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Market Access, Transparency & Pricing: Does US Trade Policy in the TPPA Conflict with the Goal of Affordable Medicines?

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Role of U.S. States Advising on Trade Policy & Implementing Health Care

- ❑ **Federalism:** States & federal government jointly govern domestic policy as set forth in US Constitution
- ❑ **States have major role regulating and providing access to health care**
- ❑ **States have limited role advising on trade policy**
 - ❑ Formal state role: IGPAC
 - ❑ Increasing state activism through state commissions on trade & sovereignty including ME, VT, NH, WA, UT, CA
 - ❑ State laws: no commitment of states without state vote

State Health Care Role

- ❑ **Medicaid** – jointly funded federal/state program for low income, disabled and children, largely implemented by state governments pursuant to federal rules

- ❑ **40 States Negotiate Medicaid Drug Prices through Preferred Drug List (PDL)** – State purchase price for branded drugs and many generics discounted through (1) federal rebate and (2) state rebates
 - ❑ **Rebates can be significant** – In aggregate, Maine receives back 50% off “market price” in rebates

- ❑ **State-by-state rebate negotiation to be replaced by national reference price list under the Affordable Care Act in 2012**

The US has significant income disparities and many people do not have health insurance

- ❑ More than 50 million people receive health care through Medicaid, an increase of 17% since the recession began in 2007 [Kaiser family Foundation].
- ❑ More than 50 million people in the US have NO health insurance and purchase medicines at the highest “market price.”
- ❑ 44% of US adults (80 million people) have either no insurance or inadequate insurance, much of which does not pay enough to cover prescription drug costs at an affordable level.

State Health Policy Role Goes Beyond Medicaid

- ❑ **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 below Medicaid pricing**

Other U.S. Programs with Below-Market Drug Prices

- Veterans' Health Care** – Reference pricing based on formulary
- Medicare Part B** – hospital drugs for elderly

US Government Share of Medicine Spending Significant

- ❑ 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 spending – 6 times what was spent in 1990.
- ❑ Government's share of prescription drug spending is 37% of the total.

Last month President Obama proposed changing the Medicare Part D Program (prescription drugs for the elderly) to require price negotiation similar to Medicaid (currently private sector insurance companies negotiate prices).

- ❑ 27.6 million enrolled in Medicare Part D

Concern: The US proposals in the TPPA and other TPAs 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 broaden health access and increase affordability

QUESTION: Does the current State & Federal rebate negotiation process meet the “transparency” and procedural requirements in the Korea-US FTA and proposed by the US in the Trans-Pacific Partnership?

NO

- ☒ **Public session** negotiating rebates (price) and determining which drugs will be “preferred” on PDL
- ☒ **Detailed written explanation** of transparent & verifiable basis for reimbursement decision
- ☒ Opportunity for **independent appeal** or review of decision
- ☒ **Consistent administration** in all 50 states, D.C. & territories

Medicaid Carve-Out in Korea-US FTA

- ❑ **Footnote:** Medicaid is a regional level government program, FTA rules only apply to central level
- ❑ No mention of 340B clinics and hospital prices
- ❑ Doesn't carve out Medicare Part D if President Obama succeeds in requiring government rebates in budget
- ❑ State Legislators & Governors: Footnote fails to carve out all public health programs, and ties hands for future changes such as Medicare Part D reference prices

Questions:

- Will the TPPA include similar carve-out language?
- Leaked text: **NO FOOTNOTE**
- Should** the TPPA require transparency and reimbursement standards that the United States does not itself fully comply with?

Other US states' concerns – reimbursement rules will increase prices

- ❑ **Reimbursement tied to market prices** within territory will forever link US reimbursement to some of the highest market prices in the world and limit affordability
- ❑ **Where is the link to affordability?**
 - ❑ **Waiting lists in US for AIDS drugs – 7,299 in 10 states as of October 2011**
 - ❑ **States cutting health care budget by limiting eligibility for public programs & increasing patient cost sharing – 15 states reducing or capping ADAP enrollment October 2011**
 - ❑ **60% of US bankruptcies cause by medical expenses – and three-fourths had insurance**

Generic availability also an issue

- ❑ Will US proposals in the TPPA prevent changes to current US policies that delay entry of generics to market?
- ❑ “Pay for Delay” deals between patent-holding manufacturer and generic manufacturer currently subject to investigation
- ❑ Providing initial monopoly for first generic version on market delays competition and keeps prices high

Other state concerns - loopholes in health & safety protections

- ❑ 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**

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]

Does the US policy in the TPPA conflict with the goal of affordable medicines?

- ❑ Impossible in a **secret process** to seek and receive **informed review** of important health & safety public health rules that will bind future governments
- ❑ There are **many concerns** with the marketing, transparency & pricing provisions of the TPPA even in the US
- ❑ **Irony: TPPA Transparency Provisions Developed in a Non-Transparent Process**

Now that key pharmaceutical and device text under consideration for the TPPA is publicly posted, it is possible to answer this question with more complete analysis and to get feedback from state Medicaid program staff, regulators and prosecutors overseeing fraud and deceptive marketing, and advocates for affordable medicines.

Contact Information

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