Sean Michael Fiil Flynn
Associate Director, Program on Information Justice and Intellectual Property

ANALYSIS OF THE POTENTIAL TPP PHARMACEUTICAL CHAPTER

Sean Flynn
Associate Director, Professorial Lecturer
Program on Information Justice and Intellectual Property, American University Washington College of Law

It has been reported that the US will propose a section or chapter in the TPP that restricts the operation of local pharmaceutical reimbursement programs that restrain medicine prices for public programs. The provision will allegedly be modeled on Chapter 5 of the Korea-US FTA.

The ultimate position of this note is that pharmaceutical pricing provisions should be excluded from the TPP in their entirety. This is because pharmaceutical pricing and reimbursement minimum standards, to the extent they do more than ban discrimination in the application of common regulations (already prohibited by GATT), are:

- **An inappropriate subject for closed door trade negotiations** because they do not regulate trade but rather set new minimum requirements for domestic legislation that impacts broad ranging public health concerns that need to included in any legitimate process;
- **An inappropriate subject for agreements with developing countries** because they limit the most important TRIPS flexibility – the ability to respond to high prices on patented medicines with price regulation; and
- **The specific chapter being considered contains many elements of bad public policy,** including attempting to force countries into using public lawmaking processes to negotiate drug prices, which may not always be the most effective way to conduct such negotiations, setting up appeal processes that may be gamed by obstructionist patent holders and requiring direct to consumer marketing over the internet.

I. General Concerns

A. Pharmaceutical price restrictions are an inappropriate subject for closed door trade negotiations.

It is inappropriate to negotiate multinational legislative minimum standards agreements in closed door sessions with minimum public oversight or input.

Academics and civil society representatives are here because we want to help ensure that the public interest is taken into account in this process. But we cannot give you timely and informed analysis of policy proposals if we do not have access to the text of those proposals.

Medicine reimbursement policy affects a broad range of interests within society, not just those of pharmaceutical companies. Setting domestic policy in this area therefore should be conducted through mechanisms of transparency and openness that encourage broad public participation. Consistent with the recently released Washington Declaration on Intellectual Property and the Public Interest, international standards on pharmaceutical regulatory policy should be negotiated only through processes in which "the texts of and forums for considering proposals are open."

If this negotiation was going on in a multilateral forum like the World Health Organization or World Intellectual Property Organization, there would be ongoing public access to negotiating text, including to proposed amendments and revisions, and stakeholders would be permitted in, and have opportunities to address, sessions at which decisions on textual amendments may be made.[1] These are basic elements of public process that allow people like me to give people like you direct, specific and hopefully helpful input when it is needed most.

I ask you to open this process. Share the text. And bolster the legitimacy of this enterprise by including meaningful public input in it.

B. The goal and ultimate effect of the pharmaceutical chapter is to raise medicine prices.

Although the provisions are styled as "transparency" provisions, in fact they regulate the substance of drug pricing programs. This is particularly clear in the provision requiring countries to give pharmaceutical companies the opportunity to appeal a reimbursement price based on whether it adequately respects the "value" of a patent. Similar provisions have led to higher drug prices and more challenges by pharmaceutical companies in the one country to implement similar provisions – Australia.[2]

Raising drug prices is, of course, the goal of pharmaceutical companies pushing for these provisions. This point was explained by President Bush's Ambassador to Poland in a recently released cable. He explained:

> While pharmaceuticals companies often assert that they would be happy with a transparent process, even if it led to

[1] See, e.g. http://keionline.org/blogs/2009/03/16/what-should-be-transparent ; Jeremy Malcolm, Public Interest Representation in Global IP Policy Institutions, PIJIP Working Paper (2010), http://digitalcommons.wcl.american.edu/research/; cf Eur. Parl., *Eur. Parl. res. of 10 March 2010 on the transparency and state of play of the ACTA negotiations*, P7_TA(2010)0058 (2010), *available at* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0058+0+DOC+XML+V0//EN&language=EN

[2] http://www.globalizationandhealth.com/content/1/1/15; http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1547563 The Korea FTA pharmaceutical chapter is more strict than the Australia chapter. It has not been implemented and therefore its effects are unknown.

> decisions not to fund their drugs, in practice they seem to resent all government measures aimed at cost containment, as these also inevitably limit drug companies' sales.[3]

C. Pharmaceutical pricing restrictions are inappropriate for developing countries

TPP would be the first trade agreement in the world to restrict policy options of developing countries to implement non-discriminatory drug pricing programs. This is a significant new direction in TRIPS-plus restrictions on developing country ability to ensure access to medicine.[4] The ability to regulate the prices of patented products directly is perhaps the most important TRIPS flexibility.

The developing countries negotiating TPP cannot afford to give up any flexibility in this area. All of the developing countries negotiating the TPP (Peru, Malaysia, Vietnam, and Chile) have been identified as having high medicine prices given their development level.[5] The case of Vietnam is particularly egregious – with local prices of patented medicines 46 times higher than international referents.[6]

II. Specific text analysis

This section analyses the text of the Korea FTA, with mention of how TPP may differ based on reports of the US position.

A. Art. 5.2: ACCESS TO INNOVATION (U.S. CARVE OUTS)

> To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government,[1] the Party shall:
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> [1.] Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for health care agencies that engage in government procurement. Chapter Seventeen (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products.
>
> *health care authorities at a Party's central level of government* means entities that are part of or have been established by a Party's

[3] http://keionline.org/node/1250
[4] See Oxfam Briefing Paper on TPP Pharmaceutical Provisions, distributed at TPP meeting, Chicago.
[5] See http://www.haiweb.org/medicineprices/surveys.php
[6] Nguyen AT, Knight R, Mant A, Cao QM, Brooks G. Medicine pricing policies: Lessons from Vietnam. Southern Med Review (2010) 3; 2:12-19; Nguyen AT, Knight R, Mant A, Cao QM, Auton M. Medicine prices, availability, and affordability in Vietnam. Southern Med Review (2009) 2; 2:2-9.

> central level of government to operate or administer its health care programs;
>
> *health care programs operated by a Party's central level of government* means health care programs in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;[3]
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> [3.] For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.

As has been widely reported, programs for the purchasing and reimbursement of medicines in the U.S. do not comply with the standards in the Korea FTA. This has raised concerns in the US both for US policy and for our foreign policy.

A letter from several senior members of congress, released this morning, includes:

> TPP should not undermine either U.S. or other member countries' current or prospective, non-discriminatory drug reimbursement policies and programs (e.g. Medicare, Medicaid, the VA, and other programs).

Neither Medicaid nor the Veterans Administration, for example, provide substantive appeals for decisions to list a drug on a preferred drug list or of the price set for reimbursement. These and other US and state administered programs receive prices on par with, and often below, those received through drug pricing programs in other countries. The Korea FTA, and presumably TPP, attempts to protect these and other U.S. programs from being affected by the proposal through a series of technical carve outs.[7]

The carve outs have not cooled opposition from US state officials to the shift in FTA proposals to include pharmaceutical price restrictions. State officials opposed the Korea and Australia FTA pharmaceutical chapters because of fear that they would damage the operation of Medicaid reimbursement programs which operate similarly to, and receive similar prices as, foreign programs. This point was made explicit in a recent letter to President Obama from Vermont Governor Peter Shumlin:

> Even if a chapter was proposed that did include a Medicaid carve-out, state leaders believe it is inappropriate for U.S. trade policy to advance restrictions on pharmaceutical pricing

[7] Other large drug price programs including purchasing by the Department of Defense and General Services Administration, reimbursement through private pharmacy benefit managers through Medicare Part D, reimbursement for drugs used in hospitals by Medicare Part B, and reimbursement for drugs used in community hospitals and other facilities that serve the poor and disabled through the 340B program.

> programs that U.S. programs do not meet but for technical carve outs.[8]

The carve outs are contained with the terms "central level" and "reimbursement." The restriction to "central" (in US terms – "federal") programs exempts the many programs administered by U.S. states, including, through a footnote, Medicaid. The restriction of the section's coverage to "reimbursement" decisions, rather than purchasing decisions, exempts most U.S. federal level drug pricing programs which operate through direct purchasing (e.g. VA hospitals, GSA, DoD).

The section appears facially applicable to several large and important reimbursement programs in the U.S., namely the 340b program (where prices for pharmaceuticals are set through a federal statutory formula), Medicare part B (covering reimbursements in hospitals). The U.S. may work to expand the Medicaid footnote to carve out these programs as well.

The position of state officials and US health advocates is that the US should not be proposing standards abroad that it is not prepared to live by at home.

B. Art. 5.2(b). Competitive Market Pricing

> . . . the Party shall:
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> ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe and effective, is based on competitive market-derived prices [TPP: "within the party's territory"]; or if its determination is not based on competitive market-derived prices, then that Party shall:

The Korea Agreement sets up a two part test for challenging the substantive operation of pharmaceutical pricing programs.

Originally, the US position in Australia and Korea was that all pharmaceutical reimbursement programs in the other country should set reimbursement prices only based on the "competitive market derived prices." Australia pushed back from this position because its system sets prices based on efficacy rather than market power. The model set up in Australia and refined in Korea allows countries to set prices other than based on market value, but exposes such programs to a series of appeals by pharmaceutical companies.

The term "competitive market" is vague and not defined.[9] It is rumored that the parallel provision in the US TPP proposal includes an additional limitation that to pass the market-

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[8] http://www.forumdemocracy.net/downloads/Letter%20from%20VT%20Gov.%20Shumlin%20to%20President%20Obama%20-%20June%201,%202011.pdf

[9] In one sense, every market for a patented drug is not competitive since there is only one supplier for that good. Every government reimbursement can be labeled non-competitive since larger buyers exert monopsony power. And every pricing program seeks to obtain prices below that which would occur with a monopoly seller

price safeguard the "competitive" price must be based on the market *within the party's territory*. This would require the application of the substantive appeals to all prices set through international reference pricing – a common practice among developed and developing health systems.

C. Art. 5.2(b)(i): "appropriately value"; 5.3(5)(e) Appeal

> 5.2(b)(i)
>
> (i) appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides;
>
> (ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on evidence of safety or efficacy, for an increased amount of reimbursement over that provided for comparator products, if any, used to determine the amount of reimbursement; and
>
> (iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product based on evidence the manufacturer provides on the product's safety or efficacy;
>
> 5.3(5)(e) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination;

The core of the Korea chapter, and perhaps its most worrisome provision, is a mandate that any reimbursement system that does not set public reimbursement prices based on "competitive-market derived prices" (Art. 5.2(b)) provide a substantive independent appeal on whether the ultimate reimbursement price negotiated with drug companies "appropriately recognize[s] the value of the patent[]." (Art,. 5.2(b)(i) and 5.3(5)(e)).

This aspect of the agreement introduces a new and undefined substantive restriction on the prices that can be set through reimbursement programs. A similar standard has led to challenges and threats of litigation and trade disputes in Australia.

The bright point in the language may be that it embraces a determination of "value" based not on the monetary value that a monopoly supplier hopes to receive in an unregulated market, but rather, expressed in (ii), "based on evidence of safety or efficacy." This notion should be safeguarded and expanded by public health advocates.

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and atomized consumers – i.e. to the maximum of willingness and ability to pay. But few economists would call such a market "competitive."

D. Art. 5.2(c): Additional indications

> (c) permit a manufacturer of the pharmaceutical product or medical device to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy.

The Korea FTA mandates that governments provide opportunities for manufacturers to receive reimbursement for "additional indications" based on information that the manufacturer provides. This section could be interpreted to mandate public reimbursement for off-label prescribing – that is, the prescribing of products for purposes not approved by the country's drug registration body. In the U.S., some Medicaid programs refuse reimbursement for certain off label uses of approved products. The provision would sacrifice this flexibility for foreign countries and would sacrifice the ability of health authorities to respond to efficacy research by withholding approval of reimbursements of listed drugs for indications proven to be less safe or less efficacious than better products.

E. Art 5.3: Transparency

Article 5.3 of the Korea FTA contains a large number of provisions essentially requiring a public notice and comment process for "any matter related to pricing," (5.3(1)) followed by "detailed written information regarding the basis for recommendations or determinations of the pricing" in individual cases (5.3(6)(d)). The ultimate effect of such provisions will be to turn the negotiation of drug reimbursement rates with pharmaceutical companies into formal rule making, complete with appeals and potential litigation at the back end.

In the US, some Medicaid reimbursement programs follow an open process of determining listing decisions and some do not. It is important to contrast the administrative rulemaking process mandated by the FTA proposal with the procedures normally followed by large private drug reimbursers (e.g. private insurers).

Private drug buyers also use drug formularies and negotiate with drug companies to exact price concessions. But they do not normally advertise their methodologies. Indeed, there are academic studies concluding that governments may be better off – individually and collectively – if they are enabled to enter into non-public price negotiations with drug companies and NOT share the ultimate prices obtained or methodologies used.[10]

At minimum, this is a section where there is academic disagreement as to the efficacy of a one size fits all standard. Some systems may work better under such provisions, others may not. The unwillingness of the US to apply these rules to its own programs suggests the range of views within that country.

F. Art. 5.4: Direct to Consumer Marketing

> Each Party shall permit a pharmaceutical manufacturer to disseminate through the manufacturer's official Internet site registered in the Party's territory and through medical journal Internet sites registered in the Party's territory, that include

[10] See Patricia Danzon.

> direct links to the manufacturer's official Internet site, truthful and not misleading information regarding the manufacturer's pharmaceutical product, provided that the product has marketing approval in the Party's territory and the information includes a balance of risks and benefits and is limited to indications for which the Party's competent regulatory authorities have granted market approval for that product.

Article 5.4 of the Korea FTA contains a controversial requirement that countries permit direct-to-consumer marketing over the internet. This would appear to make illegal a proposal by Representative Waxman that companies not be allowed to engage in certain kinds of direct to consumer promotion in the first three years of a drug's time on the market. And it would overturn the laws of many countries that prohibit the direct marketing of pharmaceuticals to consumers.

G. The ultimate goal: a new agreement on pricing

The TPP chapter may be best seen as a significant step toward the pharmaceutical industry's ultimate goal, which is a binding international agreement on drug pricing that would restrain the ability of governments to use collective purchasing power to demand prices below "market" levels.[11] This is a radical proposal that would move trade agreements completely beyond any pretense to regulate trade and instead directly regulate domestic regulation itself. If such an agreement is desired by countries, it should be negotiated in an open forum where public health experts and advocates are well represented, e..g the World Health Organization. This is a completely inappropriate subject for closed door trade negotiations.

[11] http://media.pfizer.com/files/news/kindler_testimony_sfc_071508.pdf