Health Care & Pharmaceutical Policy in the Trans-Pacific Partnership (TPP)

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Montpelier, Vermont
September 27, 2013

Disclaimer

- TPP text is secret and not available for public review
- This presentation is based on reports in the media, public statements by USTR, leaked and publicly posted negotiating texts on pharmaceutical pricing, intellectual property, and investment
- We can also look to the Model BIT (Bilateral Investment Treaty) and KORUS and AUS-FTA for guidance
- The actual text currently under consideration may differ from prior agreements and leaked text

State Health Care Responsibilities

- **State Health Exchange** – Insurance marketplace, Vermont single payer option in 2017
- **Medicaid** – jointly funded federal/state program for low income, disabled and children, largely implemented by state governments pursuant to federal rules
- **Certificate of Need** for health care facilities
- **Licensing of medical professionals and facilities**
- **Public Health** – vaccinations, tobacco regulation and enforcement, alcohol regulation

Overview of Health Care Issues

- **Access to Affordable Medicines**
  - Reimbursement/pricing & "transparency" issues
  - Internet marketing implications
  - Intellectual property provisions (patented products)
  - Biologic-specific issues ("follow-on" generics)
- **Licensing of Health Care Professionals**
- **Regulations of SOE's** – "State Owned Enterprises"
- **ISDS** – Investment chapter and corporate challenges in private dispute settlement

Pharmaceutical Market Access, Transparency & Pricing

Shift of Trade Law into Pharma Pricing

- Trade Promotion Authority 2002
  - "achieve the elimination of government measures such as price controls and reference pricing."
- Australia – U.S. Free Trade Agreement 2004
- Korea FTA 2006
  - Appeal decisions that do not "appropriately recognize the value of patented products."

State Medicaid Drug Rebates

40 States Negotiate Medicaid Drug Prices through a Preferred Drug List (PDL) – State purchase price for branded drugs and many generics discounted through (1) federal rebate and (2) state rebates

- **State rebates can be significant** – In aggregate, some states receive back as much as 50% off "market price" in rebates
- **State-by-state rebate negotiation modified by national reference price list under the ACA**

State Pharmaceutical Policy Role Beyond Medicaid – 340(B)

- **340B** – Federally Qualified Health Centers – **Clinics** provide sliding fee health care for rural, underserved urban, women, HIV/AIDS
- 340B pricing also in many **hospitals (1,673** or one-third **of** all US hospitals)
- Some states use 340B to provide lower-cost drugs **for** corrections population (740,905 inmates in Texas **alone!)**
- **340B pricing is <u>below</u> Medicaid pricing**

US Pharmaceutical & Medical Device Reimbursement Proposal ("Healthcare Transparency") In the TPP

Substantive requirements

..."ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has <u>a transparent and verifiable basis</u> consisting of <u>competitive market-derived prices</u> in the <u>Party's territory</u>, or an alternative transparent and verifiable basis consisting of other benchmarks that <u>appropriately recognize the value</u> of the patented or generic pharmaceutical products or medical devices at issue"...

[Leaked text June 2011 accessed at: **http://infojustice.org/resources-library/tpp**]

US Pharmaceutical & Medical Device Reimbursement Proposal ("Healthcare Transparency") in the TPP

Substantive requirements

... *"where a Party provides for a determination of the reimbursement amount on a basis other than competitive market-derived prices in that territory, that Party shall permit a manufacturer of the pharmaceutical product or medical device in question, before or after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product or device based on evidence the manufacturer provides on the product's superior safety, efficacy or quality as compared with comparator products;*

[Leaked text June **2011 accessed at: http://infojustice.org/resource-library/tpp]**

US Pharmaceutical/Medical Device Reimbursement Proposal in the TPP

Procedural Provisions:

- **Public session** negotiating rebates (price) and determining which drugs will be "preferred" on **PDL**
- **Detailed written explanation** of transparent & **verifiable** basis for reimbursement decision
- Multiple opportunities for **independent appeal** or review of decision
- "Reasonable, **specified" timetable for all reimbursement decisions**

Concern: Current State Medicaid Programs Don't Comply with TPP Procedural Requirements

- **NO public session** negotiating rebates (price) and determining which drugs will be "preferred" on PDL
- **NO detailed written explanation of transparent & verifiable basis for reimbursement decision**
- **NO opportunity for independent appeal or review of decision**
- **NO consistent administration in all 50 states, D.C. & territories**

Will there be a carve-out in the TPP? If so, what will it cover?

The U.S. proposal applies to *"the extent that health **care** authorities of a Party's central level of government **maintain** procedures for listing pharmaceutical products ... for reimbursement, or for setting the amount of reimbursement **for** pharmaceutical products or medical devices, under health **care** programs operated by its central level of government."*

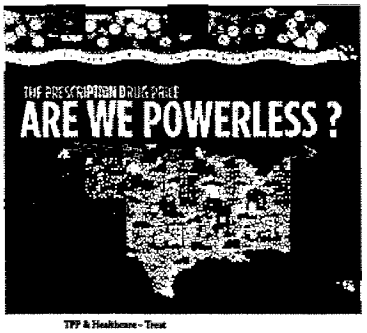
Health care programs are **defined** as those *"in which the **health care authorities** of a Party's **central level of government make the decisions** regarding matters to which this Chapter applies[2[2] ..."*

FOOTNOTE IN BRACKETS: Footnote 2: ***"[Negotiator's Note: Clarifying** footnote regarding scope of application, such as with **respect to central versus regional level of government** healthcare programs.]"*

Medicaid Carve-Out in Korea-US FTA

- **KORUS Footnote:** Medicaid is a regional **level** government program, rules apply to central **level**
  - No mention of **340B clinics and hospital prices**
  - No mention of **veterans' health care** – VA has reference pricing based on formulary
  - No mention of Medicare **Part B** – hospital drugs for **elderly** or **Medicare Part D** – prescription drug benefit
    - Recent OIG report found Medicare **Part B** could save $3 Billion/year if rebates similar to **Medicaid** were negotiated
- **TPP:** US has not offered footnote text in TPP (yet?)

Drug Prices are Highest in World



Concern: Locking US into the Most Expensive System in the World

The US proposals in the TPP and other trade agreements will lock into place the current fractured US public health "system" that lacks the more effective medicines pricing controls such as in Canada, New Zealand, Australia, which are intended to (and do) broaden health access and increase affordability.

US Drug Costs

- Spending on prescription drugs in the US was $234.1 billion in 2008. It has been one of the fastest growing components of health care sending – 6 times what was spent in 1990.
- Government's share of prescription drug spending is 37% of the total.

Compare the US to New Zealand

"PHARMAC's processes have ensured that New Zealand performs well on many measures of pharmaceutical expenditure when compared with most other OECD countries. In 2009, New Zealand's per capita expenditure for prescribed medicines was 237 USD PPP compared with ... 815 for the United States. In that year New Zealand also spent only 0.9% of GDP on pharmaceuticals ... while the United States spent more than 2%."

"Since January 2013, co- payments for fully subsidised medicines have been set at a flat rate of $5 NZD ... with additional charges for some medicines that are not fully subsidised. Once an individual/family has obtained 20 subsidised items in a 12 month period, the copayment is waived."

[Gleeson D, et al. *How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand.* Health Policy (2013), http://dx.doi.org/10.1016/j.healthpol.2013.07.012]

Concern: Loopholes in oversight of drug marketing

- Requiring Internet posting of information on drugs **and** devices for both consumers and medical professionals linking to any & all websites including social media **will** increase fraud and off-label marketing
- Between 2006-2010, 165 legal settlements by US states and federal government with pharma industry for $19.8 Billion for off-label and deceptive marketing including Internet marketing and criminal violations
  - YAZ deceptive ad lived on YouTube long **after banned**

Concern: Medical device approval provisions could jeopardize public health

- Speeding up approval for medical devices **with** "priority review" & limiting reconsideration of clinical effectiveness could jeopardize public health
- **Recent example**: metal hip joints generating "high volume of metallic debris ... absorbed into the patient's body." [NY Times]

Summary: Implications of US Pharmaceutical & Medical Device Pricing (Transparency) Proposal

- Negates government's market power
- Precludes international reference pricing
- No standard for setting value
- Excludes cost-effectiveness
- Detached from affordability
- Invites litigation
- Increases industry influence through consultation
- Promotes internet advertising of prescription medicines

TPP Intellectual Property Provisions

US Intellectual Property Leaked Text

- **Expands pharmaceutical patenting** and **creates new drug monopolies**, by lowering **patentability** standards and requiring **patentability of minor variations of older,** known medicines.
- **Lengthens drug monopolies** by requiring countries to extend **patent** terms.
- **Eliminates safeguards against patent abuse**, including among others the right of third parties to challenge patent applications.
- **Risks facilitating patent abuse** by requiring countries to condition marketing approval on patent status (patent linkage). Under patent linkage, even spurious patents may function as barriers to generic drug registration.
- **Expands exclusive control** over **clinical trial data** including through an extra three years of data exclusivity for new uses of **known products** (in addition to **five years exclusivity** for first uses) and a **new** provision on **biotech medicines.**

Concern: Delayed generic availability = increased drug costs

- US intellectual property proposals in the TPP could prevent changes to current US policies that delay entry of generics to market
  - **"Pay for Delay"** deals between patent-holding manufacturer and generic manufacturer are currently subject to investigation and litigation
  - Providing initial monopoly for first generic version **on market** delays competition and keeps prices high
- Extended timetable for generic ("follow-on") versions of biologics will increase already outrageous costs

Biologics are especially pricey & a growing share of Medicaid spending

- Of $307 billion spent on medications in the US in 2010, $67 billion (21%) was spent on biologics, a growing class of medications that are derived from biological sources and provide novel therapies for a host of disorders. [IMS Health data]
- The Congressional Budget Office has estimated that substituting generic versions of biologics for brand names would reduce federal Medicaid and Medicare spending by $25 billion over 10 years. The CBO estimates that total federal spending on prescription drugs during the same period will total $500 billion.
- On an individual level, with the cost of some medications reaching over $20,000 per year per patient, **biologics cost consumers twenty-two times more on average than on-biologic drugs.**

TPP Investment Chapter threatens integrity of drug approval process: *Eli Lily v. Canada*

- Eli Lilly just sued Canada for $500 million CAD under NAFTA Chapter 11, challenging two decisions upheld by Canada's highest court invalidating patents on attention-deficit disorder drugs Strattera and Zyprexa
- The court decisions were based on well-established Canadian law, whereby a product's "utility," and thus patentability, must be demonstrated or soundly predicted at the time of filing a patent. *The Canadian courts found that evidence of the validity of Lilly's claim that these drugs had long-term therapeutic benefits and reduced side effects was lacking.*
- Eli Lilly's NAFTA claims include violations of **minimum standard of treatment, indirect expropriation (taking), & discrimination in violation of national treatment norms**, and assert that its reasonable expectations of profits may be drawn not just from Canadian laws and practices, but rather U.S. and E.U. law.
- The proposed TPP investment chapter is even more expansive than NAFTA, directly including "intellectual property rights" **and with a broader** definition of "investment"

Other health care trade policy issues

Single Payer Issues

- **Procurement**
  - TPP includes a procurement chapter. USTR has stated it is pushing for a state "opt-in" that would give US states a choice of whether to be bound by any or all of the TPP's procurement provisions
  - Canada is pushing hard to have US state government procurement standards overridden by the TPP - implications for a single-payer system?
- **State-Owned Enterprises (SOE)**
  - USTR is seeking a first-ever SOE chapter intended to limit businesses directly run, or heavily subsidized, by governments (such as Japan's postal service insurance program) - implications for a single-payer system?

Health Care Services are Covered by the WTO General Agreement on Trade in Services (GATS)

- **Universal Health Care Coverage:** Under GATS, a country (or US state) cannot grant new public-service monopoly rights in a WTO-covered service sector without first compensating trading partners for lost business opportunities.
- **Bans on For-Profit Service Providers:** Current GATS rules would subject such state initiatives to challenge as illegal trade barriers, even if intended to protect quality and safety.
- **Preferential Tax Treatment for Nonprofit Hospitals:** Many U.S. hospital services are provided by nonprofit institutions that enjoy tax-exempt status. If a foreign firm bought a chain of U.S. hospitals and decided to run them on a for-profit basis, it could demand the preferential tax treatment that domestic nonprofits are given because it provides identical or nearly identical services.
- **State Certificate of Need Laws:** "Certificate of Need" laws for health care facilities such as hospitals, outpatient clinics and nursing homes are intended to bring oversight to health care construction and major capital expenditures which fuel health care costs. GATS prohibits economic needs tests in a covered service sector. U.S. negotiators safeguarded needs testing under hospital services, but not under construction of health buildings.

Progress of negotiations

Status of TPP Negotiations

- USTR's Goal: to finish by December 2013. Round 19 was in August, parties still negotiating but not in formal round involving all countries.
- Only "political" issues are left – including ***tobacco text, pharmaceutical transparency/pricing and patent (IP)*** *provisions*
- USTR's drug & device pricing text strongly opposed by most if not all other TPP countries; US is not planning to offer alternative text but still pushing for approval
- Pharmaceutical IP text strongly opposed by all other TPP countries; news reports Australia, Canada, Chile, Malaysia, New Zealand & Singapore tabled alternative in Round 17 (no information on what that looks like) and negotiations continue.

Watch out for the "End Game" and Fast-Track

- Political horse-trading means anything and everything can be offered up at the end just to get an agreement, eg, pharmaceutical pricing for New Zealand dairy commitments or restrictions on Japan's postal insurance.
- If fast-track Trade Promotion Authority (TPA) is approved, once negotiators agree to its provisions, the TPP can't be fixed up.

Contact Information

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National Legislative Association on Prescription Drug Prices web page on trade policy:
http://www.reducedrugprices.org/trade.asp

Maine Citizen Trade Policy Commission assessment on tobacco, pharmaceutical, and procurement policy implications of the TPP:
http://www.maine.gov/legis/opla/CTPC2012finalassessment.pdf