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## Memo

From: Todd Tucker, Public Citizen<sup>1</sup>

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Re: Proposed Trans-Pacific Partnership rules could undermine drug cost containment provisions of Medicare, Medicaid and Veterans' Health, hurting seniors, military families and the poor

### Summary

Unbeknownst to the public and many policymakers, “trade” deals that are now being negotiated by the Obama administration could undermine access to affordable medicines in the United States. It has been an open secret among trade negotiators that U.S. pharmaceutical companies have pushed to limit countries’ drug price containment measures, such as through the recent bilateral U.S. “free trade” agreements (FTAs) with Korea and Australia.

But the following analysis shows in detail (for the first time) that current U.S. efforts to reduce drug costs could be undermined by trade agreements such as the Trans-Pacific Partnership (TPP) FTA, which the Obama administration is currently negotiating. The U.S. programs that could be implicated by TPP proposals include Medicaid, Medicare, the Department of Defense’s TRICARE program for active military personnel, the Veterans Health Administration and the 340B program. We base our analysis on leaked texts of a new “Annex on Transparency and Procedural Fairness for Healthcare Technologies” that the Office of the U.S. Trade Representative (USTR) has submitted for inclusion in the TPP. We also show how proposed changes to Medicare championed by President Obama would clearly risk violating this TPP annex. Throughout, we show how trade tribunals are less likely to defer to health care program officials than do national judges, including conservatives like Justices Scalia and Thomas. We conclude with a suggested change to the TPP to insulate smart drug price containment strategies.

This analysis will be useful to health care policymakers and advocates seeking a better understanding of the intersection between “trade” policy and drug price containment. Additionally, this will help trade negotiators from other countries who may not appreciate the extent to which the TPP policies advocated by the Obama administration would not only prove detrimental to developing countries, but also not be acceptable to the U.S. public and legislators.

### Introduction

Two of the most pressing items on nations’ policy agendas are government budget deficits and rising health care costs. For the many countries that provide government support, subsidies, or administration to the health care sector, the two items are intimately connected.

In the United States, rising health care costs are the number one factor in long-term budget deficit projections. The federal government is responsible for huge volumes of expenditure on

health care through its medical assistance entitlement programs.<sup>2</sup> Growing pharmaceutical costs, in turn, are one of the most important reasons for exploding health care costs. According to the Government Accountability Office (GAO), drug prices increased 70 percent faster than prices for other health care goods and services over 2006-2010.<sup>3</sup>

In an economically rational world, the large size (and attendant negotiating leverage) of the federal government would be marshaled to aggressively lower pharmaceutical costs through direct negotiations with pharmaceutical companies in government-established health programs. Instead, current U.S. practices go in almost the opposite direction. Our government aggressively intervenes in markets to establish monopoly patent protection (which raises pharmaceutical costs), while restraining its own potentially beneficial negotiating role in bargaining down these prices.

Unsurprisingly, the burgeoning drug price-driven, long-term deficit has produced calls from diverse corners to reform how the government navigates drug prices. Various U.S. states give explicit preference for lower-cost drugs. Bills pending before Congress would empower the federal government to leverage its purchasing power to get lower drug prices for Medicare. Even as a presidential candidate in 2008, President Obama said that he supports allowing the government to directly negotiate with drug companies to keep prices low for Medicare. Such a proposal is still on President Obama's agenda to lower the federal budget deficit.

But the Office of the U.S. Trade Representative is set to undermine the administration's own domestic health care cost initiatives through the TPP. The TPP is being negotiated in secret with government officials and corporate executives from Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, Vietnam and the United States. The draft negotiating documents are hidden from the public, though over 600 corporate executives have access to the documents and the negotiations themselves.<sup>4</sup>

Drafts of a few sections of the TPP text have leaked to the public, giving a window into what draconian policies may be in store. A leaked annex text, with the Orwellian name, "Transparency and Procedural Fairness for Healthcare Technologies," indicates that even the existing modest steps that the government takes to reduce pharmaceutical costs could be undermined by the TPP. And any future change to U.S. medical assistance programs along the lines recommended by most budget and health care economists would unquestionably risk running afoul of the draft TPP rules.

Is this a case of one arm of the Obama administration not knowing what the other is doing? Do they just not understand the implications of their own TPP proposals? Are pharmaceutical companies – which want to undermine cost containment measures successfully utilized by TPP partners like New Zealand and Australia – simply pushing the administration to back their overseas agenda without disclosing the negative boomerang impact this could have on U.S. cost containment measures?<sup>5</sup> Or is undermining domestic cost containment through means obscured by complicated "trade" negotiations actually a plan of some elements of the administration?

Congress, the press and the public must begin to ask these questions. Even more importantly, they must realize the TPP's threat to pharmaceutical cost containment.

The TPP negotiations are but one element in a long-term global campaign to attack pharmaceutical cost control measures. Drug companies successfully inserted strong patent protections for drugs in the 1994 World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), largely cutting off a path to cheaper drugs through quicker-to-market generic drug production. They have since expanded monopoly patent rights beyond TRIPS via FTAs. Since the TRIPS, drug companies have trained their sights on techniques that governments employ to reduce the cost of public drug benefit programs, both in the United States and abroad. They have used U.S. courts to challenge aspects of state Medicaid drug programs. When the challenges failed, they pushed extreme proposals in the negotiations for the U.S. FTAs with Australia and Korea aimed at creating new means to challenge government drug pricing policies, and the TPP language is yet more extreme.

While this report seeks to conduct a detailed analysis to determine which parts of the U.S. public drug benefit programs could run afoul of the TPP, it is essential to keep in mind the broader context of pharmaceutical corporations' campaign against lower drug costs. This context has been consistently monitored by academic, legislative and watchdog groups like the National Legislative Association on Prescription Drug Prices, American University Washington College of Law's Program on Information Justice and Intellectual Property, Georgetown University Law School's Harrison Institute, and the Forum on Democracy and Trade, which have also begun calling attention to the specific threats posed by the TPP to formulary policy.<sup>6</sup> The present memo is in the spirit of that work, although its focus is narrower.

Our first section lays out the TPP rules on pharmaceutical reimbursement and formularies, and discusses some of the ways that these could fall afoul of U.S. cost containment efforts. The second section explores the extent to which potential "carve-outs" in the text may insulate some of the U.S. programs from challenges. USTR, which is the lead government agency on FTAs like the TPP, has claimed for years that the pharmaceutical provisions of the TPP and similar past FTAs do not implicate current U.S. programs.<sup>7</sup> While USTR maintains that our "trade" pacts are drafted in such a way as to carve out the byzantine U.S. pharmaceutical policies,<sup>8</sup> this is misleading. Indeed, the TPP would seem to require appeal rights for drug companies dissatisfied with agencies' pricing decisions, whereas they have little to no such rights now.

In any event, any move that the United States might make to address the inefficiencies and cost overruns of our current health care approach would almost certainly run afoul of the TPP (as would the successful programs of other countries like New Zealand and Australia, which seem to be the unambiguous targets of the U.S. TPP proposal). Accordingly, the third section of our report explores how some of the proposed changes to U.S. medical programs would almost certainly risk violating the TPP.

The threat is real. As we detail in the fourth section, Korea has already been pressured to water down its national health care policies following the signing of a U.S. FTA, which is less draconian than what is being proposed in the TPP.

Our final section concludes by recommending a change to the TPP to allow for the United States and other countries to address the cost explosions in health care.

Our paper assumes some knowledge of the approaches to cost containment. For those seeking a more comprehensive introduction, Appendix I notes some of the history of effective cost containment measures in other nations. In Appendix II, we review the extent to which our major drug programs – including Medicaid, Medicare, the Department of Defense’s TRICARE program, the Veterans Health Administration (VHA) and the 340B initiative – limit the government’s role in negotiating for lower prices.

(Before moving into the body of the report, it’s worth noting what we do not attempt to do below. We have no major analysis of the standard FTA chapters on intellectual property, procurement or investment, all of which could impact health care policy. We do not even explore every provision of the leaked TPP annex on health care technologies, or the implications for every U.S. health care program in existence. Instead, we focus on just a few provisions of the TPP annex, and their implications for a few of the major U.S. health care programs: Medicare, Medicaid, TRICARE, the VHA and the 340B program. Also, the potential impact of the TPP on developing countries’ drug costs is very concerning, but discussion of that issue is outside of the scope of this report.<sup>9</sup>)

### **I. The TPP Rules on Formularies / Reimbursements and Possible Implications for U.S. Cost Containment Programs**

In 2011, a copy of the TPP Annex on Transparency and Procedural Fairness for Healthcare Technologies was leaked to the press. It is different from provisions in previous trade agreements, so it merits some close attention. (The leaked text from June 2011 can be found here: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificTransparency.pdf>.)

#### ***Draft TPP Rules on Administration of Reimbursement Policies***

The first core obligation of the new annex, contained in Paragraph X.2(3), says: “Each Party shall ensure that all measures of general application at the central level of government respecting any matter related to reimbursement for pharmaceutical products or medical devices are administered in a reasonable, objective, consistent, non-discriminatory, and impartial manner.”

Other than the first adjective, this standard seems at odds with rights under U.S. law. A pharmaceutical company that disliked the administration of reimbursement practices by a U.S. agency would generally be required to show that agency action was unreasonable, arbitrary,

capricious, an abuse of discretion, or otherwise not in accordance with law. And the deference shown to agencies by courts is considerable, and the agency's interest in minimizing acquisition or regulatory costs is typically accorded great weight. In contrast, **the TPP annex appears to go beyond the U.S. standards and it contains no institutional features that would require a dispute settlement panel to defer to national regulators.**

So, what would the adjectives “reasonable, objective, consistent, non-discriminatory, and impartial” mean? They are not defined, but we can draw some conclusions based on existing trade law jurisprudence under the WTO, whose rulings are treated with reverence in other trade law contexts. While interpretations of these words in the WTO context would not constitute binding precedent for a TPP dispute settlement panel, an examination of these documents can help provide some clues as to how the words might be considered. However, it is critical to undergird this analysis with a fundamental consideration: if such standards are inserted in a “trade” agreement, then a trade agreement dispute resolution panel comprised of three trade experts would be empowered with enormous discretion to determine what the terms require. Such decisions, which could have major negative implications for domestic health policies, are not subject to outside appeal in domestic court systems.

#### *Reasonable administration*

The panel in the recent *Thailand – Cigarettes* WTO dispute stated that “The term ‘reasonable’ is defined as ‘in accordance with reason’, ‘not irrational or absurd’, ‘proportionate’, ‘sensible’, and ‘within the limits of reason, not greatly less or more than might be thought likely or appropriate’.” The panelists noted that a provision of the WTO’s General Agreement on Tariffs and Trade (GATT) prohibits “arbitrary or unjustifiable” administration of a government policy: “in examining whether an import ban provisionally justified under Article XX(b) for the purpose of protecting human health and life was applied in an unjustifiable or arbitrary manner, the Appellate Body in *Brazil – Retreaded Tyres* reasoned that ‘the analysis of whether the application of a measure results in arbitrary or unjustifiable discrimination should focus on the cause of the discrimination, or the rationale put forward to explain its existence’.” The *Thailand – Cigarettes* panel – which was tasked with examining the reasonableness of a Thai policy of putting officials responsible for collection of customs duties on imported cigarettes on the board of a state-owned domestic cigarette manufacturer – concluded that the Complainant (the Philippines) had not established that the Thai reason for this policy (conserving resources by putting people with expertise in dual functions) was not legitimate.<sup>10</sup>

Based on this case, it would seem that governmental health care administrators could aggressively push for cost savings, and that this could be seen as a “reasonable administration,” so long as the reasons for particular modes of administration were offered. It is entirely possible, however, that the goal of cost savings might justify a program administration that is not totally transparent in some instances, and where reasons might not always be provided. Indeed, not giving reasons might maximize information asymmetry and thus the government’s negotiating leverage with pharmaceutical companies. In such an instance, a health program administration

could run afoul of the TPP. This is not a mere hypothetical: U.S. administrative judges hearing challenges to TRICARE have concluded that officials are not obligated to explain the weight that they gave to various aspects of a drug company bid.

### *Objective administration*

Article VI(1) of the WTO's General Agreement on Trade in Services requires "objective" administration, but this article has not yet been interpreted by the Appellate Body. The dictionary definition of objective is "expressing or dealing with facts or conditions as perceived without distortion by personal feelings, prejudices, or interpretations." As long as government administrators weren't determining reimbursement policies through a personal or subjective lens, this provision of the TPP would be unlikely to pose a problem. However, individual administrators dealing with Medicaid preferred drug lists (PDLs) and prior authorization programs (PAP) may have a certain amount of individual discretion when it comes to administering requests for treatment or payment. It is possible that such decisions may contain elements of subjectivity. While not necessarily damaging to the goal of containing drug costs, such subjectivity in administration may violate the TPP annex rules.

### *Consistent administration*

"Consistent" is defined as "marked by harmony, regularity, or steady continuity: free from variation or contradiction." "Consistent administration" is mentioned in a WTO agreement on rules of origin, but it has not been definitively interpreted.

A requirement that pharmaceutical reimbursement policies be administered in a fashion "free from variation" would be deeply worrying. Medicaid would especially risk running afoul of these rules, since over 50 different subfederal processes are established to run the same federal program. The Veterans Affairs (VA) and TRICARE explicitly treat companies inconsistently on the basis of whether or not they sign a master agreement with the agencies, or whether they agree to additional supplemental discounts. These agreements in turn can affect drug companies' treatment under Medicare and Medicaid. This could run afoul of the TPP obligation. Likewise, decisions on PDLs made by myriad different administrators may lack consistency across the board. This may also run afoul of the draft TPP text.

### *Non-discriminatory administration*

This is another requirement that seems deeply at odds with U.S. legal practice. In 2004, pharmaceutical companies brought claims alleging that state Medicaid practices violated the Commerce Clause of the U.S. Constitution, which is a type of claim closest to trade law anti-discrimination rules. Justices Scalia and Thomas – two deeply conservative judges that are often favorable to corporations – wrote separate concurring opinions that such an argument could not prevail in U.S. law.

In the *EC-Bananas III* case, a WTO panel found that Europe's allocation of banana distribution service licenses by companies' core activities (i.e. primary importers, secondary importers and ripeners) was discriminatory. Although national origin was not an overt factor in the allocation, the latter two activity groups tended to be from Europe or recent European colonies.<sup>11</sup> The more recent *U.S.-Tuna II* case found that the U.S. dolphin-safe tuna labels discriminated against Mexico, even though there was nothing inherent to Mexican tuna that made it less able to qualify for the labels, and though the country could and did sell tuna to U.S. consumers.<sup>12</sup>

Indeed, the case law suggests that administration of pharmaceutical reimbursement policies that did not have the aim or effect of discriminating<sup>13</sup> could still constitute "discriminatory administration." Any pharmaceutical reimbursement administration that altered the conditions of competition against foreign pharmaceutical companies on a per-unit basis could run afoul of this TPP obligation. For instance, requiring paperwork or discounts from all pharmaceutical companies could contravene this TPP rule if foreign drug companies continue to complain that the paperwork is more onerous for them in practice, even if that argument has no basis in legislative intent or design.

#### *Impartial administration*

In the *Thailand – Cigarettes* case mentioned above, the panel wrote:

The term 'impartial' can be defined as 'adjective 1. not favouring one party or side more than other; unprejudiced, unbiased; fair'. The word 'partial' means 'A. adjective. 1 I a Inclined beforehand to favour one party in a cause, or one side of a question, more than the other, prejudiced, biased. Opp. Impartial'. Based on the ordinary meaning, therefore, impartial administration would appear to mean the application or implementation of the relevant laws and regulations in a fair, unbiased and unprejudiced manner... *Argentina – Hides and Leather* is the only WTO dispute to date in which the impartiality requirement under Article X:3(a) was addressed. In that dispute, the feature of the administrative process at issue was the presence of a private party with conflicting commercial interests in the customs process. The panel considered that the consistency of the customs process with the impartiality requirement of Article X:3(a) would depend on what that party is permitted to do. That panel found that the answer to this question was related directly to the question of access to information as part of the product classification process. It was the view of the Panel that whenever a party with a contrary commercial interest, but no relevant legal interest, is allowed to participate in the customs process, there is an inherent danger that the customs laws, regulations and rules will be applied in a partial manner so as to permit persons with adverse commercial interests to obtain confidential information to which they have no right. The panel nevertheless considered that this situation could be remedied by adequate safeguards to prevent an inappropriate flow of one private person's confidential information to another as a result of the administration of the implemented customs law at issue.<sup>14</sup>

“Partial administration” of a pharmaceutical reimbursement policy might then consist of an instance where a Party with a contrary commercial interest is permitted to set reimbursement rates. Health care administrators have a commercial (or at least statutory or budgetary) interest in lower reimbursement rates, and administer the program accordingly. This is an interest contrary to that of the drug companies that will be affected by the reimbursement rate. If interpreted as such, an array of U.S. medical programs could violate this proposed TPP provision.

### **Drug Companies Could Use Expansive Investment Definition to Target Regulations**

U.S. “trade” agreements, dating back to the North American Free Trade Agreement (NAFTA), have contained so-called investor-state provisions that establish a mechanism for companies to directly challenge government policies that interfere with future expected profits related to their “investments.” The definition of forms an investment can take is extraordinarily broad: (a) an enterprise; (b) shares, stock, and other forms of equity participation in an enterprise; (c) bonds, debentures, other debt instruments, and loans; (d) futures, options, and other derivatives; (e) turnkey, construction, management, production, concession, revenue-sharing, and other similar contracts; (f) intellectual property rights; (g) licenses, authorizations, permits, and similar rights conferred pursuant to domestic law; and (h) other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens, and pledges.

Pharmaceutical companies are beginning to utilize the investor-state mechanism. The Canadian drug company Apotex filed three cases under the investor-state dispute mechanism in NAFTA. This was done to demand payment for its “lost investment” due to the U.S. Food and Drug Administration’s (FDA) regulatory decisions. In two cases filed in 2008 and 2009, Apotex demanded of the U.S. government a total of \$16 million for failure to approve its drugs for sale.<sup>15</sup> Both cases are still pending. In February 2012, Apotex filed yet a third case against the United States under NAFTA in which it claims \$520 million in damages due to an FDA “import alert” against its drugs for substandard manufacturing practices.<sup>16</sup>

As of now, the leaked TPP chapter on health care technologies does not appear to be investor-state enforceable, meaning that only signatory governments could file claims. However, drug companies with qualifying investments in the United States could attempt to challenge government cost-containment measures as denials of national treatment or fair and equitable treatment, among other worrying investment chapter disciplines. (For analysis of the recently leaked TPP investment chapter, see: <http://bit.ly/KTBigf>.)

### *Pricing Disciplines in the TPP Annex – Alternative 1*

How might the U.S. cost containment programs be incompatible with the substantive obligations of the leaked TPP Annex? The ten subparagraphs within Paragraph X.3 outline the rules that these programs must comply with, but subparagraphs (d) and (e) are arguably the most



impactful: they describe the two alternative means by which a government must determine the prices that are paid for drugs.

Subparagraph X.3(d) – which contains the first alternative – reads in part that a Party to the TPP shall: “(d) ensure that the Party’s determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party’s territory, ...” **It is not clear that any U.S. health care cost containment program would meet this standard, as most involve statutory price controls or the use of government contracting to lower costs.**

The term “competitive market-derived prices in the Party’s territory” is not defined in the leaked TPP text, nor does that precise term appear in WTO agreements. However, a closely related term is utilized in the WTO’s Agreement on Subsidies and Countervailing Measures (SCM) Article 14(d). The appropriate calculation of “benefits” in subsidy analysis is defined in the following terms: “the provision of goods or services or purchase of goods by a government shall not be considered as conferring a benefit unless the provision is made for less than adequate remuneration, or the purchase is made for more than adequate remuneration. The adequacy of remuneration shall be determined *in relation to prevailing market conditions* for the good or service in question in the country of provision or purchase (including price, quality, availability, marketability, transportation and other conditions of purchase or sale).” (italics added)

The two major cases to touch on this provision involved challenges, by Canada and China, to the U.S. Department of Commerce’s methodology for calculating anti-dumping or countervailing duties on exports to the United States from Canada and China. In both cases, the United States utilized prices other than those prevailing in the Canadian and Chinese economies, on the basis that government involvement in the sectors in question made these prices non-market based. In both cases, the WTO ruled that Canada and China had not met their burden of proof with respect to Article 14(d) (thus handing the United States a partial win), but ruled against the U.S. measures on other grounds. **The TPP pharmaceutical annex may be read as an attempt to remove any uncertainty about the U.S. position on the desired characteristics of market prices.**

In the first case noted above (*U.S.-Softwood Lumber IV*), the United States attempted to persuade the lower panel and Appellate Body (AB) that the word “market” in the SCM Article 14(d) context must mean “undistorted by the government intervention.”<sup>17</sup> The AB felt that the U.S. approach “goes too far” but that nonetheless “prices of similar goods sold by private suppliers in the country of provision are the primary benchmark” for establishing the existence of non-market remuneration. The AB also noted that benchmarks must be related to local prices.<sup>18</sup> The exception to the rule of using private prices as benchmarks is if “private prices in that country are distorted because of the government’s predominant role in providing those goods.”<sup>19</sup> The AB noted that “[w]henver the government is the predominant provider of certain goods, even if not the sole provider, it is *likely* that it can affect through its own pricing strategy the prices of private providers for those goods.”<sup>20</sup> However, the AB refused to rule on the suitability of using

prices from outside the country, nor what would be precisely the appropriate alternative benchmark when the government predominates the market.<sup>21</sup>

In the second case (*US – Anti-Dumping and Countervailing Duties (China)*), the AB wrote that government predominance in the market can refer to both its market share and its “market power,” and that either can lead to “price distortion.”<sup>22</sup>

Both cases may shed some light on the U.S. formulation in the TPP of requiring reimbursement amounts to have “a transparent and verifiable basis consisting of competitive market-derived prices in the Party’s territory.”

- The requirement that the market be “competitive” suggests an attempt to close the perceived loopholes from previous trade law cases that did not read markets as necessarily needing to be competitive. Standard dictionaries do not refer to “competition” in the specific way that it is used in economic contexts. The specialized meaning of competitive market in the economics context is (as a leading textbook puts it): “a market in which there are many buyers and many sellers so that each has a negligible impact on the market price.”<sup>23</sup> In a competitive market “[e]ach buyer and seller takes the market price as given.”<sup>24</sup> The textbook notes that “[i]n some markets, a single buyer or seller (or a small group of them) may be able to control market prices,” an ability known as market power. The exercise of market power is incompatible with a competitive market since one or more market actors are no longer price takers, but are price makers.
- The requirement that the prices be “derived” from a competitive market suggests a tighter nexus than simply requiring that prices be “in relation with” competitive market prices. The verb “to derive” is defined as “*a* : to take, receive, or obtain especially from a specified source *b* : to obtain (a chemical substance) actually or theoretically from a parent substance.”<sup>25</sup> Accordingly, the TPP discipline would seem to suggest that the reference prices must be “taken from” the competitive market – not the looser standard of “relating to” explored in the *US-Softwood Lumber IV* context.
- “Consist” is defined as to be “composed or made up —usually used with *of*”<sup>26</sup> In other words, the reimbursement amount must be “made up of” the “competitive market prices.” Again, the nexus here is tighter than in the *US-Softwood Lumber IV* case.
- “Basis” is defined as “1: the bottom of something considered as its foundation 2 : the principal component of something 3 *a* : something on which something else is established or based *b* : an underlying condition or state of affairs <hired on a trial *basis*> <on a first-name *basis*>”<sup>27</sup> So a reimbursement amount must have as its foundation the competitive market prices. Again, a tighter nexus than in the WTO cases.
- “Transparent” is defined as “*a* : free from pretense or deceit : frank *b* : easily detected or seen through : obvious *c* : readily understood *d* : characterized by visibility or accessibility of information especially concerning business practices.” “Verifiable” is defined as capable of being “verified,” defined as “1: to confirm or substantiate in law by oath 2 : to establish the truth, accuracy, or reality of <*verify* the claim>”<sup>28</sup> Taken together, the reimbursement amount

should have as its basis the competitive market price, and this should be obvious and easy to document.

As noted, U.S. medical reimbursement programs may not conform to the stringent standard of setting drug prices based on “competitive market-derived prices.” The VHA uses blanket purchase agreements (BPAs) and national standardization contracts (NSCs) “to guarantee drug companies a high volume of use in exchange for lower prices.”<sup>29</sup> Thus, the VHA uses its market power, derived from large purchasing volume, to be a price maker rather than a price taker, which means that its price setting procedure is not based on competitive market-based prices. As noted below, these two programs could be protected by footnote 1 in the annex that carves out procurement practices. However, it is less clear whether the “Big Four” and general Federal Supply Schedule (FSS) procedures would be carved out of the TPP annex, since these are not necessarily procurement related, but imply substantial discounts relative to the (patent-protected) “market price” for the pharmaceuticals.

If challenged under the TPP, the United States might attempt to argue that the fact that the Big Four and FSS discounts are “relative to” the market price should imply that the prices actually paid are “market-derived prices.” However, that argument could be made with respect to virtually any national policy that paid pharmaceutical companies less than the “market price,” so treaty interpreters would be unlikely to give such a lenient reading of “market-derived” much weight, and would require a tighter nexus to the actually prevailing prices on the market. In any case, the plain language of the TPP annex goes out of its way to require a much tighter nexus than simply “relating to,” as noted above.

Medicaid’s requirement that drug manufacturers sign a rebate agreement with the federal government in order to have their drugs covered by the state Medicaid programs may also violate the proposed subparagraph X.3(d). Medicaid uses the market power of all of the state Medicaid programs to lower the effective price of the drug below the competitive market price.<sup>30</sup> Likewise, the Upper Price Limit likely exerts some downward pressure on the price of drugs.

Under Medicare Part D, the federal government approves the private plans’ formularies, and sets certain limits on their restrictiveness. Moreover, the Medicare guidelines do allow private plans to take pharmacoeconomic considerations into account. Since Paragraph X.3(d) requires that governments “ensure that... reimbursement” amounts be “market-derived,” Centers for Medicare & Medicaid Services (CMS), the federal agency charged with administering Medicare and Medicaid, could be found to be not ensuring that the private plans make reimbursement decisions based on the market. It would be ironic if pharmaceutical firms used the TPP concept of competitive markets to undermine Medicare Part D private sponsors’ reimbursement practices. The purpose of not having the government manage these plans directly is ostensibly to increase the role of the “competitive market.” However, if these private actors (operating under Medicare guidelines) produce reimbursement amounts that are seen as not based on competitive markets, then the U.S. government could nevertheless be held liable for these private companies’ actions.

Indeed, some actors, such as the National Community Pharmacists Association, have already made arguments that Pharmacy Benefits Managers (PBMs) under Medicare Part D produce uncompetitive market effects:

PBMs harm consumers by using their market power to reduce compensation to pharmacies. As noted below the PBM market is highly concentrated and that enables them to exercise ‘monopsony’ or buyer power to reduce compensation to the pharmacies that provide dispensing services. Although a reduction in compensation may appear attractive from the perspective of a buyer of PBM services, that attraction is misleading. The savings from reducing compensation is not passed on to buyers in lower prices because of the market power of PBMs. Moreover, ultimately the consumer of drugs is harmed because there are fewer pharmacies available because of reduced reimbursement rates, or other forms of pharmacy services diminish. Leaving the PBM scheme unfettered and without oversight to ensure true open competition, along with leaving matters to litigation, is unworkable.<sup>31</sup>

Under Medicare Part B, alterations to pass-through status of new drugs can lead to major changes in how much the drug manufacturer might expect to recoup. Pharmaceutical companies may complain that agency actions that strip new drugs of pass-through status constitute an attempt to impose non-market derived prices.

### **Consistent Competition?**

The TPP Annex’s requirement for “consistent” application of the concept of “competitive market prices” suggests that not only would government programs to exercise market power and push down drug prices be in violation of subparagraph X.3(d), but so would our regime of patent protection. Specifically, subparagraph X.3(d) would seem to contrast with the exercise of market power by drug suppliers. On the face of the provision, no actor must set prices below or above the price in a competitive market. Government-granted monopolies in the form of pharmaceutical patents may seem to transform the market for these drugs into a noncompetitive market.

However, treaty interpreters would examine the meaning of subparagraph X.3(d) in its context, i.e. the remainder of the TPP text. The leaked TPP chapter on intellectual property provides robust protection of patents, so treaty interpreters would interpret subparagraph X.3(d) as permitting the supplier-side market power that is the result of patents.<sup>32</sup> Furthermore, the U.S.-Australia FTA, a forerunner of the TPP, explicitly states that “a patent does not necessarily confer market power” for the purposes of determining whether a practice is anti-competitive.<sup>33</sup> Given that exercise of market power by patent would be permitted, the only market power that is not permitted is that exercised by a government regulator.

## *Pricing Disciplines in the TPP Annex – Alternative 2*

Subparagraph X.3(d) also allows Parties to determine reimbursement amounts in an alternative fashion if it has “an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue.”

The context for this alternative formulation is of course the rest of the TPP. It would seem that Alternative 2, in light of Alternative 1, would have to express a more lenient standard than “competitive market-derived” reimbursement prices. At the same time, both alternatives exist in the broader TPP context of extreme intellectual property protection. Alternative 2 would be *relatively* lenient, but still not a *carte blanche* for health administrators to reimburse at any rate they wish. In any case, **the VA and TRICARE programs could run afoul of these TPP rules, since they allow administrators to privilege drugs based on how quickly their patent is likely to expire. This is irrespective of the “value” that the manufacturer feels should be attributed to the drug.**

Let’s define the key elements of Subparagraph X.3(d):

- “Value” is defined as “1 : a fair return or equivalent in goods, services, or money for something exchanged 2 : the monetary worth of something : market price 3: relative worth, utility, or importance <a good *value* at the price> <the *value* of base stealing in baseball> <had nothing of *value* to say>.”<sup>34</sup>
- “Appropriate” is defined as “especially suitable or compatible : fitting <an *appropriate* response> <remarks *appropriate* to the occasion>.”<sup>35</sup>
- “Recognize” is defined as “: to acknowledge formally: as *a* : to admit as being lord or sovereign *b* : to admit as being of a particular status *c* : to admit as being one entitled to be heard : give the floor to *d* : to acknowledge the de facto existence or the independence of 2: to acknowledge or take notice of in some definite way: as *a* : to acknowledge with a show of appreciation <*recognize* an act of bravery with the award of a medal> *b* : to acknowledge acquaintance with <*recognize* a neighbor with a nod> 3 *a* : to perceive to be something or someone previously known <*recognized* the word> *b* : to perceive clearly.”<sup>36</sup>
- “Consist,” “transparent,” “verifiable” and “basis” were defined above.

The notion of “value,” then, seems to be anchored in the notion of “fair return.” What would constitute a “fair return” on a patented drug? Given the context of the pro-intellectual property provisions of the TPP, “fair return” is likely to be connected to the entire R&D / marketing / production cycle that patent holders cite as justification for higher drug prices in the first place. Put differently, a reimbursement policy that has its “basis” in the pro-patent interpretation of the economic value of the drug would err closer to the prices charged by patent-holding drug companies than those charged by generic drug companies. Thus it could easily be argued that the types of discounts envisioned through the bargaining of VA government negotiators – or even

Medicare Part D private plans or Medicaid state government negotiators – do not appropriately recognize “value” under the interpretation likely to be afforded to the TPP Annex.

If drug companies indeed conclude that reimbursement programs do not recognize the “value” of patented drugs, Subparagraph X.3 gives them several bits of procedural ammunition.

First, the requirement that reimbursement administrators have an “alternative transparent and verifiable basis” that “recognizes” (i.e. acknowledges formally) the “value” of a patented drug would likely mean (at a minimum) that the administrators would need to collect and disclose their valuation methods. This would give drug companies a detailed paper trail to mine for useful information to undermine the reimbursement amount.

Second, Subparagraph X.3(e) of the TPP annex provides that: “(e) 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.” In addition to having access to a paper trail as described above, this provision would allow drug companies a second chance at higher reimbursement through a new reapplication process.

Third, Subparagraph X.3(i) of the TPP annex states that Parties must “make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices.” In the case of all of the U.S. programs evaluated in this memo, pharmaceutical companies have limited ability to appeal the reimbursement decisions of the federal, private or state agencies. More often, the reimbursement rates are arrived at through negotiation, or set through price controls. Courts grant great deference to agency officials, and usually only look for evidence that the agency action was not unreasonable, arbitrary, capricious or otherwise in violation of law. Pharmaceutical companies have a very difficult time even gaining standing in administrative or judicial courts to have their grievances about pricing heard. **The TPP Annex seems to be an effort to grant appeal and standing rights to pharmaceutical companies where none exist currently.**

## **II. Implications of Carve-outs**

The previous section explored the implications of the substantive rules of the TPP annex for U.S. health care programs. This section explores the extent to which the United States could be shielded from the proposals by various carve-outs in the leaked text.

### ***Draft TPP Rules on Content of Reimbursement Policies – Scope***

The second core obligation in the draft TPP text, Paragraph X.3, has a range of procedural and substantive requirements related to reimbursement practices. The introductory chapeau to this paragraph establishes the scope of measures that must comply with this substantive requirement as:

To the extent that health care authorities of a Party's central level of government maintain procedures for listing pharmaceutical products, medical devices, or indications 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...[1]

Note that the Paragraph X.3 obligations are limited to measures taken by the "central level of government," which in the United States is the federal government. While this would seem to exclude actions by private companies or state governments, to the extent that the federal government established programs like Medicaid, it is possible that some state level or private decisions could be implicated. Indeed, U.S. court cases have treated various aspects of Medicaid as federal questions.

This would seem to be a relatively straightforward description of scope, focused on federal government pharmaceutical reimbursement policies. However, **two footnotes conspire to convert this seemingly straightforward scope paragraph into an interpretive minefield.**

For starters, footnote 1 at the end of the chapeau to Paragraph X.3 reads:

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 X (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products.

In addition, the annex defines "health care authorities of a Party's central level of government" as "entities that are part of or have been established by a Party's central level of government to operate or administer its health care programs." It defines "health care programs operated by a Party's central level of government" as "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." A second footnote at this point reads: "[Negotiator's Note: Clarifying footnote regarding scope of application, such as with respect to central versus regional level of government health care programs.]"

Unlike the phrases "health care authorities" and "health care programs," the phrase "health care agencies" is not defined in the Annex, nor is the phrase: "engage in government procurement." If we assume that "agencies" are defined the same as "authorities," and that "engage in government procurement" has its common sense meaning, we could restate the foregoing: for a country's

measure to have to comply with the obligations of Paragraph X.3 of the TPP annex, the country must:

1. Have “health care programs” that relate to reimbursement, either through listing methods of the setting of reimbursement amounts;
2. Have “health care authorities” that either are from the “central level of government” or “have been established by a Party’s central level of government...”;
3. These “authorities” must “operate or administer its health care programs”; and
4. These “authorities” must “make the decisions regarding matters to which this Chapter applies”.
5. However, the listing (i.e. formulary) activities of authorities that conduct government procurement do not have to comply with Paragraph X.3.
6. Moreover, the health care programs of subnational health care authorities would seem to be generally excluded, unless an argument could be made that these authorities were “established by a Party’s central level of government.”

#### **Implication of Procurement “Carve-out” in Draft TPP Annex**

Since 1994, the United States has committed to the disciplines of the WTO’s plurilateral Agreement on Government Procurement, which applies to drug purchases made by the VA and other agencies in excess of about \$200,000.<sup>37</sup> Our bilateral trade agreements tend to simply incorporate these WTO rules. There are not any obvious ways in which these procurement chapters would hinder drug price containment, so long as these were applied on a non-discriminatory basis.<sup>38</sup>

(Indeed, the main impact of procurement chapters is to limit Buy American programs and technical and supplier specifications for contract bids. Pharmaceutical cost containment policies would not be likely to establish rules offering to pay more for American-made drugs, for instance, so the procurement chapter is unlikely to be a problem for the set of policies explored in this memo.)

#### *VHA – Scope*

The VHA’s drug programs clearly qualify as programs operated by the central government that involve “setting the amount of reimbursement for pharmaceutical products or medical devices.” The Big Four prices are defined as being at least 24 percent lower than the average market price, the FSS prices are linked to most-favored customer rates or BPAs, and the NSCs also set prices through a procurement-linked bargaining process. TRICARE utilized similar tactics. Therefore, the VHA and TRICARE could only escape the scope of the chapeau of Paragraph X.3 if they were exempted under footnote 1 on procurement.



Would these programs be carved out? They each conduct both formulary activities and procurement activities. The footnote could be construed in two ways. It may be interpreted as a broad carve-out: because the VHA engages in procurement, all its formulary activities (see numbers 1-9 in Figure 1) are carved out from the Annex. Alternatively, it could be a narrow carve-out, since some of the VHA's formulary activities (i.e. Big Four and FSS price setting) can be distinguished from its procurement activities (i.e. the NSC process) and therefore the former group of reimbursement/formulary activities are covered by the Annex. While U.S. courts have seemed willing to consider certain aspects of formulary development to be procurement related, there is a line between the two in terms of what appeals and remedies are available to drug companies.

The narrow carve-out would mean that at least numbers 3, 5, 7 and 9 in Figure 1 in Appendix II would still have to comply with Paragraph X.3 of the TPP annex. (And in any case, even the NSC process could be obligated to comply with the “consistent (etc.) administration” requirements of Paragraph X.2(3) explored in the previous section, since the footnote 1 on procurement only appears in Paragraph X.3.)

#### *Medicare – Scope*

In contrast to the VHA, Medicare Part D does not directly procure, nor does it outright develop formularies or reimbursement amounts. Hence, its activities would not so clearly fall under the scope of Paragraph X.3.

However, as shown in Figure 2 in Appendix II, the federal government (through CMS) does set general guidelines for the private plans (Roman numeral I), must approve the privately run formulary development practices that are described in the private sponsor's proposed contract with the CMS (Roman numeral II), and ultimately reimburses the private plan for most of the cost of the drug (Roman numeral III). A TPP partner could make a colorable case that Medicare must comply with the TPP provisions to the extent that the actions taken by the private plans were established by the federal government, and/or to the extent that CMS' approval and government-to-plan reimbursement procedures impact formulary development and plan-to-drug company reimbursement.

In contrast, since Medicare Part B is entirely operated by the federal government, it clearly would qualify as a “health care program operated by its central level of government” in Paragraph X.3. Since the CMS sets the rate that it will reimburse doctors for dispensing drugs, the calculation of the reimbursement amount would qualify as “setting the amount of reimbursement for pharmaceutical products” under Paragraph X.3. Hence, Medicare Part B would be subject to the disciplines of Paragraph X.3.

#### *Medicaid – Scope*

Medicaid would be subject to requirements under Paragraph X.3 if it is deemed a “health care program operated by [the U.S.] central level of government.”

The leaked TPP text defines “health care programs operated by a Party’s central level of government” as “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.”

Advocates and legislators have been very concerned about the strength of such carve-outs. For instance, California State Senator Liz Figueroa warned in a letter to USTR that Medicaid could be considered “federal” under the Australia FTA: “Given that California’s Medi-Cal program operates under federal guidelines and that California must submit a State plan for federal approval in order to change or expand that program, it is certainly with the scope of reason to conclude that a close-door, FTA dispute panel could potentially interpret the federal guidelines and approval process as a ‘decision,’ thereby making state programs ‘federal’ and covered by the provisions of the trade agreement.”<sup>39</sup> State legislators from at least eight other states have expressed concerns that their Medicaid programs could fall within the scope of the Australia FTA since they could be classified as federal programs.<sup>40</sup>

A footnote in the Korea FTA’s Pharmaceutical Products chapter is clearer in respect to Medicaid’s exclusion than the Australia FTA, and states, “For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.”<sup>41</sup>

But the bald assertion seems contradicted by the facts. U.S. courts have interpreted challenges to certain aspects of state Medicaid programs as federal questions. As Figure 3 in Appendix II shows, Medicaid is a program established by the federal government, but operated in part by the states (Roman numeral I).<sup>42</sup> The federal government does not create the formularies, but it establishes rules governing their restrictiveness (Roman numeral II). Medicaid also establishes private-to-state rebate rates (Roman numeral III) and sets upper limits for federal-to-state reimbursement rates (Roman numeral IV). Both actions arguably incentivize certain state-to-private pharmaceutical reimbursement rates. In other words, the federal government “makes the decisions” about these federal-to-state reimbursement rates, which is a matter mentioned in the leaked TPP Annex. Therefore, Medicaid may fall under the scope of Paragraph X.3, and the United States may be unable to maintain as asymmetric and non-fact-based a Medicaid carve-out as it had in the Korea FTA.

Furthermore, Medicaid may be implicated by Paragraph X.3 by the mere fact that the federal government established the program. If challenged under the TPP, the United States might argue that Medicaid is not a central government program, as required by the scope provisions of the TPP annex. However, a TPP panel might conclude that the programs were nonetheless established by the federal government, and that U.S. courts have noted this in granting federal question jurisdiction. They can note that it would be absurd to allow countries to evade the substantive requirements of the TPP simply by outsourcing some of the administration of a

reimbursement program to subfederal governments. Such an interpretation would substantially weaken the Annex disciplines in violation of the Parties' expectations when they agreed to the TPP.

### **TPP Could Force Changes in the 340B Drug Pricing Program**

Since the 340B program is operated by the federal government, it would qualify as a "health care program operated by its central level of government" in Paragraph X.3. Since the Department of Health and Human Services signs agreements with the drug companies that specifies the price that drug companies can charge the health centers, the agreement would qualify as "setting the amount of reimbursement for pharmaceutical products" under Paragraph X.3. Hence, program 340B would be subject to the disciplines of Paragraph X.3.

The price-setting under 340B would thus have to have a "basis consisting of competitive market-derived prices" or another basis that recognizes the value of the patented product. The statutorily-defined prices set in the 340B program that are below the market price may be incompatible with Paragraph X.3. Finally, since prices in the 340B program are set by statute and cannot be appealed by drug companies, the program would have to be altered to allow for the appeal process required under subparagraph X.3(i).<sup>43</sup>

### **III. Possible TPP Threats to Proposed Reforms of Medicare and Medicaid**

As discussed above, the federal government is prohibited from directly negotiating with drug companies to get better drug prices for Medicare Part D plans. President Obama supports repeal of the Medicare nonintervention clause so as to lower costs for the government and Medicare beneficiaries. While campaigning for president in 2008, Obama supported giving the federal government the authority to negotiate for better Medicare drug prices.<sup>44</sup> Obama's April 2011 plan to reduce the deficit included a proposal to "limit excessive payments for prescription drugs by leveraging Medicare's purchasing power," seemingly a reference to allowing Medicare to engage in drug price negotiations.<sup>45</sup> The stringent provisions of the TPP may frustrate President Obama's domestic agenda since such reform may run afoul of the proposed TPP text that suggests reimbursement amounts must be derived from competitive market prices.

Senator Dick Durbin (D-Ill.) and Representative Jan Schakowsky (D-Ill.) have proposed legislation to require the Secretary of Health and Human Services to offer one or more Medicare Part D plans like private sponsors do.<sup>46</sup> The plan(s) would exist alongside private plans. The bill would require the Secretary to negotiate with drug manufacturers for lower prices and establish formularies.<sup>47</sup> The Secretary would establish a Part D plan's formulary to "encourage use of" drugs with lower cost "after taking into consideration" the effectiveness of the drugs.<sup>48</sup>

The Durbin-Schakowsky bill could fall under the scope of Paragraph X.3. Instead of private entities being solely responsible for setting prices, the bill would allow the federal government to set drug prices for some Medicare plans. In the language of Paragraph X.3, this would clearly make the Department of Health and Human Services become a “health care authorit[y] of a Party’s central level of government central level of government” that sets “the amount of reimbursement for pharmaceutical products or medical devices.” Since the bill envisions formulary development, it would also lead to the federal government “maintain[ing] procedures for listing pharmaceutical products, medical devices, or indications for reimbursement.”

This approach may run into conflicts with the TPP if it uses the market power of the federal government to reduce drug prices below the market price. And, because many of these proposals do not implicate actual procurement by CMS nor decisions by state governments, they would be likely to bring Medicare outside of any “carve-outs” represented by the TPP annex’s footnotes 1 and 2.

The text of the bill describes in broad terms the method that the government would use to set cheaper prices: “the Secretary shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, including the use of a formulary and formulary incentives in subsection (e), to reduce the purchase cost of covered part D drugs.”<sup>49</sup> Speaking about her desire to repeal Medicare’s nonintervention clause, bill sponsor Rep. Jan Schakowsky indicated the intended negotiation strategy: “It just makes sense that Medicare should use its bargaining power to negotiate for lower drug prices – just as the VA does.”<sup>50</sup> Using the huge bargaining power of the federal government to obtain lower prices would be an exercise of market power and would run afoul of subparagraph X.3(d) of the proposed TPP text. This type of direct negotiation is broadly supported by the public. A poll conducted by the Kaiser Family Foundation in November 2006 found that 81 percent of Americans over age 65 supported “Allowing the government to negotiate with drug companies for lower prices for Medicare Rx drugs.”<sup>51</sup>

More proposals are on the table. In 2007, a report from the Congressional Research Service (CRS) noted that the incoming congressional leadership for the 110<sup>th</sup> Congress considered the repeal of the noninterference clause a priority.<sup>52</sup> The report offered three options for how price negotiation could work after repeal of noninterference. It suggested that ceiling prices for reimbursements similar to those in Medicaid could be established.<sup>53</sup> It noted that a formulary would have to be developed to allow Medicare to exclude high-cost drugs to give Medicare bargaining power.<sup>54</sup> A second option would be to mandate that drug manufacturers give rebates to Part D plan sponsors, similar to the Medicaid rebate system.<sup>55</sup> A third option would involve the federal government directly purchasing drugs from manufacturers and sell them to Medicare beneficiaries at low cost, similar to the VHA system.<sup>56</sup> These options would shift the responsibility for “operating” these drug price and formulary management systems from private sponsors to the federal government, which would make them subject to the provisions in the TPP pharmaceutical “transparency” provisions.

Proposals to take the administration of Medicaid out of state hands and put it in the hands of the federal government have existed for decades. Proponents of these proposals argue that the current structure on Medicaid is inefficient and opens Medicaid to abuse by states that may not treat all their Medicaid beneficiaries equally.<sup>57</sup> Making Medicaid a fully federal program would certainly bring it into the scope of Paragraph X.3 of the proposed TPP and subject its price-setting activities to its rules. Even U.S. trade negotiators recognize this as a clear peril, as indicated by the inclusion of the footnote in the Pharmaceutical chapter of the Korea FTA that aims to define Medicaid as a “regional level of government health care program in the United States, not a central level of government program.”<sup>58</sup> Without the protection that its regional-level status may afford, Medicaid would certainly be impacted by the TPP.

Finally, it is worth assuming that the United States may be hard pressed to maintain its carve-outs, as other countries will justifiably accuse the United States of double standards and hypocrisy. Accordingly, the U.S. public and Congress would be well served by a study projecting what the TPP annex would look like without its carve-outs, and deciding whether these substantial disciplines on cost-saving are something they can live with.

#### **IV. Korea’s Public Drug Programs in Big Pharma’s Crosshairs**

Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry’s lobbying arm, has already used the U.S.-Korea FTA, just implemented this year, to ensure that Korea’s public drug benefit program pays more for drugs. The Korea FTA contains provisions on drug pricing that resemble the leaked TPP text, but are less strict.<sup>59</sup> Since the Korean legislature approved the FTA in November 2011, the government has moved to comply with its provisions by establishing an appeal process that drug companies can use to ask for higher prices from the Korean drug benefit program.<sup>60</sup> PhRMA has complained that the review process does not cover all drugs, but it has gained assurances from USTR that the U.S. government will pressure the Korean government to comply through an FTA dispute settlement proceeding if necessary.<sup>61</sup>

Beyond the price appeal process, PhRMA has also referred to the Korea FTA as a way to alter other policies so that drug companies’ revenues rise, leading to correspondingly higher costs for Korean consumers and the government. PhRMA’s 2012 submission for the annual U.S. report on intellectual property practices abroad featured ominous language about bringing Korea’s laws into conformity with various standards via the FTA.<sup>62</sup> For example, PhRMA urged the Korean government to make its patent system “consistent with commitments in the Korea-U.S. Free Trade Agreement” so that drug companies can stave off the introduction of generic drugs through a dispute system.<sup>63</sup> Also on PhRMA’s agenda is an attempt to hinder the development of generic drugs through stricter protection of drug trial data.<sup>64</sup> PhRMA’s attempts to raise prices in Korea are especially inappropriate because drugs already comprise 30 percent of health expenditures in Korea – greater than the OECD average.<sup>65</sup>

#### **V. Conclusion**

The foregoing analysis attempted to document one strand of drug companies' efforts to battle pharmaceutical cost containment. We showed that U.S. drug cost containment measures are susceptible to challenge under the types of rules being proposed in the TPP. In particular, we showed that the carve-outs that U.S. negotiators have touted as protecting U.S. drug cost containment programs do not clearly do so in all cases. We show that proposed changes to U.S. health programs would open up the programs (like Medicare) to even greater attack under the TPP. Press reports indicate that other TPP partners are deeply upset with the U.S. proposal, and that they may insist on eliminating the annex altogether, or ensuring that the United States is equally susceptible by removing the carve-out footnotes.<sup>66</sup>

The United States can preempt the threats created by the proposed annex by simply deleting the proposal altogether. It was a mistake to include similar language in prior "trade" deals, and it would be a mistake to build on these intrusive terms even more.

## **Appendix I. Effective Cost Containment Abroad**

By Travis McArthur

Other nations have utilized a wide range of measures to control pharmaceutical costs, from direct governmental setting of prices charged in private markets (Brazil, China, India), to setting of prices for government reimbursements to private firms under national health care programs (France, Italy), to voluntary private-public partnerships that set target returns on investment in R&D (United Kingdom). U.S. pharmaceutical companies have been skeptical of all of these approaches.

There are several countries that have earned special scorn, including many that utilize preferred drug lists. These lists are usually called “formularies,” defined as “an official list giving details of prescribable medicines.”<sup>67</sup> (The term “formulary” emerged in the 16<sup>th</sup> century from a Latin word that meant “book of formulae.”<sup>68</sup>)

Australia has a Pharmaceutical Benefits Scheme (PBS) that was established after World War II that reimbursed community pharmacies for the cost of dispensing outpatient medicines. For several decades, clinical considerations dominated the process of adding drugs to the formularies. Beginning in the late 1980s, however, Australia became the first country to actually include cost considerations into the decision to add drugs to a formulary. As one study put it,

...unless a new drug offers an additional clinical benefit over an appropriate comparator, it may be added to the formulary, but cannot receive a higher price for subsidy purposes. A drug listed on this basis is subject to reference pricing – that is, it is linked by a ‘therapeutic relativity’ to its comparator, either joining an existing reference pricing group or forming a new one. The price the government pays for any drug in a reference group is then set by the lowest price (known as the benchmark), which has been secured for any drug in the group. One of the effects of the reference pricing system is that the prices of drugs may be linked irrespective of patent status. Although the pharmaceutical industry perceives this as undermining the value of the patent, from the payer’s perspective, however, it may be argued that it is neither rational nor efficient to pay more for a drug just because it is patented if it confers no additional health benefit, than a drug whose patent has expired and is cheaper. Where a sponsor presents evidence that a new drug offers a clinical advantage over its comparator, the additional benefits are weighed against the additional costs in a cost-effectiveness or (preferably) a cost-utility analysis, and a determination is made as to whether the drug is acceptably cost effective at the price proposed by the drug’s sponsor. In this respect, the PBS operates as a therapeutic-value based pricing system: it may be thought of as ‘purchasing outcomes’ rather than drugs... As the PBS accounts for around 80 percent of prescriptions dispensed in Australia, and more than 90 percent of those dispensed in the community, the government wields significant monopsony power, and medicines which are not listed on the PBS generally have a limited market.<sup>69</sup>

PhRMA complains that, more recently, the Australian Cabinet has also added a cabinet layer of review before items are listed on the national formulary.<sup>70</sup>

Canada and New Zealand have also adopted a similar model.<sup>71</sup> The Canadian Patented Medicine Prices Review Board sets maximum prices that drug companies can charge for patented drugs.<sup>72</sup> Public drug benefit programs are administered at the province level in Canada.<sup>73</sup> The drug benefit programs of each province varies in the covered populations (e.g. just the elderly, children, the poor, etc.), and private programs cover other groups.<sup>74</sup> In New Zealand, the government's drug benefit program only covers a few drugs for each disease and drug companies must keep prices very low for the privilege of being chosen as one of the winning drugs.<sup>75</sup> According to PhRMA, New Zealand supplements the overall formulary approach with a capping of total medical reimbursements per patient and for the nation as a whole.

The Japanese government, for its part, requires individuals to purchase health insurance and negotiates with drug companies to set nationwide drug prices, but the insurance companies rather than the government directly pay for drugs.<sup>76</sup>



## **Appendix II. U.S. Approach: Private Market, Plus Limited Entitlement Programs**

By Travis McArthur and Todd Tucker

The United States is an outlier among developed countries, having no universal health care programs or aggressive cost containment measures. Unsurprisingly, this has resulted in the most common prescription drugs being 60 percent more expensive in the United States than in comparable European countries.<sup>77</sup>

Nonetheless, the United States does maintain several health care programs for targeted populations (veterans, the poor, the elderly) that deal with pharmaceutical cost issues. These are explored in detail below.

### ***Veterans Health Administration***

The Veterans Health Administration (VHA), a part of the Department of Veterans Affairs (VA), helps provide health care to individuals who served in the U.S. armed forces. A government-operated network of hundreds of medical centers, outpatient clinics, and other health facilities treat about five million veterans per year.<sup>78</sup>

The VA uses a variety of measures to control pharmaceutical costs for veterans:

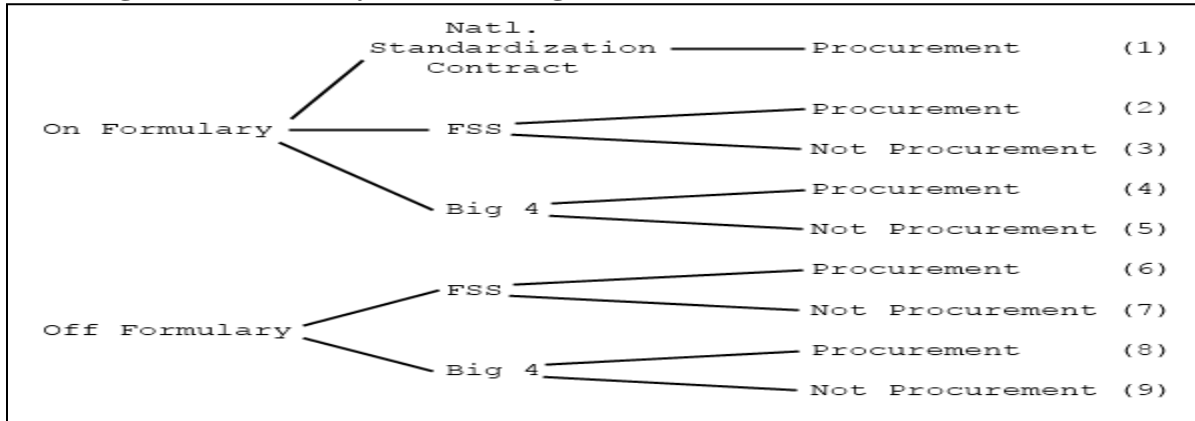
- The VA – along with the Department of Defense, Public Health Service (Indian Health Service), and U.S. Coast Guard – has access to the “Big Four” prices. By statute, these prices are an automatic 24 percent discount over average market prices for a wide range of drugs (including patented drugs).<sup>79</sup> This is known as the “Federal Ceiling Price” (FCP). The VA doesn’t necessarily have to procure these drugs at all, but it has access to these prices. Pharmaceutical manufacturers are pressured into offering the Big Four price through the signing of “master agreements” with the VA, which they must have in place as a condition for reimbursement under state Medicaid programs and Medicare Part B. As one legal study put it, “The master agreements are not procurement contracts and thus are not subject to the provisions of the Contract Disputes Act. Instead, the agreements provide for dispute resolution concerning the calculation of FCP through adjudication by the Board of Contract Appeals. All other disputes relating to the terms of the master agreements are governed by federal common law.”<sup>80</sup> As the Master Agreement contained in Securities and Exchange Commission (SEC) filings for one pharmaceutical company indicate, these appeal rights are very limited.<sup>81</sup>
- The VA also manages the Federal Supply Schedule (FSS), a list of virtually every product on the market (including drugs) that any federal agency might procure. By law, the prices that are set in supplier contracts must not exceed the prices manufacturers charge their Most-Favored Customers under comparable terms and conditions.<sup>82</sup> The FSS price for some (but not all) drugs is below the Big Four price.<sup>83</sup> Blanket purchase agreements, a subprogram within the FSS, allow the VA to negotiate bilaterally with drug companies for even lower discounts in exchange for a commitment to make bulk purchases.<sup>84</sup> Like with the Big Four

master agreements, drug manufacturers must have an FSS contract in order to have their drugs covered by Medicaid, so nearly all FDA-approved drugs are in the FSS.<sup>85</sup>

- The VA also can negotiate national standardization contracts (NSCs) with drug companies. These contracts can yield discounts of 10 to 60 percent below the FSS price, in exchange for a promise to procure these drugs and adding them to the VHA’s formulary.<sup>86</sup> This national formulary has been in place since 2009.<sup>87</sup> According to the GAO, the VHA “contracts for one or more of these therapeutically interchangeable drugs using competitively bid national committed-use contracts. By committing to use these drugs to treat veterans throughout its health care system, VHA can assure the drug companies a high volume of use and drug companies in turn are more likely to offer a lower price.”<sup>88</sup> The winners of these competitive contracts are included in the formulary, while other drugs that are therapeutically equivalent are not included.<sup>89</sup> According to the CRS, the process for establishing these contracts works as follows: “The VA selects from among confidential bids submitted by pharmaceutical manufacturers and announces the winning bid. Thus, the process more resembles a round of silent bids rather than a negotiation through which each party bargains with offers and counteroffers.”<sup>90</sup>

Drugs making their way through the VA system can be grouped by three processes: 1) whether or not they are on the VA formulary; 2) through what channel their price is set; and 3) whether or not the VA ends up procuring them. The nine possible combinations are depicted visually in Figure 1.

**Figure 1: Formulary, Price-Setting, and Procurement Activities of the VHA**



The decision-making process for adding new drugs to the national VHA formulary is a two-phase procedure. First, a request to add a drug is submitted by an arm of the VHA and a clinical pharmacist prepares a document on the drug’s effectiveness, side effects and cost, including a comparison with other drugs. Second, the VA’s Medical Advisory Panel (composed of practicing physicians) makes the final decision about whether to include it. According to the GAO,

...cost is not a major consideration during the initial phase of reviewing a drug. Decisions to add or delete drugs on the national formulary are made using criteria similar to those used by pharmacy benefit managers in the private sector—safety and effectiveness. Purchasing the drug at the lowest price possible is the responsibility of VHA’s NAC [National Acquisition Center], which uses several purchasing techniques, including competitive bidding for drugs available from multiple sources. VHA officials believe this two-phased process ensures that the drugs on the national formulary include those representing the ‘best value’—the most effective treatment at the least cost—rather than simply the least expensive drug available.<sup>91</sup>

Drugs that are not on the formulary may be prescribed, but the prescribing doctor must first obtain a waiver.<sup>92</sup> A drug does not have to be on the VHA formulary in order for it to have a reference price under the FSS or Big Four. Lipitor is an example of a drug that is not on the VA formulary but is included in the FSS and the Big Four.<sup>93</sup> In 2006, the VHA filled over 700,000 prescriptions for Lipitor.<sup>94</sup> In contrast, the VHA only accepts National Standardization Contract bids for drugs that it wishes to put on the formulary since the contracts grant the drugs’ inclusion in the formulary.<sup>95</sup>

Finally, the third procedural dimension explored in Figure 3 is whether or not there is actually procurement of the drug. The VA is a significant procurer of drugs, spending an estimated \$3.7 billion on prescription drugs in 2009.<sup>96</sup> Under the VA system, a drug could be procured whether or not it is on the formulary, and it could be on the formulary even if it is not procured. To return to our previous example, Lipitor is an example of a drug that is not on the VHA formulary but is procured by the VHA.<sup>97</sup> Moreover, prices could exist for a drug under the FSS or Big Four, even if there is no actual procurement within a given year or time period. As we show above, it is precisely the setting of prices and reimbursement rates (rather than outright procurement) that appears to be targeted by the leaked TPP annex. These non-procurement scenarios are indicated in Figure 1 by numbers 3, 5, 7 and 9.

Appeal rights under VA programs are very limited. As with other procurement contracts, drug manufacturers can appeal their treatment by federal agencies under FSS or NSC to the U.S. Court of Federal Claims or VA Board of Contract Appeals.<sup>98</sup> In 2000, the Comptroller General denied a protest by SmithKline Beecham Corporation against the VA’s cost estimation methods for its formulary. The Comptroller noted that NSC-related formulary decisions are distinct from FSS contracts, and that the law gives the VA wide latitude to make reasonable evaluations of likely costs to government.<sup>99</sup>

When similar complaints were heard by U.S. courts, similar conclusions were reached:

In *Garufi*, the United States Court of Appeals for the Federal Circuit wrote: ‘Under the APA standards that are applied in the *Scanwell* line of cases, a bid award may be set aside if either: (1) [T]he procurement official's decision lacked a rational basis; or (2) the procurement procedure involved a violation of regulation or procedure.... When a

challenge is brought on the first ground, the courts have recognized that contracting officers are ‘entitled to exercise discretion upon a broad range of issues confronting them’ in the procurement process... Accordingly, the test for reviewing courts is to determine whether ‘the contracting agency provided a coherent and reasonable explanation of its exercise of discretion,’ *id.*, and the ‘disappointed bidder bears a ‘heavy burden’ of showing that the award decision ‘had no rational basis.’ ... When a challenge is brought on the second ground, the disappointed bidder must show ‘a clear and prejudicial violation of applicable statutes or regulations.’...

A disappointed bidder has the burden of demonstrating the arbitrary and capricious nature of the agency decision by a preponderance of the evidence. The United States Supreme Court has identified sample grounds which can constitute arbitrary or capricious agency action: ‘The agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.’... Under an arbitrary or capricious standard, the reviewing court should not substitute its judgment for that of the agency, but should review the basis for the agency decision to determine if it was legally permissible, reasonable, and supported by the facts... Barring arbitrary and capricious behavior or a violation of law, the wide discretion afforded contracting officers extends to a broad range of procurement functions, including the determination of what constitutes an advantage over other proposals.<sup>100</sup>

## ***TRICARE***

The Department of Defense separately maintains TRICARE, a health program for active duty and retired military personnel and their families. It includes a pharmacy benefits program (PBM) that contains various incentives to use generic drugs, formulary drugs, and use military and mail order “points of service” to purchase the drugs.<sup>101</sup> The Department of Defense Pharmacy and Therapeutics Committee, comprised of representatives of pharmacies and providers of the uniformed services facilities, makes the determinations on what drugs to include in a uniform formulary through evaluations of clinical and cost effectiveness.

The federal regulations indicate that, “Information considered by the Committee concerning the relative cost effectiveness of pharmaceutical agents may include but is not limited to: (A) Cost of the pharmaceutical agent to the Government; (B) Impact on overall medical resource utilization and costs; (C) Cost-efficacy studies; (D) Cost-effectiveness studies; (E) Cross-sectional or retrospective economic evaluations; (F) Pharmacoeconomic models; (G) Patent expiration dates; (H) Clinical practice guideline recommendations, and (I) Existence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts.”

When TRICARE beneficiaries attempt to purchase drugs that are not generics or not on the uniform formulary, they will typically incur greater copays and out-of-pocket costs – thereby

providing a disincentive from using these drugs.<sup>102</sup> The military and mail order “points of service” are able to buy drugs at the Big Four prices, while other pharmacies servicing TRICARE beneficiaries cannot, and are thus subject to a complicated pricing and rebate scheme.

The Committee also controls costs through its power to subject non-formulary drugs to prior authorization requirements before they can be dispensed or cost shared; one of the criteria for subjecting a drug to this hurdle is cost effectiveness. In order for its drug to be included on the uniform formulary and avoid preauthorization requirements, a drug manufacturer must have a “master agreement” described in the VA section above to offer drugs for sale at the FCP.<sup>103</sup> As explained in a U.S. court case, “if a manufacturer does not agree to meet the Federal Ceiling Prices through such an agreement, but nevertheless provides pharmaceuticals through the retail pharmacy program, DoD may obtain refunds on transactions in excess of the Federal Ceiling Prices through a debt collection action.”<sup>104</sup>

As with the VA programs, pharmaceutical companies have very limited appeal rights under TRICARE, as shown by a 2005 administrative appeal by Merck & Co of the process whereby TRICARE evaluated cost effectiveness. The Comptroller General noted that procurement was distinct from formulary pricing decisions,<sup>105</sup> but found that administrative decisions which could lead to procurement could be reviewed by the Comptroller nonetheless.<sup>106</sup> However, the standard of review is loose, only examining for reasonableness and non-arbitrariness of the decisions of TRICARE, whose authorities were seen as having substantial discretion. Moreover, TRICARE does not need to inform pharmaceutical companies of the relative weight that they assigned to various factors.<sup>107</sup>

A series of U.S. court cases brought by pharmaceutical companies against TRICARE’s off-military base pharmacy reimbursement scheme illustrated the relatively open standard of review of agency cost effectiveness decisions under U.S. law. A 2009 decision stated that “This Court reviews an agency’s regulations according to the familiar two-step framework articulated in *Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, ... The first step determines ‘whether Congress has spoken directly to the precise question at issue,’ for if it has, ‘the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.’ ... If, however, the statute is silent or ambiguous on the specific issue, ‘the question for the court is whether the agency’s answer is based on a permissible construction of the statute.’”<sup>108</sup> The latter is a reasonableness criteria.<sup>109</sup> Elsewhere, the scope of review required by the Administrative Procedure Act has been defined by U.S. courts as, “We will uphold an agency rule unless it is (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law ....”<sup>110</sup>

A 2011 decision elaborated, “At *Chevron* step one, the Department need only show that Congress has not spoken directly to the question at issue, not that its reading of the statute is superior to others. Indeed, at neither stage of the *Chevron* analysis need an agency show that its

choice was comparatively better than other choices. See *Dep't of Treasury, IRS v. FLRA*, 494 U.S. 922, 928, 110 S.Ct. 1623, 108 L.Ed.2d 914 (1990) (“We must accept that construction if it is a reasonable one, even though it is not the one we ourselves would arrive at.”)... The Coalition argues that “[i]t is well established that when the government acts in its commercial capacity, it cannot exercise its ‘sovereign’ authority to impose terms unilaterally on a private party.’ Pl.’s SJ Mot. at 18. The modern cases the Coalition cites, however, all concern instances in which the government was alleged to have breached a pre-existing contract. ... Those cases do not stand for the proposition that the government cannot change the terms on which it participates in ongoing commercial transactions. Moreover, the government is here hardly imposing terms on pharmaceutical manufacturers. If the manufacturers do not like the prices being offered for their products, they can always walk away from TRICARE. See 75 Fed.Reg. at 63,393 (‘Manufacturers make a voluntary choice to do business with DoD under the applicable terms.’).”<sup>111</sup>

### ***Medicare Part B***

Medicare is a national social insurance program established in 1965 whose aim is to provide health insurance for Americans 65 and older.<sup>112</sup> Since it was created, Medicare has expanded to cover people younger than 65 who have a permanent disability. The program now covers 47 million Americans, or about 15 percent of the population.<sup>113</sup>

Medicare Part B handles payment for outpatient medical services for Medicare beneficiaries.<sup>114</sup> As part of this area of responsibility, Part B covers drugs that are typically administered in physician offices and hospitals.<sup>115</sup> Drugs provided under Part B comprise a substantial portion of drugs used by Medicare beneficiaries: Medicare payments under Part B amounted to one-third of spending on Part D drugs in 2007.<sup>116</sup>

The CMS does not set the amount of money that doctors pay to drug companies. Rather, each year it sets the amount that CMS will pay to doctors or hospitals for dispensing the drug in the year to come, based on past costs.<sup>117</sup> Hospitals also receive “pass-through” payments to cover the costs of new drugs, and CMS has the discretion to order additional equitable payments.<sup>118</sup> CMS does not seek significant discounts when setting drug reimbursement levels for Medicare Part B because it fears that doctors will send patients elsewhere to obtain the drug if their drug purchase costs are not covered by their Medicare payment.<sup>119</sup> Medicare computes the reimbursement amounts for doctors based on a few different calculations of the average price that other purchasers pay for the drug.<sup>120</sup> The CMS bases its calculations on data submitted by drug companies.<sup>121</sup> Most payments are set at 106 or 104 percent of the average price that is calculated in this way.<sup>122</sup> (Payments for the few remaining drugs are set at 95 percent of the “sticker price” of the drug, i.e. the price without any of the usual discounts.)<sup>123</sup>

Despite the generous prices paid to pharmaceutical companies under Medicare Part B, the industry has not always been happy with the program. In a 2004 case brought by drug manufacturer Amgen Inc. against CMS, the company complained of having lost its pass-through

status. The agency argued that there was another drug that served the same function, so Amgen's drug was not new. Amgen complained that this de-listing violated the Medicare Act and the Administrative Procedure Act.

The U.S. court hearing the case wrote, "the Administrative Procedure Act, 5 U.S.C. § 702 (2004) ('APA') provides that '[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.' The Supreme Court has held that to qualify as 'adversely affected or aggrieved ... within the meaning' of a statute, a plaintiff must establish that the injury he complains of ... falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint.' ... Amgen's commercial interest in selling Aranesp is congruent with the interests of beneficiaries in obtaining access to the technology because Congress' reason for providing supplemental passthrough payments was that hospitals inadequately reimbursed for new drugs or biologicals are less likely to provide them and more likely to steer beneficiaries towards older, less expensive treatments.... just as beneficiaries desiring access to Aranesp and hospitals desiring reimbursement for providing it would have prudential standing to challenge passthrough payment amounts, Amgen as a vendor does as well."

While Amgen was granted standing, its case did not ultimately prevail. The Medicare statute forbids administrative or judicial review of the type of pricing adjustments at issue. Accordingly, the court wrote that "If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective... It is difficult to see how a decision by the Secretary to adjust passthrough payments for a specific treatment downward, based on the Secretary's conclusion that the treatment is too costly relative to its benefits, would not lie at the heart of" the authority envisioned in the act.<sup>124</sup>

### ***Medicare Part D***

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 created a prescription drug benefit for Medicare beneficiaries under the moniker "Medicare Part D." Under the program, Medicare recipients can enroll in drug benefit plans developed by private companies (sponsors) that contract with CMS.<sup>125</sup>

Currently, the federal government is explicitly prohibited from being involved in setting drug prices for Medicare. CRS explains: "One provision of [the Medicare Modernization Act], the 'noninterference' clause, expressly forbids the Secretary of Health and Human Services (HHS) from interfering with drug price negotiation between manufacturers and Medicare drug plan sponsors, and from instituting a formulary or price structure for prescription drugs. The framework created by the law emphasizes competition among the Medicare drug plans to obtain price discounts."<sup>126</sup>

However, the federal government is involved in the plans in myriad ways. First, federal regulations set certain minimum requirements for the contracts between CMS and the private sponsors.<sup>127</sup> Once CMS approves the contract, the sponsor can begin offering Medicare drug plans for those who are eligible, for a 12-month period. As of December 2011, there were about 4,200 Medicare Part D prescription drug plans.<sup>128</sup>

Second, CMS sets certain rules about the private plans' development of formularies. There are a wide variety of Part D plans that have varying levels of premiums and coverage of drugs. Sponsors establish the details of the formularies for their plans, but the formularies must conform to minimum standards.<sup>129</sup> The CMS reviews formularies for conformity to these standards and approves them.<sup>130</sup> The plans must "cover all, or substantially all of the drugs in the following six drug categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic."<sup>131</sup> Some economists have noted that these requirements limit the cost effectiveness of Part D:

... providing Medicare the authority to negotiate directly with manufacturers would not lead to price reductions on its own. To achieve savings, Medicare would also need the ability to exclude drugs from its formulary (Congressional Budget Office 2007). This ability to tighten the formulary would provide the leverage to bargain for lower prices. Medicare's inability to negotiate program-wide prices and tighten plan formularies is in stark contrast to another large public provider of prescription drug benefits, the Veterans Health Administration (VA), which negotiates directly with drug manufacturers. The VA has implemented a national formulary more restrictive than those of Medicare plans and obtains lower drug prices...<sup>132</sup>

However, the Medicare handbook says that "Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy."<sup>133</sup> Plan sponsors may negotiate with both pharmacies and drug manufacturers to obtain lower prices for drugs that enrollees purchase.<sup>134</sup> While private plans can choose to take cost savings into account when including drugs on their formulary or not, the federal government does not have tools to require them to do so.

Drug manufacturers do not appear to have a path to appeal Medicare Part D sponsors' decisions about formularies and drug reimbursements. In fact, most Part D sponsors farm out the task of making these decisions to private pharmacy benefit managers (PBM).<sup>135</sup> The full terms of the agreements that PBMs strike with drug manufacturers are often not even available to the Part D sponsors themselves, so it is not possible to be certain that there are no appeal mechanisms at the disposal of drug manufacturers.<sup>136</sup> This contrasts with the appeal rights of plan beneficiaries, who have the ability to appeal drug coverage determinations with the Part D sponsor, then administrative appeal judges, Medicare Appeals Council, and ultimately federal courts.<sup>137</sup> In a typical decision from last year, a Medicare beneficiary wanted to have access to an off-formulary drug, and also pay the on-formulary price. The Medicare Appeals Council decided that the statute or plan requires access to off-formulary drugs, but not necessarily the discounts.<sup>138</sup>

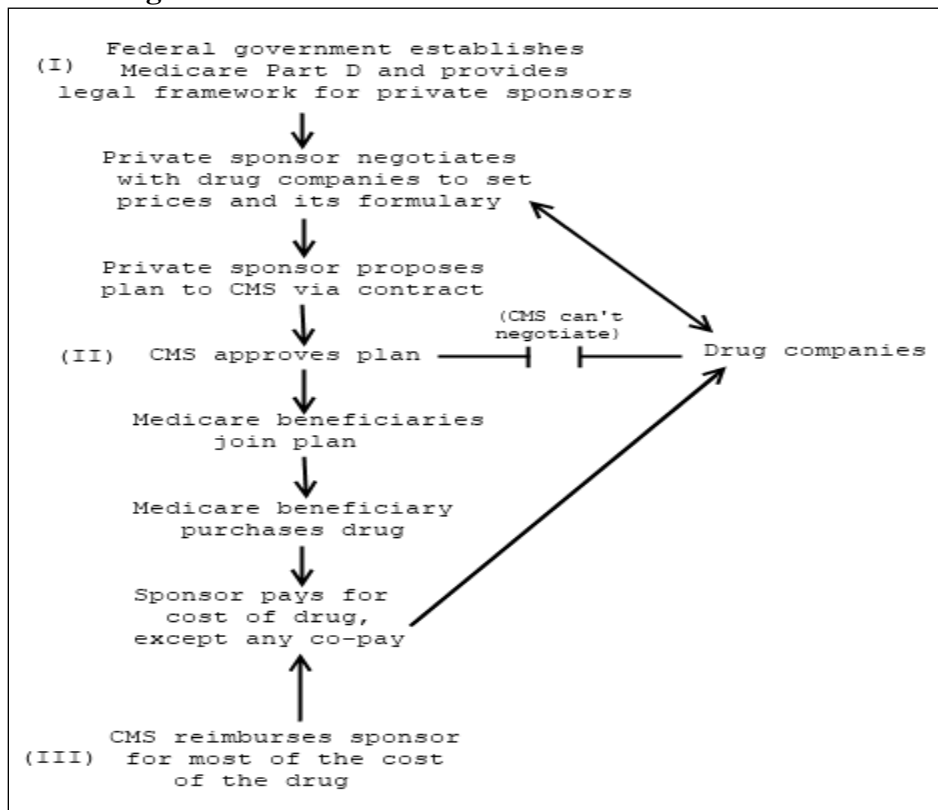


Third, the federal government collects information about the relationship between private sponsors and drug companies. For instance, Part D sponsors are required to disclose the price concessions negotiated with drug companies and other entities to the CMS, which keeps this information confidential.<sup>139</sup>

Fourth, CMS sets the premium that each sponsor may charge. Plan sponsors compute their estimated costs for each Medicare beneficiary (including administrative costs and return on investment) and submit this estimate as part of its proposed contract with CMS.<sup>140</sup> Plan sponsors give CMS information on each prescription filled under its plan and each Medicare beneficiary that is part of its plan to compute the reimbursement that CMS will pay the sponsors.<sup>141</sup>

Figure 2 illustrates the current pharmaceutical benefits scheme for Medicare.

**Figure 2: Federal Involvement with Medicare Part D**



Roman numerals I, II and III indicate the moments of federal government interaction with the Part D program.

**Medicaid**

The Medicaid program was established in 1965 under the same legislation that created Medicare.<sup>142</sup> In contrast to Medicare, eligibility is based on income and/or wealth rather than age.<sup>143</sup> Children and adults in poor families, poor people with disabilities, and poor elderly people make up most of the 68 million people who are enrolled in Medicaid.<sup>144</sup>

Medicaid also differs from Medicare in that the program is administered by states, with 25 to 50 percent of the funding coming from state budgets.<sup>145</sup> These state-administered Medicaid programs are not required to cover prescription drugs, but most of them do offer drug coverage.<sup>146</sup> Unlike Medicare, private entities do not provide drug coverage. Unlike the VHA, the federal government does not directly purchase drugs, so it does not involve procurement.

There are several points of ongoing federal involvement in Medicaid, including the initial establishment of the program in federal law; the setting of discount agreements and federal upper limits; and the regulation of state formularies.

Under a program that has been around since 1990, if drug manufacturers wish to have their drugs covered under Medicaid, they must sign discount agreements with the federal government to keep down costs for the state programs.<sup>147</sup> These discount agreements take the form of rebate schemes.<sup>148</sup> Drug manufacturers pay rebates to states each quarter for the drugs that state Medicaid programs use.<sup>149</sup> State governments share a portion of these rebates with the federal government.<sup>150</sup> The dollar value of the rebates is calculated with a complicated formula as a percentage of either the average price wholesalers are charged by drug manufacturers or the best price that any purchaser pays for the drug.<sup>151</sup> The purpose of requiring companies to sign these discount agreements if their drugs are to receive coverage is to ensure that Medicaid obtains discounts similar to private large buyers of drugs.<sup>152</sup> State Medicaid drug benefit programs must provide coverage and reimbursement for drugs covered under these discount agreements.<sup>153</sup>

Additionally, according to CRS, “[State-to-private] Reimbursement levels for all Medicaid covered items and services, including prescription drugs, are set by the states. Unlike many other Medicaid items and services, however, prescription drug prices are subject to upper limits established in federal law that restrict the amount of federal matching payments available for those products.”<sup>154</sup> These Federal Upper Limits apply to generic drugs that are manufactured by multiple companies. The Federal Upper Limit is the price ceiling above which the federal government will not reimburse states for costs of a certain drug.<sup>155</sup> Hence, Federal Upper Limits define the limits of the federal government’s reimbursements to states, whereas the discount agreements between the federal government and drug manufacturers define the rebate amounts that drug manufacturers reimburse to state governments.

Under federal law, a state is permitted to establish a formulary and a prior authorization program. These concepts are linked, but there are some differences between them.

Federal law limits the restrictiveness of state Medicaid formularies.<sup>156</sup> Such formularies are written by a committee of physicians, pharmacists, and similarly qualified individuals created by

the governor of the state that wishes to have a Medicaid formulary.<sup>157</sup> Forty-eight states have established formularies for their Medicaid programs or their other state public drug benefit programs.<sup>158</sup> States must cover drugs that are part of the discount agreements between drug manufacturers and the Department of Health and Human Services, but states are permitted to exclude such drugs from their formulary if they have no significant therapeutic advantage over other drugs in the formulary.<sup>159</sup> Medicaid formularies are key policies for states trying to save money. Texas managed to save an estimated \$140 million over two years by using a formulary, while Florida saved nearly \$500 million over three years with a similar policy.<sup>160</sup> Oregon's Medicaid program has saved around 40 percent per prescription as a result of instituting formularies in 2009.<sup>161</sup>

In contrast, federal statute requires that states have a "prior authorization" program to ensure that Medicaid beneficiaries have access to off-formulary drugs.<sup>162</sup> Under prior authorization programs, states can require physicians to obtain approval before prescribing medications. The federal statute requires a prior authorization program to be used if a state sets up a formulary that fits into the definition of "formulary" used in the Medicaid statute.<sup>163</sup> However, states can also have prior authorization programs without having formularies. All but one state – even states with no Medicaid formulary – require prior authorization for prescription of certain drug classes and brand-name drugs.<sup>164</sup>

Prior authorization programs do not have the requirements as formularies. Under the Medicaid statute, a formal formulary must comply with a set of conditions, including being developed by a committee of physicians and pharmacists and only excluding drugs that do not "have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome."<sup>165</sup>

Some states have set up "Preferred Drug Lists" (PDLs) that function like formularies in some respects but are essentially exceptions to prior authorization programs. As MaineCare explains, "A formulary is a list of drugs that are available and approved for use by a variety of insurance companies, managed care organization, hospitals and governmental entities. Drugs must be prescribed from the formulary and no exceptions are typically available. In contrast, a Preferred Drug List (PDL) is a component of the Prior Authorization (PA) process. In order for reimbursement to occur, MaineCare requires that certain medications must be approved beforehand. This approval is based on previously specified criteria. Medications deemed to be clinically and/or economically superior to other clinically similar drugs are placed on the PDL. Most medications on the PDL can be prescribed and dispensed without prior authorization."<sup>166</sup> States may prefer to establish a PDL because federal law does not require a formal committee to be established to develop the PDL as is required for formularies.<sup>167</sup>

States also tackle cost containment in other ways. For instance, about 70 percent of states require generic substitution for brand-name drugs when they are available.<sup>168</sup>

Rules for allowing drug companies to appeal formulary decisions vary from state to state. But the overall thrust of the program can be and has been appealed in federal courts. In 2003, pharmaceutical companies sued CMS over state Medicaid formulary and prior authorization practices, on the basis that CMS approved the state programs and thus was responsible for them. In that case, Maine’s prior authorization practices were at issue: drug manufacturers subject to them complained that the procedural hurdle (which was apparently applied to attempt to coerce the companies into offering Maine discounts for non-Medicaid patients) led to a decline in their market share against competitor products, and that the prior authorization programs were unconstitutional because of federal preemption.

The Supreme Court ruled against the drug companies, opining that the states have substantial discretion in structuring their Medicaid programs and, “The record does demonstrate that prior authorization may well have a significant adverse impact on the manufacturers of brand name prescription drugs and that it will impose some administrative costs on physicians. *The impact on manufacturers is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program.* The impact on doctors may be significant if it produces an administrative burden that affects the quality of their treatment of patients, but no such effect has been proved. Moreover, given doctors’ familiarity with the extensive use of prior authorization in the private sector, any such effect seems unlikely.” [italics added]

In a concurring opinion, Justice Scalia wrote that, “I would reject petitioner's statutory claim on the ground that the remedy for the State's failure to comply with the obligations it has agreed to undertake under the Medicaid Act ... is set forth in the Act itself: termination of funding by the Secretary of the Department of Health and Human Services, see 42 U.S.C. § 1396c. Petitioner must seek enforcement of the Medicaid conditions by that authority—and may seek and obtain relief in the courts only when the denial of enforcement is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” Justice Thomas went further and stated that pharmaceutical companies don’t have a right to bring preemption claims against CMS.<sup>169</sup>

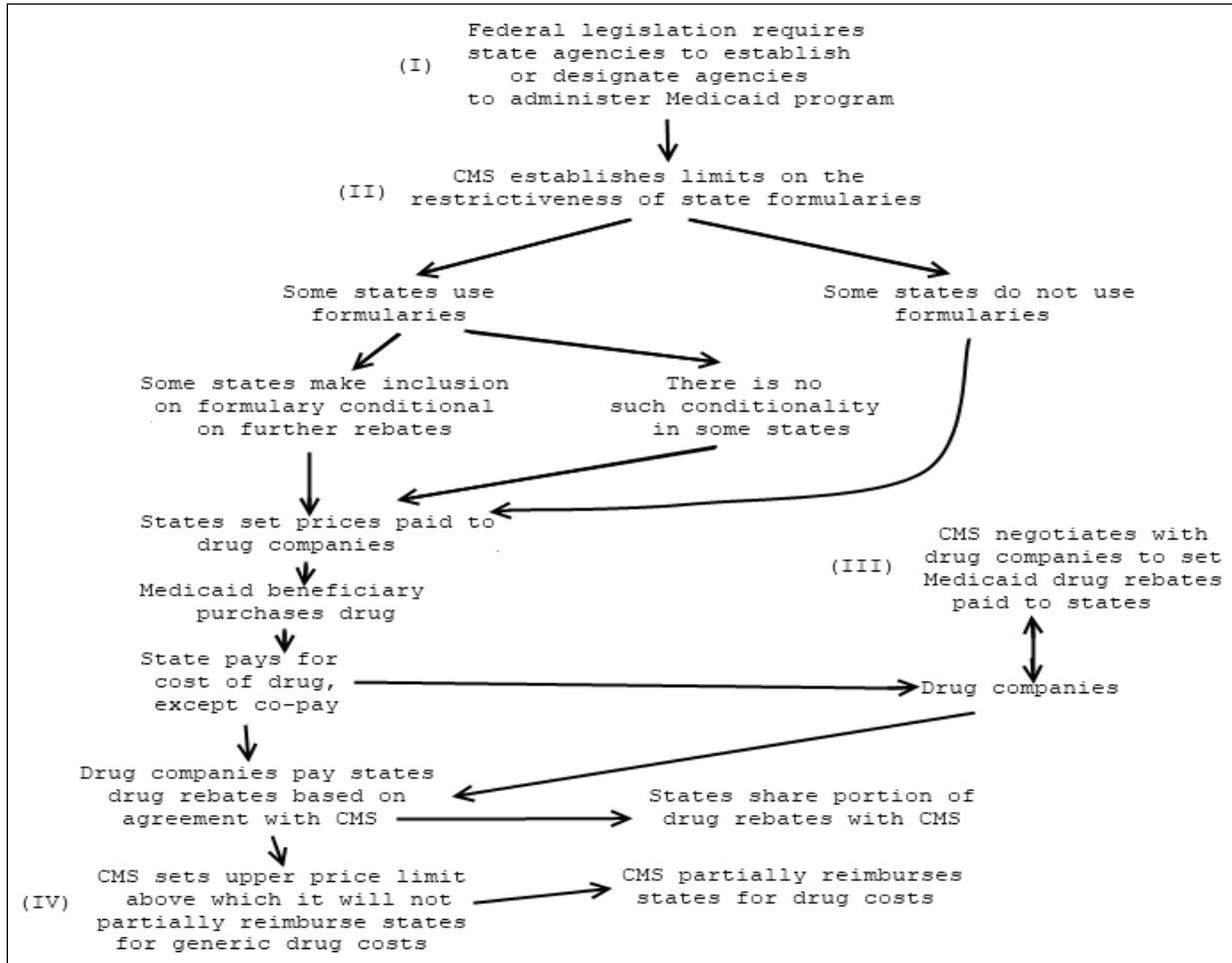
A major issue in that case was whether ensuring greater drug access for non-Medicaid populations helps further a Medicaid related goal. In another court challenge brought by the pharmaceutical industry against CMS, the manufacturers argued that Michigan’s similar prior authorization program violated the federal Medicaid law. The courts applied the Chevron test familiar from Administrative Procedure Act jurisprudence, and determined that CMS’ allowance of the Michigan procedure – while not “entirely satisfactory” and producing “an alternate, and more cumbersome, means of subjecting drugs to prior authorization” was nonetheless reasonable and not arbitrary or capricious.<sup>170</sup>

Finally, state attorneys general have sued various drug companies over alleged overpayments, citing violations of state consumer protection statutes and other laws. The sheer breadth of these cases has led to a push for them to be consolidated, and many proceeded in federal rather than state courts. In one of these cases, the judge wrote that while Medicaid is administered by both

the federal and state governments, some of the most central aspects of the Medicaid program that relate to drug companies are federal in nature.<sup>171</sup>

Figure 3 details the moments of federal involvement in the Medicaid program.

**Figure 3: Interaction of CMS, State Medicaid Programs, and Drug Companies**



**340B program**

The 340B program allows certain nongovernmental health centers to purchase drugs at prices similar to prices that state Medicaid programs pay, meaning that the health centers get a discount of 20 to 50 percent.<sup>172</sup> The 340B program is administered by the Health Resources and Services Administration (HRSA), a federal agency within the Department of Health and Human Services.<sup>173</sup> Many different health centers qualify for the program, such as migrant health centers, homeless health centers, family planning centers receiving certain government grants

and contracts, and children's hospitals receiving certain federal funds.<sup>174</sup> About 16,500 health centers were participating in the program as of 2011.<sup>175</sup>

Although the program is separate from Medicaid, if drug manufacturers want their drugs to be covered by Medicaid they must sign an agreement with the Department of Health and Human Services to provide drugs at a discount to 340B health centers.<sup>176</sup> The agreements prohibit drug manufacturers from imposing conditions on the sale of drugs to health centers that are more burdensome than conditions for sale to other entities.<sup>177</sup> According to the GAO, the drug prices in these agreements are set by statute: "In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers."<sup>178</sup>

Health centers are free to negotiate with drug manufacturers to obtain prices below the "ceiling price" set by the agreements between drug companies and the Department of Health and Human Services.<sup>179</sup> The program has no explicit link to formulary development; community health centers set their formularies through their own processes.<sup>180</sup>

According to a 2011 U.S. Supreme Court case, HHS has lacked the authority to ensure that 340B entities are not charged higher than the ceiling price by drug manufacturers. This lacuna led Santa Clara County to challenge the pharmaceutical companies directly, an effort that the Court rejected. The Court noted that the 2010 Affordable Care Act will institute a more streamlined authority to enforce these prices, which would ultimately be reviewable by courts under the Administrative Procedure Act.<sup>181</sup>

## ENDNOTES

- <sup>1</sup> Tucker is research director of Public Citizen's Global Trade Watch. Travis McArthur, a former Public Citizen researcher, co-authored the appendices of this report and provided research on an earlier version of this paper. We thank Sean Flynn, Burcu Kilik, Peter Maybarduk, Mike Palmedo, Bob Stumberg and Sharon Treat for their very helpful comments on an earlier draft of this paper. Section V was updated on June 25, 2012 to remove references to the Australia FTA pending further investigation.
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- <sup>7</sup> Office of the U.S. Trade Representative, "Remarks of U.S. Trade Representative Rob Portman and Australian Deputy Prime Minister and Minister for Trade Mark Vaile, March 7, 2006, Available at: [http://www.ustr.gov/sites/default/files/uploads/speeches/2006/asset\\_upload\\_file478\\_9124.pdf](http://www.ustr.gov/sites/default/files/uploads/speeches/2006/asset_upload_file478_9124.pdf)
- <sup>8</sup> The leaked health care technology section of the TPP is similar to previous trade deals in that its scope is limited to price setting by federal agencies. Medicare's drug benefit is operated by private companies that contract with the federal government, while states are responsible for the functioning of Medicaid programs in their states. In addition, the leaked TPP text places formulary development into the government procurement chapter, so the health care technology section of the TPP may not apply to some parts of the Veterans Health Administration's drug purchasing procedures.
- <sup>9</sup> See Sean M. Flynn, Margot Kaminski, Brook K. Baker, and Jimmy Koo, "Public Interest Analysis of the US TPP Proposal for an IP Chapter," Northeastern University School of Law Research Paper No. 82-2012, December 6, 2011, Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1980173](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1980173)
- <sup>10</sup> Panel Report, *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines*, WT/DS371/R, circulated to WTO Members 15 November 2010m at paras 7.918 – 7.929.
- <sup>11</sup> Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591, at paras 242-246.
- <sup>12</sup> Appellate Body, *U.S. – Measures Concerning the Importation, Marketing And Sale Of Tuna And Tuna Products*, WT/DS381/R, circulated 16 May 2012, paras 235-284. Available at: <http://www.worldtradelaw.net/reports/wtoab/us-tunamexico%28ab%29.pdf>
- <sup>13</sup> See Robert E. Hudec, GATT/WTO Constraints on National Regulation: Requiem for an 'Aim and Effects' Test, 32 *International Lawyer* 619 (1998).
- <sup>14</sup> Panel Report, *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines*, WT/DS371/R, circulated to WTO Members 15 November 2010, at paras 7.899 – 7.900.
- <sup>15</sup> Public Citizen, "Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals," January 2012, at 5 and 6, Available at: [www.citizen.org/documents/investor-state-chart1.pdf](http://www.citizen.org/documents/investor-state-chart1.pdf)
- <sup>16</sup> Jeff Gray, "Apotex challenges U.S. import ban under NAFTA," *Globe and Mail*, March 14, 2012, Available at: <http://www.theglobeandmail.com/report-on-business/international-news/apotex-sues-us-government-over-import-ban/article2369028/>
- <sup>17</sup> Panel Report, *United States – Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada*, WT/DS257/R and Corr.1, 29 August 2003, at paras 7.51-7.60.
- <sup>18</sup> Appellate Body Report, *United States – Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada*, WT/DS257/AB/R, adopted 17 February 2004, DSR 2004:II, 571, at para 87. The AB noted that: "the phrase 'in relation to' implies a comparative exercise, but its meaning is not limited to 'in comparison with'. The phrase 'in relation to' has a meaning similar to the phrases 'as regards' and 'with respect to'. These phrases do not denote the rigid comparison suggested by the Panel, but may imply a broader sense of 'relation, connection, reference'. Thus, the use of the phrase 'in relation to' in Article 14(d) suggests that, contrary to the Panel's understanding, the drafters did not intend to exclude any possibility of using as a benchmark something other than private prices in the market of the country of provision. This is not to say, however, that private prices in the market of provision may be disregarded. Rather, it must be demonstrated that, based on the facts of the case, the benchmark chosen relates or refers to, or is connected with, the conditions prevailing in the market of the country of provision."
- <sup>19</sup> Appellate Body Report, *US – Softwood Lumber IV*, at para 90.

<sup>20</sup> Appellate Body Report, *US – Softwood Lumber IV*, at para. 100.

<sup>21</sup> Appellate Body Report, *US – Softwood Lumber IV*, at para. 108, 118.

<sup>22</sup> Appellate Body, *United States – Definitive Anti-Dumping and Countervailing Duties on Certain Products from China*, WT/DS379/AB/R, 25 March 2011, at paras 444, 446, 456. “the more predominant a government’s role in the market is, the more *likely* this role will result in the distortion of private prices. Moreover, we note that the concept of predominance does not refer exclusively to market shares, but may also refer to market power. . . . we are of the view that an investigating authority may reject in-country private prices if it reaches the conclusion that these are too distorted due to the predominant participation of the government as a supplier in the market, thus rendering the comparison required under Article 14(d) of the *SCM Agreement* circular. It is, therefore, price distortion that would allow an investigating authority to reject in-country private prices, not the fact that the government is the predominant supplier *per se*. There may be cases, however, where the government’s role as a provider of goods is so predominant that price distortion is likely and other evidence carries only limited weight. We emphasize, however, that price distortion must be established on a case-by-case basis and that an investigating authority cannot, based simply on a finding that the government is the predominant supplier of the relevant goods, refuse to consider evidence relating to factors other than government market share. . . . In the present dispute, it seems to us that, given the evidence regarding the government’s predominant role as the supplier of the goods, that is, the 96.1 per cent market share, and having considered evidence of other factors, the Panel properly concluded that the USDOC could, consistently with Article 14(d) of the *SCM Agreement*, determine that private prices were distorted and could not be used as benchmarks for assessing the adequacy of remuneration.”

<sup>23</sup> N. Gregory Mankiw, *Principles of Economics*, Sixth Edition, South-Western Cengage Learning, 2009, at 66.

And Amazon profile of N. Gregory Mankiw, Available at: <http://www.amazon.com/N.-Gregory-Mankiw/e/B001H6Q104>

<sup>24</sup> N. Gregory Mankiw, *Principles of Economics*, Sixth Edition, South-Western Cengage Learning, 2009, at 280.

<sup>25</sup> *Competition*, Merriam-Webster, <http://www.merriam-webster.com/dictionary/competition> (last visited May 25, 2012)

<sup>26</sup> *Consist*, Merriam-Webster, <http://www.merriam-webster.com/dictionary/consist> (last visited May 25, 2012)

<sup>27</sup> *Basis*, Merriam-Webster, <http://www.merriam-webster.com/dictionary/basis> (last visited May 25, 2012)

<sup>28</sup> *Verify*, Merriam-Webster, <http://www.merriam-webster.com/dictionary/verified> (last visited May 25, 2012)

<sup>29</sup> Gretchen A. Jacobson, Sidath Viranga Panangala, and Jean Hearne, "Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies," Congressional Research Service RL33802, April 13, 2007, at 9, Available at: <http://wikileaks.org/wiki/CRS-RL33802>

<sup>30</sup> The Department of Health and Human Services says, “The rebate program was designed to tap Medicaid’s purchasing power by giving the program the same kind of volume discounts afforded to other large purchasers of prescription drugs, thus holding down costs.” The Congressional Research Services says, “The Medicaid rebates were established to achieve a ‘best price’ policy—based on the philosophy that Medicaid as a health coverage program of last resort should have access to the lowest prices offered to other drug purchasers in the market.” U.S. Department of Health and Human Services, "HCFA Releases Study on Medicaid Drug Rebate Program," Press Release, November 8, 1995, Available at: <http://archive.hhs.gov/news/press/1995pres/951108.html>

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<sup>31</sup> See: <http://www.ncpanet.org/pdf/mrileywtestimony.pdf>

<sup>32</sup> “Trans-Pacific Partnership: Intellectual Property Rights Chapter,” September 2011, Available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>

<sup>33</sup> U.S.-Korea Free Trade Agreement, "Chapter Seventeen: Intellectual Property Rights," at page 17-15, footnote 17-16, Available at:

[http://www.ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset\\_upload\\_file469\\_5141.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file469_5141.pdf)

<sup>34</sup> <http://www.merriam-webster.com/dictionary/value>

<sup>35</sup> <http://www.merriam-webster.com/dictionary/appropriate?show=1&t=1335896173>

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<sup>37</sup> This corresponds to the SDR rate of 130,000 in the current U.S. procurement commitments. See:

[http://wto.org/english/tratop\\_e/gproc\\_e/appendices\\_e.htm#taipei](http://wto.org/english/tratop_e/gproc_e/appendices_e.htm#taipei)

<sup>38</sup> See GPA text here: [http://wto.org/english/docs\\_e/legal\\_e/gpr-94\\_01\\_e.htm](http://wto.org/english/docs_e/legal_e/gpr-94_01_e.htm)

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<sup>39</sup> California Senator Liz Figueroa, “Letter to Ambassador Zoellick,” February 16, 2005, Available at:

<http://www.wcl.american.edu/pijip/go/figuera-kuehl2005>

<sup>40</sup> Representative Kevin Ryan et al., “Letter to Ambassador Rob Portman,” Legislative Working Group on Prescription Drugs & Trade, August 20, 2005, Available at: <http://www.wcl.american.edu/pijip/download.cfm?downloadfile=85EBC111-BDD7-A048-CE2E574C4B93D089&typename=dmFile&fieldname=filename>

<sup>41</sup> [http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset\\_upload\\_file899\\_12703.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf)

<sup>42</sup> “A State plan for medical assistance must...either provide for the establishment or designation of a single State agency to administer the plan, or provide for the establishment or designation of a single State agency to supervise the administration of the plan...” (P.L. 89-97 §1902(a)(5), Available at: <http://www.brockport.edu/~govdoc/SocPol/pl89-97c.pdf>)

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<sup>44</sup> Nancy Cordes, “How Obama And McCain Differ On Medicare,” CBS News, October 28, 2008, Available at:

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<sup>51</sup> Library of Congress, "H.R.4: Medicare Prescription Drug Price Negotiation Act of 2007," Available at: <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR00004:@@D&summ2=m&>

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And see

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<sup>98</sup> 8,406-6 Disputes.

(a) Disputes pertaining to the performance of orders under a schedule contract.

(1) Under the Disputes clause of the schedule contract, the ordering activity contracting officer may—

(i) Issue final decisions on disputes arising from performance of the order (but see paragraph (b) of this section); or

(ii) Refer the dispute to the schedule contracting officer.

(2) The ordering activity contracting officer shall notify the schedule contracting officer promptly of any final decision.

(b) *Disputes pertaining to the terms and conditions of schedule contracts.* The ordering activity contracting officer shall refer all disputes that relate to the contract terms and conditions to the schedule contracting officer for resolution under the Disputes clause of the contract and notify the schedule contractor of the referral.

(c) *Appeals.* Contractors may appeal final decisions to either the Board of Contract Appeals servicing the agency that issued the final decision or the U.S. Court of Federal Claims.

(d) *Alternative dispute resolution.* The contracting officer should use the alternative dispute resolution (ADR) procedures, to the maximum extent practicable (see [33.204](#) and [33.214](#)).

<https://www.acquisition.gov/far/html/Subpart%208.4.html>

<sup>99</sup> "Finally, we note that the national formulary is a listing of drugs, not a set of guidelines for their use. The drug that prevails in this competition will be listed on the formulary for VA physicians and pharmacies dispensing a 5HT3 receptor antagonist. How the drug is prescribed, how it is dosed, and which drug is prescribed for which indication, remains within the medical judgment of the VA's treating physician. This is not a requirements contract; the two other 5HT3 drugs will remain on the FSS, and will continue to be available to VA physicians if the contracted item is not the appropriate drug treatment therapy. Further, the record here shows that simply increasing the dosage of a 5HT3 drug--which is the foundation of SKB's argument that the solicitation's PDP evaluation method may not yield the lowest price in practice--may not be the most desirable medical approach to treating high CINV. These facts, unrebutted during this protest, further dilute the possibility that the VA's price evaluation method will fail to reflect the most likely actual cost to the government of using these drugs. Accordingly, without some reason to conclude that the agency's approach will lead to an unreasonable evaluation of the likely cost to the government, and given the fact that the VA lacks data on the percentage of its patients that will need treatment for high, versus moderate, CINV, we have no basis to conclude that the solicitation's intended approach to evaluating prices is improper." See B- 283939 (Comp.Gen.), 2000 CPD P 19 (Comp.Gen.), 2000 WL 85036 (Comp.Gen.) (Matter of: SmithKline Beecham Corporation, 2000).

<sup>100</sup> *Mobile Medical Intern. Corp. v. U.S.*, 95 Fed.Cl. 706, (2010)

<sup>101</sup> <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=792ad0df54ffebc108060b8f403a81c2&rgn=div8&view=text&node=32:2.1.1.8.0.1.20&idno=32>

<sup>102</sup> "Cost-sharing amounts. Active duty members of the uniformed services do not pay cost-shares. For other categories of beneficiaries, cost-sharing amounts are as follows:

(i) For pharmaceutical agents obtained from a military treatment facility, there is no co-payment.

(ii) For pharmaceutical agents obtained from a retail network pharmacy there is a:

(A) \$9.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment per prescription for up to a 30-day supply of a non-formulary pharmaceutical agent.

(D) \$0.00 co-payment for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy there is a 20 percent or \$9.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20 percent or \$22.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(v) For pharmaceutical agents obtained under the TMOP program there is a:

(A) \$9.00 co-payment per prescription for up to a 90-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent."

<sup>103</sup> <http://www.law.cornell.edu/uscode/text/38/8126>

<sup>104</sup> *Coalition for Common Sense in Government Procurement v. U.S.*, 671 F. Supp.2d 48, (2009).

<sup>105</sup> "...under TRICARE's formulary scheme, a committee of health care professionals makes the decision about both the clinical and cost effectiveness of pharmaceutical agents under consideration, and the committee may elect to make that decision without using any dedicated procurement vehicle whatsoever-meaning that the committee can simply import pricing information from existing Federal Supply Schedule contracts, and other relevant pricing information, to inform its formulary decisions." See B- 295888 (Comp.Gen.), 2005 CPD P 98 (Comp.Gen.), 2005 WL 1226132 (Comp.Gen.) (Matter of: Merck & Company, Inc., 2005).

<sup>106</sup> "TRICARE contends that the statute which governs its uniform formulary is not a procurement statute, and points out that even if it canceled its request for BPA price quotations, it could continue with its planned decision about which agents to include on the formulary. ... With respect to the statutory grant of authority to TRICARE to establish a uniform formulary, we agree with the agency that the central purpose of this statute is to task TRICARE with providing pharmacy benefits to its beneficiaries, and with establishing a process for making pharmaceutical agents available to beneficiaries at each of the possible prescription dispensing venues. See generally [10 U.S.C. 1074g](#). For purposes of determining whether our Office has authority to review this protest, however, we believe that the TRICARE pharmacy benefits statute is appropriately viewed as a procurement statute as well. It is abundantly clear that formulary decisions made by TRICARE (at least for MTFs and the TMOP) will lead to the purchase of pharmaceutical agents using the FSS-that is, to procurements of goods by a federal agency. This is precisely the kind of statute which bears directly on a federal agency procurement, even though the statute exists primarily for other purposes. As a result, we have jurisdiction to consider whether the agency is reasonably complying with the TRICARE pharmacy benefits statute, and is conducting the procurement fairly." See B- 295888 (Comp.Gen.), 2005 CPD P 98 (Comp.Gen.), 2005 WL 1226132 (Comp.Gen.) (Matter of: Merck & Company, Inc., 2005).

<sup>107</sup> "Merck's fourth basis of protest is that the agency failed to explain the relative importance of clinical effectiveness and cost in the P & T Committee's evaluation, and that the relative importance of these two considerations had to be identified in the request for price quotations. We disagree. The statute authorizing TRICARE's pharmacy benefits program requires that the agency make decisions about the inclusion of pharmaceutical agents on its formulary based on a consideration of the relative clinical and cost effectiveness of the agents. [10 U.S.C. 1074g\(a\)\(2\)\(A\)](#). There is nothing in the statutory scheme (or in the regulations that implement it) that identifies the relative importance of clinical and cost effectiveness; the statute mandates only that both be considered. Similarly, there is no requirement under the statutory scheme here that manufacturers of pharmaceutical agents be advised of the relative importance of these two considerations."

<sup>108</sup> Coalition for Common Sense in Government Procurement v. U.S., 671 F. Supp.2d 48, (2009).

<sup>109</sup> "Having concluded that the statutory language does not speak to precisely how the Department should implement the statute, the Court ordinarily would move to [Chevron](#) step two, and ask whether the agency's interpretation of the statute is reasonable." Ibid.

<sup>110</sup> Coalition for Common Sense in Government Procurement v. V.A., 464 F.3d 1306 (2006).

<sup>111</sup> Coalition for Common Sense in Government Procurement v. U.S., 821 F.Supp.2d 275 (2011).

<sup>112</sup> Patricia A. Davis, "Medicare Primer," Congressional Research Service report R40425, July 1, 2010, at 1, Available at: <http://aging.senate.gov/crs/medicare1.pdf>

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<sup>114</sup> Department of Health and Human Services, "Medicare Part B (Medical Insurance)", Available at: <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-b.aspx>

<sup>115</sup> Amanda Cassidy, "Coverage and Payment for Prescription Drugs Under Medicare Part B: A Complex Patchwork," National Health Policy Forum, Background Paper No. 70, August 31, 2009, at 6-7, Available at: <http://www.nhpf.org/library/details.cfm/2755>

<sup>116</sup> Amanda Cassidy, "Coverage and Payment for Prescription Drugs Under Medicare Part B: A Complex Patchwork," National Health Policy Forum, Background Paper No. 70, August 31, 2009, at 4, Available at: <http://www.nhpf.org/library/details.cfm/2755>

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<sup>119</sup> Amanda Cassidy, "Coverage and Payment for Prescription Drugs Under Medicare Part B: A Complex Patchwork," National Health Policy Forum, Background Paper No. 70, August 31, 2009, at 8, Available at: <http://www.nhpf.org/library/details.cfm/2755>

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- <sup>167</sup> 42 U.S.C. 1396r-8(d)(5), Available at: [http://www.ssa.gov/OP\\_Home/ssact/title19/1927.htm](http://www.ssa.gov/OP_Home/ssact/title19/1927.htm)
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- <sup>169</sup> *Pharma v. Walsh*, 123 S.Ct. 1855 (2003).
- <sup>170</sup> *Pharma v. Thompson*, 362 F.3d 817 (2004).
- <sup>171</sup> "In this action, West Virginia claims injuries arising from payments for drugs made as part of its participation in the federal Medicaid program. The parameters and requirements of that participation are governed by federal law. See Part II.B, *supra*. The state claims damages resulting from its coverage of the drug Zyprexa. That coverage was mandated by federal law. See [42 U.S.C. § 1396r-8\(d\)\(4\)\(B\)](#). Resolution of the question of the state's obligation to reimburse its insureds for Zyprexa, using funds largely provided by the federal government, is essential to the state's theory of damages and presents a substantial and disputed federal issue under *Grable...*" See *West Virginia v. Eli Lilly*, 476 F.Supp.2d 230 (2007).
- <sup>172</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 2 and 7, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>173</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 2, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>174</sup> Health Resources and Services Administration, "Introduction to 340B Drug Pricing Program," Available at: <http://www.hrsa.gov/opa/introduction.htm>
- <sup>175</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 8, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>176</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 10, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- Krista Maier, "The 340B Program is Not Exempt from the US-Korea Free Trade Agreement," June 29, 2011, Available at: <http://infojustice.org/archives/4050>
- <sup>177</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 13, footnote 29, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>178</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 11, footnote 29, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>179</sup> U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Report GAO-11-836, September 2011, at 11, footnote 29, Available at: <http://www.gao.gov/assets/330/323702.pdf>
- <sup>180</sup> See The Lewoin Group, "Analysis of the Effectiveness of Title X Family Planning Providers' Use of the 340B Drug Pricing Program," October 2009, Available at: <http://www.hhs.gov/opa/pdf/304b-analysis-of-effectiveness.pdf>
- <sup>181</sup> *Astra USA, Inc. v. Santa Clara County*, 131 S.Ct. 1342 (2011).