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SYMPOSIUM ON INDUSTRY ASSOCIATIONS IN TRANSNATIONAL LEGAL ORDERING

INDUSTRY, REGULATORY CAPTURE AND TRANSNATIONAL STANDARD SETTING

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In this essay I discuss the rise in industry's participation in transnational standard setting, which implicates transnational legal ordering,[1] and address the risks such participation generates: Economic globalization has led to increased demand for transnational standards. Yet regulators lack the expertise needed to write increasingly complex and rapidly changing standards, and turn to those that hold the expertise: industry. Thus, industry engagement in standard setting has clear benefits. Such engagement introduces, however, a problem well known from the national context: the risk of capture. In the context of standard setting, two kinds of capture are of particular importance: (i) information and (ii) representational capture. The consequence of such capture, in the transnational context, is that it may (i) undermine the global public interest, (ii) lead to unfair competitive advantages, and (iii) undermine the public interest in developing countries. I illustrate these risks with examples from health law and policy. While states have national laws to manage capture (albeit not effectively at times), at the transnational level, organizations are largely free of such legal constraints. As the "new frontier" of standard setting, transnational bodies should introduce reforms for balancing the benefits and risks of industry engagement, otherwise, they risk impairing the public interest and undermining trust in their integrity.

The Rise in Industry Participation in Transnational Standard Setting

In the past two decades, industry's participation in transnational standard setting has increased: Intergovernmental organizations, traditionally limited to member governments, have opened up to nonstate actors, including industry.[2] Industry also increasingly collaborates alongside other actors in public-private partnerships (e.g. ICANN[3]), transgovernmental regulatory networks (e.g. FATF[4]), and private standard setting bodies (e.g. GlobalG.A.P.[5]).[6]

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[1] *See* Terence C. Halliday & Gregory Schaffer, *Transnational Legal Orders*, *in* TRANSNATIONAL LEGAL ORDERS 3 (Terence C. Halliday & Gregory Schaffer eds., 2015).

[2] JONAS TALLBERG ET AL., THE OPENING UP OF INTERNATIONAL ORGANIZATIONS (2013).

[3] *See* ICANN.org.

[4] *See* FATF-GAFI.org.

[5] *See* GlobalG.A.P.org.

[6] Kenneth W Abbott et al., *Organizational Ecology and Institutional Change in Global Governance*, 70 INTERNATIONAL ORGANIZATION 247 (2015).

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This rise in industry's participation is linked to the rising demand, since the 1990s, for transnationally harmonized standards, and the growing dependency, in turn, on industry expertise. With trade liberalization, explicit trade barriers imposed at the border, such as tariffs, have fallen, and many transnational initiatives have focused on harmonizing differences in regulations or standards. This has led to the rise of new transnational bodies (e.g. Basel Committee on Banking Supervision[7]), and bolstered existing ones (e.g. ISO,[8] which in its first fifty years (1947–1997), issued about the same amount of standards as it has since 2000). With the increasing complexity of products and markets, and their rapid change, their effective regulation and standardization requires expertise which industry has, but which regulators find difficult to keep up with. This expertise gap has driven regulators to increasingly engage industry in their transnational standard setting initiatives.[9]

The Risks of Industry Engagement

While industry engagement is beneficial in overcoming the expertise gap, such collaboration introduces the risk—well known from the national context—of regulatory capture.[10] Whereas national laws manage capture (although often ineffectively), transnational standard setting's growing engagement with industry is, for the most part, carried out without a parallel framework for managing the risks associated therewith. If not properly managed, I argue, these developments could undermine the public interest, or impair public trust in transnational institutions.

In what follows I note the main risks of industry involvement in transnational standard setting. I first address the "input" stage, that is, the stage at which decisions regarding standards are made. I then address the consequences of capture. I illustrate these risks with examples from health law and policy.

Input

Capture is often equated with corruption, but actually, in the context of standard setting, capture is often caused legally, at the "input" stage. That is, it is caused at the decisionmaking stage, through the one-sided provision of information, resulting in information and/or representational capture.

Information capture

Capture may be caused subtly through the provision of information, or so called "information capture." The information imbalance between regulators and industry, and the consequent dependency of the former on the latter, empowers industry to influence standards, and tilts the outcome toward industry interests. Thus, as policy becomes more complex, and regulators become more dependent on industry, there is a higher likelihood that standards will be biased towards industry preferences.[11]

[7] *See Basel Committee on Banking Supervision*, Bank for International Settlements.

[8] *See* International Organization for Standardization.

[9] *See also,* Melissa J. Durkee, *Industry Lobbying and "Interest Blind" Access Norms at International Organizations*, 111 AJIL Unbound 119 (2017).

[10] George Stigler, *The Theory of Economic Regulation*, 2 Bell J. Econ. & Mgmt. Sci. 3, 21 (1971).

[11] Daniel Carpenter & David A. Moss, *New Conceptions of Capture - Mechanisms and Outcomes*, *in* Preventing Regulatory Capture: Special Interest Influence and How to Limit It 69(Daniel Carpenter & David A. Moss eds., 2013). Nolan McCarty, *Complexity, Capacity, and Capture*, *in* Preventing Regulatory Capture: Special Interest Influence and How to Limit It 99, 102 (Daniel Carpenter & David A. Moss eds., 2013).

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Representational capture

Representational capture occurs when there is an imbalance in the representation of the competing interests, such as between commercial and public interests. In such cases, a regulator is at higher risk of adopting an industry friendly point of view if the only people that it hears from, or primarily hears from, are industry members.[12]

In practice, transnational bodies are selective in granting stakeholder participation, which suggests that representational capture could be a considerable risk, if not managed mindfully. The recent OECD report "International Regulatory Cooperation: The Role of International Organizations in Fostering Better Rules of Globalisation" surveys fifty international organizations and shows that most select which stakeholders are entitled to engage in their rulemaking.[13]

Moreover, participation is often formally open to commercial and noncommercial actors alike, but in practice, industry representation outweighs public interest representation. Take the Codex Alimentarius Commission,[14] which develops international food standards: Membership in Codex is limited to states, but allows NGOs "observer status."[15] Codex doesn't distinguish between NGOs representing commercial interests and those representing the public interest and, formally, either type may become observers.[16] In practice, however, industry NGOs vastly outweigh NGOs representing public interests, such as of consumers.[17]

Thus, Codex is commonly perceived as an industry dominated organization, and at risk of "representational capture." One case that plausibly reflects the power of industry interests over the public interest is the case of genetically modified food labelling. The labeling of such food has been debated for twenty years in Codex, and most opposition has reflected the power of the biotechnology and food industries' interests.[18] It is only recently that the consumer opinion on labelling has been adopted.

A second example concerns public-private partnerships: Recent evidence shows that these partnerships do not escape power asymmetries between commercial and noncommercial interests.[19] For example, IMPACT—The Partnership for Safe Medicines, is a partnership whose purpose is to combat counterfeit drugs, which is a serious public health problem in developing countries.[20] Critics point out that the industry (mis-)uses the partnership to

[12] Sidney A. Shapiro, Testimony before the Sub-committee on Administrative Oversight and the Courts of the Senate Committee on the Judiciary; Hearing on Protecting the Public Interest: Understanding the Threat of Agency Capture 4 (2010).

[13] OECD, INTERNATIONAL REGULATORY CO-OPERATION: THE ROLE OF INTERNATIONAL ORGANIZATIONS IN FOSTERING BETTER RULES OF GLOBALISATION (2016).

[14] *See What is the Codex Alimentarius?*, Codex Alimentarius.

[15] *See Principles concerning the participation of International Non-Governmental Organizations in the work of the Codex Alimentarius Commission*, Codex Alimentarius.

[16] *See also*, Durkee, supra note 9.

[17] Consumers International, Codex Alimentarius Commission Governance in Brief (2005); Sanderjin Duquet & Dylan Gereats, *Food Safety Standards and Informal International Lawmaking*, in INFORMAL INTERNATIONAL LAWMAKING: CASE STUDIES 395 (Berman et al. eds., 2012).

[18] Elizabeth Smythe, *In Whose Interests? Transparency and Accountability in the Global Governance of Food: Agribusiness, the Codex Alimentarius, and the World Trade Organization*, *in* Corporate Power in Global Agrifood Governance 107 (Jennifer Clapp & Doris Fuchs eds., 2009).

[19] Kent Buse & Gill Walt, *The World Health Organization and Global Public-Private Health Partnerships: In Search of "Good" Global Health Governance*, *in* Public Private Partnerships for Public Health 169, 185 (Michael R. Reich ed., 2002).

[20] *See Impact*, The Partnership for Safemedicines.

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shape IMPACT policies to push industry's IP enforcement agenda.[21] Such focus on IP enforcement risks undercuts the focus on public health risks.

Effects

Information or representational capture is rarely illegal, but it can nevertheless lead to significant, and at times devastating, consequences. Once transnational standards are set, national regulators and other private actors will often adopt and apply them or otherwise follow them. Thus, as Gregory Shaffer points out, transnational standards may have an impact at the national and local level, and generate state change.[22] In the context of industry involvement in transnational standard setting, three kinds of potential changes, or effects, warrant special attention:

(1) Effects on the "global" public interest.

(2) Effects on competitive advantage among industries.

(3) Effects on the public interest in developing countries.

In what follows I address each of these three consequences, and provide examples of cases that demonstrate the potential risk of unregulated industry engagement in transnational standard setting.

Global public interest

The first consequence of capture is that it may lead to rules that prioritize private gains over the "global" public interest in say health,[23] the environment, or financial security. To the extent regulators or other private actors adopt such standards at the national level—as they often do[24]—transnational standards may undermine the public interest in such countries.

Take, for example, the case of the WHO, in which industry has often attempted to influence standard setting.[25] For example, the Tobacco industry infamously undertook many activities, including using stakeholder consultation, to undermine the WHO's tobacco control initiatives and influence policies (consequently, now any WHO engagement with the tobacco industry is altogether banned).[26] It was also revealed that the International Food and Beverages Alliance (IFBA),[27] an alliance of the world's largest food and beverages companies, including Coca Cola, Pepsico, Nestle, and McDonalds, had been trying to influence regulations that—as part of the campaign against noncommunicable diseases—recommend ceilings on sugar intake, or set restrictions on sugary drinks.[28] In the case of the swine flu pandemic, there were accusations that the WHO was influenced by the pharmaceutical

[21] KM GOPAKUMAR & SANGEETA SHASHIKANT, UNPACKING THE ISSUE OF COUNTERFEIT MEDICINES 19, 22–26, 33 (2010).

[22] Gregory Schaffer, *Transnational Legal Process and State Change*, LAW AND SOCIETY INQUIRY, 2012.

[23] The Lancet-University of Oslo Commission on Global Governance for Health, *The Political Origins of Health Inequality: Prospects for Change*, 383 THE LANCET 630 (2014).

[24] Shaffer, *supra* note 22, at 21.

[25] *See* WORLD HEALTH ORGANIZATION.

[26] Kent Buse & Chris Naylor, *Commercial Health Governance*, *in* MAKING SENSE OF GLOBAL HEALTH GOVERNANCE (Kent Buse et al. eds., 2009); Heide Weishaar et al., *Global Health Governance and the Commercial Sector: A Documentary Analysis of Tobacco Company Strategies to Influence the WHO Framework Convention on Tobacco Control*, 9 PLOS MED. (2012).

[27] *See* IFBALLIANCE.ORG.

[28] Rema Nagaranji, *How Food, Beverage Giants Influence WHO Rules*, THE TIMES OF INDIA (May 22, 2015, 04:05 AM).

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industry in its decision to recommend the purchase of the vaccine, that key scientists involved in the WHO pandemic planning were funded by pharmaceutical firms that stood to gain from the guidance they were drafting, and that the WHO did not publish the conflict of interest.[29]

Competitive advantage

Standards impose requirements that affect the costs of production and service, and thus generate distributional consequences. Representational capture may be used to garner, through standards, a competitive advantage over nonrepresented competitors: There is a likelihood that participating industries will provide information that tilts standards towards their interests, to the detriment of their competitors.

The International Conference on Harmonization (ICH) provides a good example.[30] The ICH is a network of drug regulators and the commercial, patent drug industry associations from the United States, the European Union, and Japan (i.e., FDA[31], PHRMA,[32] EFPIA,[33] and JPMA[34]). The purpose of the ICH is to develop harmonized standards for market approval of newly developed, *patented*, medicines.

Originally, ICH standards were intended for assessing new commercial (*patented*) drugs. In practice, however, regulators also assess copy-cat (*generic*) drugs according to ICH standards. ICH standards are high and put a significant cost burden on the generic sector—a poorer sector than the patent industry. Experts agree that applying ICH requirements to generics—given their "copying" nature—is unnecessary and scientifically unjustified.

ICH standards, therefore, impede generic drug manufacture, and put the generic industry at a disadvantage.[35] This effect has become more important in the past two decades as the generic drug market has significantly grown. ICH standards, therefore, generate distributional effects which benefit the "insider" patent industry and negatively affect the "outsider" generic industry, which does not have a seat at the table. Despite a recent governance reform granting the generic industry new participation rights, the generic industry is far from enjoying an equal status to the patent industry.[36]

Public interest in developing countries

Transnational standards are often set by "clubs" of developed countries, which are captured by their industries. They may be clubs because a limited set of states are members, or, in practice, a limited set of states de facto make the decisions in what formally are universal international organizations. Either way, such "club" standards often embed the interests of particular national industries. Despite being set by a "club," such standards are often followed by a much broader set of countries, including developing countries. Consequently, standards designed to cater to developed country industry interests are applied in developing country settings, which have different needs and interests. This mismatch and misalignment of interests may cause detrimental effects on the public interest in developing countries.

[29] Deborah Cohen & Philip Carter, *Conflicts of Interest: WHO and the Pandemic Flu "Conspiracies"*, BMJ (June 3, 2010); Zosia Kmietowicz, *WHO Admits to "Inconsistencies" in its Policy on Conflicts of Interest*, BMJ, (June 15, 2010).

[30] *See* ICH.org.

[31] *See* U.S. Food and Drug Administration.

[32] *See* PHRMA.org.

[33] *See* EFPIA.eu.

[34] *See* JPMA.or.jp.

[35] WHO, The Impact of Implementation of ICH Guidelines in Non-ICH Countries (2002).

[36] *ICH Announces Organisational Changes*, ICH.org (Oct. 26, 2015).

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ICH standards have indirectly led to the reduction in the development of drugs for neglected diseases: Neglected diseases are tropical diseases endemic in low income populations in developing countries. Drugs for such diseases are not developed by the drug industry but through noncommercial initiatives, due to the absence of a commercial prospect. ICH standards were written by drug regulators and industry for authorizing *commercial* patent drugs in *developed countries*. Nevertheless, because of a certain dynamic of incentives (which go beyond the scope of this essay), in practice, *noncommercial drug developers* are required to follow them as well, which has led, in turn, to a reduction in drug development for neglected diseases.[37] Scientists have been calling for "sensible" guidelines which would adapt ICH standards to noncommercial settings, but in the meantime, the situation remains.[38] Thus, ICH standards—embedding the interests of the developed country patent industry—indirectly (and perhaps unintentionally) undermine the public interest of developing countries in drugs for neglected diseases.

The Future: Finding the Right Balance

The examples above are mostly from the field of health policy, but industry participation prevails in many policy fields, and the risks are similar. The challenge before us is to find a solution that strikes a balance between the benefits and risks of industry engagement. Standard setting has shifted from the national to the transnational level, and has thereby left behind national legal constraints on industry participation. If the "new frontier" of standard setting is to stay responsive to the public's interest, transnational bodies need to be reformed to this end.

Currently, most transnational bodies have opened to stakeholder engagement, but do not properly regulate or oversee the attached risks. Most bodies are oblivious to the negative externalities they have on outsiders, and on the broader public interest. Some organizations, however—concerned about public trust—are introducing reforms. Such reforms, if they prove to be effective, may serve as a source of inspiration for other transnational bodies. Notably, the WHO adopted in 2016 the Framework of Engagement with Non-State Actors.[39] Among other reforms, it introduces a welcome distinction between different types of nonstate actors and manages the interaction with each differently. Interaction with industry is now covered by the overarching framework and the Policy and Operational Procedure on Engagement with Private Sector Entities.[40] The Global Fund to Fight AIDS, Tuberculosis and Malaria [41] issued in 2015 a new Code of Ethical Conduct for Governance Officials which states that in case of conflict, the Global Fund's interest in putting an end to AIDS, tuberculosis, and malaria should prevail over board members' (including industry's) interests.[42] Further, Codex has introduced a Codex Trust

[37] Trudie A. Lang et al., *Clinical Research in Resource-Limited Settings: Enhancing Research Capacity and Working Together to Make Trials Less Complicated*, 4 PLOS Neglected Tropical Diseases 619 (2010); Thomas Bollyky et al., *Bridging the Gap: Improving Clinical Development and the Regulatory Pathways for Health Products for Neglected Diseases*, 7 Clinical Trials 719, 727 (2010); Salim Yusuf, *Damage to Important Clinical Trials by Over-Regulation*, 7 Clinical Trials 622 (2010); Nicholas J. White, *Clinical Trials in Tropical Diseases: A Politically Incorrect View*, 11 Tropical Med. & Int'l Health 1483 (2006); Patrice Trouiller et al., *Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?*, 6 Tropical Med. & Int'l Health 945 (2001).

[38] Trudie Lang et al., *Clinical Research: Time for Sensible Global Guidelines*, 377 The Lancet 1553 (2011).

[39] *See* Sixty-Ninth World Health Assembly, Framework of Engagement with Non-State Actors (May 28, 2016).

[40] *See id.*

[41] *See* GLOBALFUND.org

[42] *See* The Global Fund, Code of Ethical Conduct for Governance Officials, art. 3b.

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Fund to strengthen developing country capacity to participate in standard setting.[43] Transnational bodies should likewise proactively reach out to stakeholders representing noncommercial, public interests to assure their meaningful participation. Finally, transnational bodies should be aware of the effects, even if unintended, that their standards have on developing countries, and assist in adapting rules sensible to the needs of those states. The EU's impact assessment guidelines, which require regulators to assess the impacts of EU rules on developing countries, could serve as an initial source of inspiration for the design of such a mechanism.[43]

In the absence of compliance mechanisms, one may wonder how effective, if at all, such frameworks could be. To overcome this gap, transparency could play a vital role: More transparency about whom organizations interact with, and what they interact about, could induce better behavior. The WHO is trying to improve transparency by setting up an Internet-based, publicly available WHO Register of Non-State Actors, which should include "high level descriptions" of the engagement WHO has with these actors.[44] The EU Transparency Register, which allows the public to search for information about the groups and organizations with which the European Parliament and European Commission interact, takes a similar approach.[45]

[43] *See Codex Trust Fund*, World Health Organization.

[44] *See European Commission Impact Assessment Guidelines*, SEC (2009) 92 (Jan. 15, 2009).

[45] *See WHO Register of Non-State Actors*, World Health Organization.

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