To the extent that a Party’s national health care authorities operate or maintain procedures for listing new pharmaceutical products or medical devices for

¹⁴ Legislation for the protection of animals used for scientific purposes
http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm.

¹⁵ See: WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, revised October 2013. <http://www.wma.net/en/30publications/10policies/b3/>

reimbursement purposes, or setting the amount of such reimbursement, under national health care programmes operated by the national health care authorities [11][12]¹⁶”

For the United States, a “national health care authority” is defined as “The Centers for Medicare & Medicaid Services (CMS), with respect to CMS’s role in making Medicare national coverage determinations.” The coverage outside the United States varies from country to country.

The purpose of this Annex is to give drug and medical device manufacturers additional leverage to oppose decisions that would curb reimbursements, even when prices are excessive. To the extent that Medicare has some discretion in setting reimbursements, and when Medicare eventually obtains more discretion in setting reimbursements, as many expect, this Annex will be another tool for companies to protect high prices.

4. Investor-state dispute settlement, known as ISDS.

Corporations intend to use ISDS to get around domestic laws, and take away the ability of legislatures and domestic courts to shape the law in ways that would be beneficial to citizens. One relevant example is the case in Canada where U.S. drugmaker Eli Lilly is using an arbitration panel to challenge Canadian patent rules that the company finds too strict. Eli Lilly ultimately lost its case before the Canadian Supreme Court but is now taking it to investor-state arbitration under the NAFTA provisions, and seeking a different outcome. It is not difficult to imagine any or all TPP member countries being at risk for investor arbitrations, particularly given the ease with which drug company lawyers can manipulate the nationality of patent or stock ownership, in order to obtain standing to bring an ISDS case. One predictable consequence of the ISDS mechanism is to intimidate governments seeking to introduce measures to protect consumers and patients. We note that consumers, including cancer patients, cannot bring ISDS cases, as the right to pursue an ISDS case is confined to those claiming to be investors.

UACT believes that the focus of trade negotiations should change from pursuing an agenda of promoting high prices to forging agreements that provide robust and sustainable funding for R&D through other mechanisms, including in particular, those that would delink R&D costs and funding levels from drug prices. The TPP is the very opposite of what is needed.

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¹⁶ These two footnotes read: [10] For purposes of this Annex, each Party shall define the scope of the products subject to its statutes and regulations for pharmaceutical products and medical devices in its territory and make such information publicly available. [11] This Annex shall not apply to government procurement of pharmaceutical products and medical devices. Where a public entity providing healthcare services engages in government procurement for pharmaceutical products or medical devices, formulary development and management with respect to such activity by the national healthcare authority shall be considered an aspect of such government procurement.