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Transnational Transparency: Why Does it Matter for Global Health

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This paper is part of the "Global Health Inequities: Bridging the Gap" project

Introduction

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• In the days leading up to the announcement of the 2013 Nobel Peace Prize, Edward Snowden and Chelsea/Bradley Manning had both made the shortlist of pundits and the public.[a]

• The Nobel announcement preceded the first ever Global Transparency Week from 24-31 October 2013, an international effort by a group of organizations concerned with increasing openness in aid and development to spotlight how transparency could be used as a tool for accountability.[b]

• Before 1990, only 14 countries had right-to-information (RTI) laws or regulations, but over 90 countries have them today, two-thirds of which were adopted since 2002.[c]

These three developments each signal the rapid emergence of a powerful norm around transparency. Information transparency is widely recognized as a central pillar in good governance. Better access to information can strengthen the accountability of decision-makers, enable broad public debate on critical issues, and address power imbalances. In an era in which technology allows for instant, low-cost, global information flows, RTI policies hold tremendous potential for improving the quality of global governance. However, norms on transparency at the national level have not yet translated into analogous policies or practices at the international level.

a Snowden was listed by some UK-based bookmaking houses (see http://www.nytimes.com/2013/10/11/world/europe/malala-yousafzai-wins-sakharov-prize.html) and Snowden and Manning were front-runners in The Guardian's readers' poll (see: http://www.theguardian.com/world/poll/2013/oct/07/nobel-peace-prize-2013-pick-winner-malala-yousafzai)
b See more here: http://globaltransparencyweek.org/
c Country counts vary depending on how right-to-information policies are defined, but multiple sources concur that the total is over 90. See Toby McIntosh 2011: http://www.freedominfo.org/2011/10/foi-laws-counts-vary-slightly-depending-on-definitions/. For a discussion of how RTI principles can be balanced with national security , see the Tschwane Principles: http://www.opensocietyfoundations.org/briefing-papers/understanding-tshwane-principles. I am grateful to Elina Suzuki for her research assistance on this topic.

Trade

An important example is the world of trade policy, where secrecy seems to carry far greater normative weight than transparency. Intergovernmental negotiations over trade agreements have traditionally been carried out behind closed doors, both at bilateral and multilateral levels. For most of the 20th century, trade agreements primarily addressed technical questions such as tariff reduction schedules, were restricted to the least politically-sensitive sectors, and had limited impact on domestic policymaking.[1] However, since the 1980s Uruguay Round of trade negotiations that created the World Trade Organization (WTO) in 1995, the scope and enforceability of trade policy has increased dramatically. Trade agreements now involve a much broader range of issues of public interest, including workers' rights, environmental protection, and public health. Of particular concern in the public health community has been the impact on medicines prices of intellectual property obligations, whether those contained in the multilateral WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) or bilateral or regional treaties such as ongoing negotiations for a EU-India Free Trade Agreement or the Trans-Pacific Partnership (TPP). Recently, several high-profile challenges to domestic laws in Australia and the US filed at the WTO have also raised concerns that trade rules may restrict national policy space to regulate tobacco.

Despite widespread recognition that trade agreements touch on important questions of public policy, repeated calls from civil society, legislators, and scholars for increased transparency and public review of draft agreements have yet to change practices in a significant way.[d] While the degree of public and parliamentary consultation may have increased,[e] draft texts are still generally not released. The main counter-arguments are that too much transparency would undermine a government's negotiating strategy and also prevent any agreement from being reached, since industries that would be hurt by certain provisions would mobilize against them. The only way to prevent the protectionism that would result, goes the argument, is to shield policymakers from the pressures of industry lobbyists by allowing them to negotiate behind closed doors and strike a deal that would best serve the broader public interest. Such an argument, however, suffers from at least three weaknesses. First, it is common practice to involve industry representatives in trade delegations. Second, it is not only industry lobbyists protecting private interests that may mobilize against a draft agreement, but also broader public interest groups that should be considered legitimate voices in democratic deliberations. Conducting trade negotiations in secret excludes them from participating in these debates. Finally, and relatedly, since trade agreements can create or amend national laws (*de facto or de jure*, depending on the national legal system), basic principles of democratic governance should apply. As US Senator Elizabeth Warren wrote to the

d While countries are likely to have varied approaches to the degree of transparency they adopt in trade negotiations, confidentiality may be required as a precondition of joining certain trade talks, which can then override pre-existing domestic policies favoring transparency. Negotiating parties to the TPP have agreed to keep all documents related to the negotiation confidential throughout the process (http://www.ustr.gov/about-us/press-office/fact-sheets/2012/june/transparency-and-the-tpp). Such confidentiality may be used to block the release of documents under freedom-of-information requests. See, for example, USTR refusal to release documents they had classified as confidential, in response to a Freedom of Information Act request from the Center for International Environmental Law in 2000 regarding negotiations for a Free Trade Area of the Americas, a decision that was upheld by a federal court: http://earthjustice.org/sites/default/files/FOIA.USTR13-06-07DCCirOpinion.pdf

e See descriptions of various approaches to transparency by the US (http://www.ustr.gov/about-us/press-office/fact-sheets/2012/june/transparency-and-the-tpp) and EU (http://trade.ec.europa.eu/doclib/docs/2013/june/tradoc_151381.pdf

US Trade Representative on the TPP, "I have heard the argument that transparency would undermine the Administration's policy to complete the trade agreement because public opposition would be significant. If transparency would lead to widespread public opposition to a trade agreement, then that trade agreement should not be the policy of the United States."[2]

The norm of confidentiality has its roots in an earlier era of trade policy. Yet such outdated norms continue to shape practices today. For example, the WTO TRIPS Council is restricted to governmental delegations and does not allow civil society or journalists even to observe the proceedings. The TRIPS Council is not a negotiating body creating new deals, but rather is charged with monitoring TRIPS implementation. Thus, even the main argument for why proceedings must be kept out of the public-eye – to protect delicate negotiations – does not hold. That said, it is important to note that the discussions are not shrouded in secrecy - a summary of the meeting is made available online by the Secretariat, minutes of the meetings are published several months later, and well-connected reporters or advocates can often get access to information much sooner.[f] Nevertheless, the practice highlights one way in which the norm of confidentiality, rather than transparency, continues to permeate trade policymaking.

With the increasing integration of the global economy, the types of public health issues likely to be affected by trade agreements will continue expanding. In addition to access to medicines and tobacco, trade agreements can impact food and nutrition policies, the regulation of toxins and pollutants, policies intended to combat climate change, and the cross-border provision of medical services, among others. At the same time, it is important to recognize that change has been possible. For example, access to information on the WTO (e.g. meeting minutes, disputes, dispute resolution decisions, and even some draft negotiating texts) has improved considerably, particularly in response to critiques regarding a democratic deficit in how it operates. But, with the exception of leaked texts and the occasional *ad hoc* release of draft text – which are a far cry from a system of democratic accountability – the negotiation of new trade rules remain a tightly guarded process. And plurilateral negotiations outside the WTO are far more secretive. Improving the transparency of the trade system will be critical for strengthening the protection of public health within the global economy.

Investment

The global trade system has attracted significant critical attention, but in many ways, there is reason for greater concern regarding the global investment regime. One reason why it hasn't yet attracted such scrutiny may

f For example, summary of October 2013 meeting available: http://www.wto.org/english/news_e/news13_e/trip_10oct13_e.htm

be precisely because of the high degree of secrecy with which it operates. Unlike the trade regime, there is no central multilateral institution like the WTO for the global investment system. Efforts to create a multilateral agreement governing cross-border capital flows have not succeeded, and in its place has emerged a web of over 3100 bilateral, regional, or plurilateral investment treaties and other trade or economic agreements containing investment chapters (generally referred to as International Investment Agreements, IIAs).[3] Countries also seek new investment provisions in agreements such as the EU-India FTA or the TPP.

IIAs are agreements between governments, but generally allow a private party (an investor) to sue the state in which an investment was made for alleged violations of the IIA through "investor-state dispute settlement (ISDS)" arbitration processes. National laws, regulations or policy decisions that can potentially decrease the value of an investment – including but not limited to public health policies –have been challenged as violations of such agreements. ISDS can take place at a number of international arbitration bodies established for the purpose, with the most frequently used being the International Court for the Settlement of Investment Disputes (ICSID) housed at the World Bank. Cases are generally decided by a panel of three arbitrators who frequently come from law firms that also represent clients in other IIA cases, creating potential conflicts of interest.[4,5] The investment regime has recently attracted concern within the global health community because it has been used by firms to challenge national health-related policies: in 2010 tobacco firm Philip Morris sued the governments of Uruguay and Australia over expected losses linked to their domestic laws on cigarette packaging[6]; in 2013 pharmaceutical firm Eli Lilly sued the government of Canada under NAFTA for $500 million over court decisions that invalidated patents on two of its drugs.[7]

The functioning of the investment regime has been critiqued on a number of grounds,[8,4] but most relevant here is that major aspects of its functioning are carried out behind closed doors. IIAs often give investors a choice between several sets of arbitration rules, and investors may choose which ones to apply to a particular dispute. Thus, policies and practices vary, but some overall practices dominate (For a more detailed discussion, see Johnson and Bernasconi-Osterwalder 2013[9]): for example, some rules permit the mere existence of a case to be kept confidential, such that the public may not even be aware that a domestic law has been legally challenged at an international tribunal. The proceedings are generally confidential and documents related to a dispute may also be kept out of the public domain. The final arbitration decision may also be kept confidential, even if it requires awards of large sums of public money (rewards have reached $1.77 billion and claims can exceed a $100 billion) or spurs changes to national laws. Nor are arbitrators bound by the precedent set by other tribunals or cases, providing significant leeway to a handful of individuals to make decisions with major public policy consequences behind a veil of secrecy. There has been a significant increase in (known) cases, from a handful per year in the 1990s to 30-50 per year over the past decade.[4] However, because of the confidentiality surrounding cases and the lack of a single tribunal or body of investment law, it is not publicly known how many cases have been filed, on what topics, and with what outcomes. Thus, public scrutiny of particular cases, treaties, or the overall system is very limited.

There have been some important efforts to increase the transparency of the system: A few countries – most prominently the US and Canada – have adopted transparency requirements in the IIAs that they

negotiate.[10] And in 2013 the UN rules under which some arbitration takes place were amended to address a number of the abovementioned concerns.[g] However, while the new rules are quite progressive, these rules will only apply to treaties concluded after April 2014 and may only apply to new cases arising under existing treaties if the state parties proactively adopt them.[9] Nevertheless, the normative shift reflected in the rules is significant – Johnson and Bernasconi-Osterwalder characterize it as "a shift in the underlying presumption toward openness, rather than privacy."[9] However, the extent to which the system will in fact become more transparent remains unclear. And many disputes arising under IIAs may use entirely different arbitration rules that have no transparency requirements. Thus, despite these important steps forward, overall, the lack of transparency in the ISDS system should remain a serious cause for public health concern.

Pharmaceutical R&D

Transparency is not only an issue in transnational policy processes, such as the trade and investment regimes discussed above, but also in the practices of private actors that have significant public health impact. Of particular relevance for global health are the R&D processes for new health technologies such as drugs, vaccines, diagnostics and other medical devices (referred to as "medicines" for brevity). Two important elements of the R&D process are not publicly-disclosed by the pharmaceutical industry: the outcomes of all clinical trials and the specific R&D costs associated with a product, each of which is discussed in turn below.

Clinical trials:

A few public health advocates have long decried the industry practice of withholding negative clinical trial results from the public domain. This practice means that the body of published information on a product is likely to be positively skewed, painting an inaccurate and too rosy picture of the risks and benefits of a medicine. Concern over this issue has led to some measures, such as calls for registration of the existence of clinical trials in public databases[h] backed by a 2005 policy adopted by the International Committee of Medical Journal Editors (ICMJE) to only publish results of trials that have previously been registered. However, studies have found that these measures are neither enforced[11] nor adequate to ensure that negative results, in particular, are published. While the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) has issued a position statement on registering and publishing clinical trial results, the position lays out voluntary norms and also makes exceptions for information that might harm the competitive advantage of a firm – presumably, negative results could fall under the broad umbrella of this clause.[i] The past year has seen increasing mo-

g FSee 2013 UNICTRAL Rules on Transparency, available here: http://www.uncitral.org/pdf/english/texts/arbitration/rules-on-transparency/pre-release-UNCITRAL-Rules-on-Transparency.pdf

h One of the most widely-used registries is clinicaltrials.gov, hosted by the US government. WHO has also created an international database through the International Clinical Trials Registry Platform to facilitate searching national databases at http://apps.who.int/trialsearch/

i See "Joint Position" statement at http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/November_10_2009_Updated_Joint_Position_on_the_Disclosure_of_Clinical_Trial_Information_via_Clinical_Trial_Registries_and_Databases.pdf

mentum pushing regulatory authorities to publish clinical trial results to which they have access following the 2012 publication of medical journalist Ben Goldacre's book "Bad Pharma,"[12] which reported that half of trial results have not been published, and has helped to raise public awareness of this issue. The All Trials campaign (led by a coalition of health and research organizations) is driving a new push at the UK and EU levels for mandatory public disclosure of all clinical trial results. At the European Medicines Agency (EMA), a draft policy has been developed to disclose all clinical trial data it holds starting in January 2014. Pharmaceutical companies AbbVie and Intermune have sued the EMA to block release of such data, but on the other end of the spectrum, GlaxoSmithKline has voluntarily offered to publish all its clinical trial data. The EMA policy and GSK's decision signal the possibility of increasing the transparency of a system whose opacity has for decades gone virtually unchallenged – and suggests that the transparency norm is indeed a powerful tool for change.

R&D costs:

While the price of patented drugs has long been an issue of public concern, industry has kept an important component of that price – the R&D cost of a particular medicine –a tightly-guarded secret. Studies on average R&D costs have produced estimates of over $1 billion per drug,[13,14] but have also attracted considerable controversy,[15,16] such that there is little agreement on average R&D costs, let alone on costs for a particular product. Public-private product development partnerships (PDPs) focusing on neglected diseases have been somewhat more transparent about costs, given that the bulk of their funding comes from public or philanthropic sources; however, such data are not necessarily applicable to broader R&D processes beyond the special case of commercially-unattractive neglected diseases. In general, reliable data on R&D costs remains elusive. R&D costs are an important piece of data for several reasons: first, R&D costs can help policymakers (e.g. health technology assessment centers) and the public decide on what is a "fair" price for a medicine to ensure the dual goals of efficient use of healthcare funds (whether public or private) and a fair reward for inventors. Second, a more accurate understanding of average R&D costs can help to design appropriate public policies to pay for, incentivize and reward research in a way that is more efficient and/or equitable than the status quo, including alternatives to monopolies such as prizes or patent buyouts. This issue becomes even more important in light of recent debates among WHO Member States on how countries should share the joint burden of financing R&D.[j] Third, a transparent accounting of R&D investments can clarify when important contributions have come from publicly-financed research, such as government grants or academia – which in turn may inform public decisions on pricing. All of these reasons, however, imply a shift in negotiating- and decision-making power from private to public hands, and it is perhaps no surprise that industry has tightly-guarded its R&D costs. While governments have a strong incentive and the authority to require disclosure of R&D costs and investments, none has yet done so. Fortunately, recent progress on increasing the transparency of clinical trial results suggests that similar measures should be possible for R&D costs if there is sufficient political will.

j See WHO Consultative Expert Working Group 201217

Proposals for change

These critiques of the trade, investment and pharmaceutical R&D systems are not new. But the importance of transparency has arguably not received the attention within the global health community that it should. Here are three simple, interlinked proposals for how to tap into the growing power of the transparency norm in governance:

1. "Transparency in all policies"
Civil society organizations (CSO) and health campaigners could consider including a transparency plank in every advocacy platform – that is, to advocate for increased transparency regarding inputs and processes of policymaking in all issue areas (e.g. trade, investment, pharmaceutical R&D, food & nutrition, alcohol, environment, taxation, etc.).[k] The authority of governments to mandate transparency in the practices of both public and private actors should not be underestimated.

2. Stronger right to information policies at national level
There is considerable variation among the 90-some countries that have adopted RTI policies. Such policies can include the periodic release of documents, procedures for information requests, justification for any denial of such requests, and appeals procedures. In countries with weak RTI laws, advocates could push to strengthen them. There are also over 100 countries that have not yet adopted such laws, with Latin America, Asia, Africa and the Middle East (in descending order from least to furthest behind) lagging behind Europe and North America.[l] Advocates should push for the strongest possible RTI laws in these countries.

3. Stronger right to information policies at international institutions:
Stronger transparency policies at national level will surely translate into more transparency at the intergovernmental level – but that is not likely to be enough. Yet, with several important exceptions (notably the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria and the World Bank[m]) major international institutions such as the World Health Organization, Global Alliance for Vaccines and Immunization, World Trade Organization, International Monetary Fund and World Intellectual Property Organization do not have RTI policies. Member States and civil society should push for intergovernmental organizations with important implications for health to adopt strong RTI policies and to operate on the presumption of transparency as the baseline. In some cases, RTI policies at the international level may also help to address weaknesses or the absence of such policies at national level. Adopting RTI policies is likely to strengthen the political legitimacy of international institutions, and to help them achieve their public interest goals.

k For a useful example of how transparency can be assessed, see the Global Accountability Reports (2003-2008) of the One World Trust: http://www.oneworldtrust.org/publications/cat_view/65-global-accountability-project/83-main-reports
l See http://right2info.org/access-to-information-laws/access-to-information-laws-overview-and-statutory#_ftnref7
m See the Global Transparency Initiative, which focuses on transparency at international financial institutions: http://www.ifitransparency.org/

Conclusions

This paper has argued that transparency is critical for global health by offering three illustrations: closed-door negotiations over trade agreements, which can contain provisions that are harmful for public health; secretive investor-state dispute settlement processes of the global investment regime, which can tie the hands of governments to regulate for health; and pharmaceutical R&D, where lack of transparency can lead to skewed information on drug safety and efficacy, and provide a justification for unaffordable pricing. These are certainly not the only areas where transparency matters for health, but they illustrate the types of issues at stake.

The mere existence of an RTI policy does not guarantee disclosure of the relevant information – pro-active use of such policies by civil society, journalists and academics is a crucial piece of the puzzle.[n] And even when transparency and information are available, they are not in and of themselves enough to change the status quo. Nor is perfect information transparency in all cases realistic or necessarily desirable. But in an increasingly interconnected world, they are – as Snowden reminded us – formidable tools for change that should be adopted more systematically in policymaking processes that impact global health. In light of the many intractable challenges in protecting health in global governance processes, the growing strength of the transparency norm means that broader adoption of RTI policies is relatively low-hanging fruit.

n See a useful compilation of information on implementation of the US Freedom of Information Act here: http://www.wcl.american.edu/lawandgov/cgs/about.cfm

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