

Statement and Analysis: Leaked US Proposal for a TPP Pharmaceutical Chapter

By Sean Flynn

October 22, 2011

STATEMENT

All countries negotiating the Trans Pacific Partnership agreement should reject the US proposal regulating pharmaceutical reimbursement programs. This is an extreme proposal that has no place in a trade negotiation, particularly one with some of the poorest countries in the world.

Although the provisions are styled as “transparency” provisions, in fact they regulate the substance of drug pricing programs. The heart of the proposal would require that countries establish new administrative and judicial appeal systems to contest whether public drug reimbursement rates “appropriately recognize the value” of pharmaceutical patents. Similar provisions have led to higher drug prices and more challenges by pharmaceutical companies in the one country to implement similar provisions – Australia.[\[1\]](#)

At the core of this proposal is a false distinction between government reimbursement prices and “market” prices. Government reimbursement prices ARE market prices. Suppliers can refuse to supply to governments, just as they can with any private purchaser demanding a better deal. The fact that governments obtain better prices than atomized consumers does not make their roles as purchasers anti-market. Drug price restraint is a natural, inevitable and beneficial result of public health expenditure or any other form of pooled purchasing. Large purchasers in free markets obtain better prices; governments obtain better prices when they pool consumers and negotiate as a volume purchaser.

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 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.[\[2\]](#)

This proposal is contrary to the demands of democracy, is bad for the development interests of poorer countries, and represents an affront to best practices in evidence-based health policy, including such practices in the US.

- **Pharmaceutical price regulation is an inappropriate subject for closed door trade negotiations.** The proposed pharmaceutical chapter regulates public health policy, not trade. This is perhaps most notable in the fact that the provisions apply to policies regardless of any trade distorting or discriminatory effect of the given policy. Using secretive trade negotiation processes to set minimum requirements for domestic health policy like this is democratically illegitimate. Enactment of reimbursement policies to advance public health outcomes lies in the core of domestic sovereignty. These

policies do not affect a limited range of companies, justifying closed door processes where only those companies are meaningfully consulted. Public health policies affect all citizens and a wide variety of stakeholders that deserve to be included in policy making processes. Indeed, access to decision making processes that impact public health programs is an internationally recognized human right.

- **Pharmaceutical price regulation is an inappropriate subject for agreements with developing countries.** This would be the first-ever international agreement regulating the efficacy of pharmaceutical price regulations in developing countries. The ability to regulate the prices of patented products directly is one of the most important TRIPS flexibilities. Without some kind of price control, patents on pharmaceuticals demonstratively and predictably lead to excessive pricing of medicines in developing countries with very high income inequality. This is because the most profitable behavior of an unregulated essential service monopolist in high inequality countries will be to price to the richest tier of the population. [3] 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. [4] The case of Vietnam is particularly egregious – with local prices of patented medicines 46 times higher than international referents. [5]
- **The U.S. proposal would require bad public policy contrary to best practices in the US itself.** Ironically and ominously, US drug pricing programs do not comply with the standards that the US is proposing. In particular, the operation of preferred drug lists by the Federal Medicaid program would violate the terms of the agreement, including because they do not provide appeals for pharmaceutical companies on whether the prices achieved adequately value patents. Previous FTAs with Australia and Korea carefully exempted all U.S. programs from their coverage, including through a footnote defining the federal Medicaid program as a “regional,” rather than “central,” level government program. That footnote has been removed from the draft TPP proposal. This may indicate that the US has not decided whether to propose exempting Medicaid from the TPP requirements or to give in to demands of other countries for full reciprocity in the agreement.

SECTION BY SECTION ANALYSIS

X.1: Agreed Principles. The agreed principles are verbatim restatements from the KORUS agreement. As in KORUS, they understate the role and importance of promoting affordability through pharmaceutical reimbursement policies. The provisions mainly discuss the promotion of “access” and “availability” of pharmaceuticals. The concept of affordability is mentioned only once. USTR’s recent white paper on TPP and medicines also defines “access” without reference to affordability concerns. One of the key purposes of drug reimbursement programs must be to promote *affordable* access to pharmaceuticals, not mere availability of the products themselves. This concern applies throughout the proposal.

X.2: Transparency Related to Healthcare Technologies. The provision creates a vague requirement that “all measures” related to pharmaceutical reimbursement be administered in an “objective” manner. This concept of “objective” administration of the law is not a current US legal requirement and is not defined in the agreement. What it means in this context is unclear, which may open opportunities for pharmaceutical companies to attempt to define it through litigation. What is a non-objective administration of the law? Would public interest standards violate the test? What about the choosing of drugs for a formulary based on a

multitude of factors including price and availability decisions?

X.3: Procedural Fairness Related to Healthcare Technologies. This is the core section forcing countries to use formal rulemaking processes rather than market negotiations to determine reimbursement prices. International law should not determine this important policy choice. Countries must be free to use reimbursement programs as a player in the market rather than as its regulator.

X.3(a): The term “reasonable period” has no definition in the agreement or in US or international law. It invites litigation.

X.3(b): The requirement to disclose all methodologies used to negotiate drug prices is one of many rules forcing the government to operate as a price regulator rather than market participant. Private companies do not disclose such information to their suppliers.

X.3(c): The requirement to give notice and comment opportunities during reimbursement decisions prevents health authorities from using negotiation rather regulation to set drug prices. Private entities do not invite public comments on their negotiations with suppliers.

X.3(d): This is one of the most worrisome provisions in the text. The provision has two parts:

- The first part encourages countries to abandon any economy of scale benefits from pooled purchasing through government and instead reimburse pharmaceutical companies at rates “consisting of competitive market-driven prices in the Party’s territory.” The restriction to “in the Party’s territory” was not included in previous agreements and is designed to restrict countries from the common practice of using international reference prices to determine reasonable reimbursement rates. This rule is not followed in the US. Medicaid programs receive discounts of up to 50% off the list price for pharmaceuticals due to their increased purchasing power. The provision is also practically unworkable since other large private purchasers in the market will not be under any obligation to disclose their “market-driven” prices.
- The second part of this section, read with paragraph (i), provides that if countries do not set reimbursement prices at the “competitive market-driven” price, then they must provide companies with appeals of whether reimbursement prices “appropriately recognize the value” of patents. There is no objective measure of the “value” of a patent. Economists normally define value as a function of market price. But in a monopoly market for an essential good, particularly in countries with high income inequality, this market price will be excessively high absent government regulation. It is impossible to know how this provision would be implemented. It invites litigation and promotes uncertainty.

X.3(e): This provision mandates that countries allow companies to “apply for an increased amount” in reimbursement based on evidence of “superior safety, efficacy or quality.” This provision is potentially beneficial in embracing the idea that prices should be set based on efficacy rather than market value. Nonetheless, affordability concerns must also be an integral part of reimbursement decisions, but are not mentioned.

X.3(f): This provision mandates that governments allow companies to “apply” for reimbursements for additional medical indications for products. The provision has no requirement that the additional indications applied for first be approved by the government’s medical registration authorities. It rather suggests that the safety and efficacy information would be submitted directly to the reimbursement entity, side stepping regulatory authorities.

X.3(g, h, i): These provisions require that governments provide written reasons for every

decision [(g) and (h)] and then provide an “independent appeal” of any reimbursement decision (i), presumably based on the substantive restrictions on reimbursement programs defined in X.2(d). These provisions will likely increase pharmaceutical company negotiating power to exact higher prices from governments through litigation threats.

X.3(k): This provision requires that all members of reimbursement committees be made public, presumably to enable targeted lobbying from pharmaceutical companies. Such lobbying can be detrimental to public decision making, especially when linked to unethical gift giving that has plagued pharmaceutical marketing in the US and elsewhere.

X.4: Dissemination of Information to Health Professionals and Consumers. This provision attempts to set drug marketing policy through trade agreements. It would mandate that countries allow certain kinds of direct-to-consumer and direct-to-physician marketing efforts over the internet. This is a subject currently subject to regulatory investigations in the US and would be contrary to the drug marketing laws of many countries. The provision 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.

X.5: Ethical business practices [no text]. As in other areas of the TPP, provisions protecting corporate concerns are well developed and those potentially protecting consumers are absent. This section should consider standards that would ban gift giving and other pecuniary relationships between pharmaceutical companies and prescribers or government health officials. It should ban off-label marketing of drugs. It should mandate private and public rights of action against fraudulent and misleading marketing practices.

X.6: Cooperation. As in the agreed principles, this provision appears tailored to promote a conception of “availability” that does not include affordability. The key concern of countries in the region, and in particular the US, should be on sharing information on how best to ensure the affordability of medicines in the context of the ongoing economic crisis.

X.7: Definitions. Few of the key terms in the agreement are defined, including “access,” “value,” “reimbursement” and “health care programs” as applied to the scope of coverage, “transparent,” “verifiable,” “objective,” “competitive-market derived,” “independent” as related to “appeal or review.”

X.7 fn 2. (US carve out?). In previous agreements with the US including pharmaceutical chapters, the US has claimed that they have no application to programs in the US. The KORUS agreement included a footnote stating: “For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.” This footnote has been criticized in the US for potentially leaving vulnerable other US programs that control prices on drugs in government programs, including through Medicare and the so-called 340b program. TPP removes this footnote from the proposed text and substitutes a bracketed place holder for clarification of the scope of application. This should be concerning to US health advocates and officials. A letter from several senior members of the US Congress, released during the Chicago round of negotiations, instructed that “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).” Vermont Governor Peter Shumlin wrote President Obama with respect to a possible TPP pharmaceutical chapter:

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

programs that U.S. programs do not meet but for technical carve outs.[6]

Conclusion: A New International Agreement on Pharmaceutical Price Regulation?

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.[7] 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.

[1]

<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.

[2] <http://keionline.org/node/1250>

[3] See Flynn, Hollis, Palmedo, An Economic Justification for Open Access to Medicine Patents in Developing Countries

[4] Oxfam Briefing Paper on TPP Pharmaceutical Provisions; see <http://www.haiweb.org/medicineprices/surveys.php>

[5] 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.

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

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