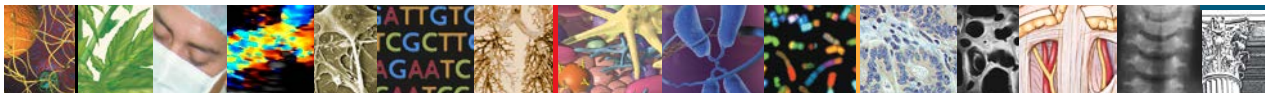

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Perspective

The Trans-Pacific Partnership — Is It Bad for Your Health?

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International trade deals once focused primarily on tariffs. As a result, they had little direct effect on health, and health experts could reasonably leave their details to trade professionals. Not so today.

Modern trade pacts have implications for a wide range of health policy issues, from medicine prices to tobacco regulation, not only in the developing world but also in the United States.

The Trans-Pacific Partnership Agreement (TPP) is a case in point. A massive trade deal now reportedly on the verge of completion, the TPP has nearly 30 chapters. A draft chapter on intellectual property (IP) alone runs 77 single-spaced pages.

The full health implications of the TPP are hard to judge, not only because its provisions are complex but also because the draft text is a closely held secret. Even members of the U.S. Congress can see it only if they agree not to talk publicly about it and if they leave their pens and phones (and, until recently, their expert staffers) at the door. But several key chapters have recently been leaked and reveal that the TPP could have a substantial impact on health.

Groups including Médecins sans Frontières and Oxfam warn, for example, that the agreement could threaten the lives of millions of people in developing countries. Their concerns stem primarily from the leaked IP chapter and the effect that patents have on the prices of medicines. In the context of human immunodeficiency virus, for example, patents increase the annual cost of antiretroviral therapy from around $100 per person to $10,000 per person.

The TPP could impose obligations on developing countries that go far beyond any existing trade agreement. Indeed, some proposals in the leaked IP chapter seem directly targeted against innovative measures that developing countries have used to maximize the use of low-cost generic medicines.

For example, India allows patents on new drugs but not on new uses of old drugs or new forms of known drugs that do not increase therapeutic efficacy. These provisions have paved the way for generic versions of lifesaving drugs such as the cancer treatment imatinib mesylate (Gleevec) in that country.[1] But such limits on patent eligibility could be outlawed by the TPP.

Reports suggest that there may be some kind of phase-in period for developing-country members, but only for some parts of the agreement. And at best, a phase-in period would merely postpone some of the TPP's effects for a few years.[2]

India is not a party to the TPP negotiations, which have been conducted by 12 Pacific Rim countries: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. Why, then, would India's laws — sometimes word for word — be targeted in the TPP negotiations? For one thing, other developing countries have started to follow India's lead. For another, the TPP is a platform agreement designed for other countries to join, and it will establish a new baseline for future international negotiations. The risk regarding access to medicines in developing countries is real.

Though it is less widely recognized, the TPP could also have a direct effect on health in developed countries. For example, the leaked IP chapter contemplates major extensions of "data exclusivity" provisions. These laws prevent drug regulatory agencies like the Food and Drug Administration from registering a generic version of a drug for a certain number of years — and as a result can substantially affect the prices of medicines.

In recognition of this fact, President Barack Obama's fiscal year 2016 budget proposes rolling back the data-exclusivity period for biologic drugs in the United States to 7 years from 12 years, yielding a projected savings of more than $4 billion over the next decade.[3] In the TPP negotiations, however, the United States is proposing a 12-year term of exclusivity. Such a requirement would lock the United States into a policy that many observers, including, apparently, the President himself, believe inflates the cost of medicines unjustifiably. Even if the number of years required by the TPP is negotiated downward, the lock-in effect remains a concern, because trade agreements can be extremely difficult to amend.

The cost of medicines is no small concern in the United States today: spending on prescription drugs in the United States jumped 13% in 2014 alone. The recent experience with new hepatitis C treatments shows that even life-saving cures may be rationed in the United States — whether implicitly or explicitly — if we fail to contain drug costs and promote more efficient innovation. The TPP, however, could make moves toward more rational drug pricing in the United States difficult and even imperil existing provisions that help to contain costs for government programs.

A 2011 "annex" to the TPP, apparently proposed by the United States, would have mandated that all countries use "competitive market-derived prices" or benchmarks that "appropriately recognize the value" of the drug in question when establishing drug prices. A just-leaked December 2014 draft omits these provisions but still contemplates substantial procedural obligations for governments and makes clear that these rules apply to the Centers for Medicare and Medicaid Services (CMS). The text is difficult to decipher and still in flux. But consumer groups argue that the annex could create opportunities for interference in the decisions of CMS and render health programs in all TPP countries more vulnerable to drug-company influence and more difficult to reform.[4]

In March 2015, a third bombshell dropped: a draft chapter on "investor-state dispute settlement" (ISDS). It would empower foreign companies to sue member countries for hundreds of millions of dollars in damages in a wide range of cases in which they argue that their expected future profits have been undermined. These challenges would be heard by "arbiters" — typically private lawyers, many of whom cycle in and out of industry — with no prospect of independent review by a national court. Such provisions have been included in trade agreements before. But the scale of the TPP would substantially increase the number of companies that could bring such challenges. Firms have already used provisions like these to challenge an astonishing range of laws, from minimum-wage laws in Egypt, to tobacco regulations in Uruguay and Australia, to core aspects of patent law as they apply to medicines in Canada. The ISDS provisions alone could interfere with domestic health policy for decades to come. Under their auspices, policies covering a wide range of issues, from food and tobacco labeling, to patent law, to drug-pricing rules, to environmental protection could be challenged in participating countries — including, of course, the United States.

The course that the TPP takes is not yet set in stone. Negotiations continue, and the Obama administration could work toward an agreement that excludes provisions such as ISDS and the health care "annex" or that in-

corporates robust safeguards to protect health. Congress has an important role, too. As of early June, it was in the midst of a fierce legislative battle over whether the TPP and deals like it should be "fast-tracked." If Congress takes this route, its ability to influence the treaty will be much diminished: fast tracking allows passage of a trade treaty with only a simple majority vote in Congress and also denies Congress any opportunity to make changes to the agreement's text.

Much hangs in the balance in the coming weeks and months. If the TPP includes robust ISDS provisions and the expansive provisions proposed in the IP chapter and the health care annex, the United States could be signing away its authority to regulate critical aspects of health policy for years to come.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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