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Comments Re: WHA Agenda 17.5
Global strategy and plan of action on public health, innovation and intellectual property

My name is Andrew Spencer Goldman, and I am an attorney with Knowledge Ecology International, a non-profit organization that among other topics, focuses on innovation and access to medical technologies.

On behalf of KEI, I wish to comment on the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property provisions on trade agreements, and in particular, the provisions in the Trans-Pacific Partnership (TPP) that are in conflict with goals and aims of the Global Strategy.

Principle 18 of the Global Strategy states that, "Intellectual property rights do not and should not prevent Member States from taking measures to protect public health."

This principle is further supported by Element 5 ("Application and management of intellectual property to contribute to innovation and promote public health"), particularly section 5.2, which, in subsections (a) through (e) is explicit in its support for the right of countries to use the space in the WTO TRIPS agreement for limitations and exceptions to intellectual property rights.

Section 5.2 also calls for an accounting of the "impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States."

The current text of the IP chapter of the TPP Agreement -- only available to the public because it has been leaked -- directly conflicts with the Global Strategy.

The TPP will have harmful effects on public health, and constricts TRIPS flexibilities by altogether eliminating the broad compulsory licensing provisions of TRIPS Article 31 and leaving only the far narrower three-step test of Article 30, and by requiring member states to adopt a large number of TRIPS+ provisions on medical technologies, including patent extensions, exclusive rights in drug test data, obligations to grant patents on new uses of old drugs, and linkage of drug registration to patent status, even in countries that have a low capacity to distinguish between patents that are relevant or valid, and patents that are neither.

KEI would like DHHS to reflect upon the gap between the language in the Global Strategy, and the proposals in the TPP. Mr. Ambassador, I ask you: will you take the opportunity to rectify these issues and be remembered for having the courage to stand against the pharmaceutical industry? Or do you intend for your long tenure in the field to be remembered for standing in opposition to global norms and trampling on public health?

Annex 1 - Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

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34. The actions to be taken in relation to this element are as follows:

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(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products:

(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;

(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States;

(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;

(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to facilitate, through export, access to pharmaceutical products in

countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;

(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider, where appropriate, legislative and other measures to help to prevent misappropriation of such traditional knowledge.

Annex 2 - TRIPS Article 30 and 31

Article 30. Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public noncommercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.