COUNCIL on FOREIGN RELATIONS

International Institutions and Global Governance Program

POLICY INNOVATION MEMORANDUM NO. #48

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Re: Designing a Global Coalition of Medicines Regulators

Globalization has transformed the marketplace for medicines in recent decades, giving rise to new threats including the poor traceability of global supply chains, counterfeit and substandard medicines, and antibacterial resistance. Aware that public drug authorities must cooperate to meet the emerging challenges of modern medicines regulation, the U.S. Food and Drug Administration (FDA) has been discussing with counterpart agencies abroad creating a "global coalition of regulators." Yet a coalition alone is not enough; the devil, as always, will be in the details. In pursuit of this goal, the FDA and partner medicines regulatory agencies should design a coalition with five distinct features: *narrow scope,* to promote realistic goals; *flexibility,* to adapt to future circumstances; *selective membership,* to maximize like-mindedness, particularly in the early stages; *nongovernmental (NGO) participation,* to leverage the capacities of both NGOs and for-profit corporations; and *institutional partnerships,* to orchestrate the activities of other regulatory organizations.

MEDICINES OVERSIGHT IS INCREASINGLY COMPLEX IN A GLOBAL CONTEXT

Since the early 1990s, firms and products have proliferated in the global drug market, leading to stiffer competition and pressures to improve productivity. Drug companies have adapted by outsourcing a large share of services to other countries. Their reliance on tens of thousands of foreign subcontractors has resulted in an acutely segmented supply chain. Medicines may be processed, packaged, sold, and resold multiple times before reaching consumers. For regulators, it can be difficult to ensure the safety of drugs before they hit pharmacy shelves. As a result, the global supply is vulnerable to a host of threats that can have deadly consequences. In 2007 and 2008, fraudulent doses of heparin, imported from China, killed at least 149 Americans. Even when the effects are not fatal, adulterated therapies can intensify illness, introduce new health concerns, or lead to costly delays in recovery. Such cases of deadly or ineffective medicines will likely become more frequent in the absence of more effective global regulation.

For national regulatory authorities, enforcing a safe and secure medicines sector is no longer a singularly domestic undertaking. The FDA, for instance, is supposed to regulate products destined for the U.S. market originating in roughly

300,000 manufacturing facilities located in over 150 countries. But neither the FDA nor any other national regulatory authority has the capacity to fulfill this remit on its own. According to a 2010 U.S. Government Accountability Office report, it would take the FDA eighteen years to inspect all registered manufacturing firms in China just once. This point underscores the fact that most foreign facilities have never received a single inspection from the FDA, and never will, if the status quo persists. Tackling these concerns requires strong multilateral cooperation among national regulatory agencies.

To this end, a handful of international institutions and initiatives populate the regulatory space. These include the Pharmaceutical Inspection Cooperation Scheme (PIC/S), International Conference on Harmonization (ICH), and International Pharmaceutical Regulators Forum (IPRF). These schemes operate within specific, technical mandates and, since they perform their respective tasks well, should not be the focus of unnecessary reforms. At the same time, such specialized entities leave critical areas of regulation unattended. What has been missing from the institutional landscape is a high-level, strategic body capable of coordinating these and other existing regulatory approaches, closing the policy gaps among them, and proposing solutions to emerging challenges not currently addressed. Doing so would also empower a body to assume responsibility for new and pressing commitments, including harmonizing medicines standards, establishing coordinated monitoring systems, and building capacity in countries that need it most.

HOW TO DESIGN A GLOBAL COALITION OF REGULATORS

As the world's premier national regulatory body for medicines (and food), the U.S. FDA is ideally positioned to facilitate a multilateral coalition composed of heads of medicines agencies. Yet the success of any such institution hinges on its initial design. Getting it right the first time is critical, since institutions are notoriously resistant to change. More than a few regulatory arrangements have been hobbled by design flaws. A case in point is the International Organization of Securities Commissions, a network of domestic securities authorities that has struggled to harmonize standards because its large membership (124 agencies) and consensus decision-making rules impede cooperation. To improve the odds of success, the FDA and its counterparts should incorporate five design features into a coalition of medicines regulators:

- *Narrow scope*. The global coalition should identify select issues it could reasonably address with the resources and expertise at its disposal, and where it can add value. When it comes to medical products, top priorities include: harmonizing standards; increasing monitoring capabilities in jurisdictions where the production of drugs is burgeoning, such as China and India; and helping to build capacity in countries with weaker regulatory authorities. Only after the coalition has begun to attain these objectives should it consider expanding its remit to other issues, such as tackling barriers to generic drug access or scaling up the FDA's Secure Supply Chain pilot program—a voluntary initiative that expedites the entry of imported drugs for firms meeting designated security criteria.

- *Flexibility*. The supply chain for medicines will evolve in unexpected ways, as will the policy preferences of national medicines agencies. Therefore, it is important to design a coalition that can adapt its mission, membership, and mandate to future circumstances. First, coalition members should pursue soft approaches rather than treaty-based solutions because they are easier to negotiate, even if rules become "harder," or more detailed, over time. Examples of soft law are principles, action plans, and recommendations, such as those published by the Financial Action Task Force. Second, if decisions cannot be reached by consensus, a majoritarian voting system would help overcome obstacles to action and improve responsiveness. Electing members to the governing board, adopting a strategic plan, or urgently responding to a public health crisis are different scenarios in which voting may prove useful. Third, building mechanisms for self-evaluation beyond annual reports, such as requiring the coalition to renew its mandate every five years, can encourage its members to revisit and revise institutional goals.

- *Selective membership*. Initially, the coalition should maintain a selective membership of approximately twenty jurisdictions representing willing and capable regulatory leaders. This modest size will allow members to more easily identify actionable goals while accelerating plans to meet them. Meanwhile, the coalition should consider its future target membership, in order to forecast preferences down the line. This means that even if the body is mainly

composed of advanced market democracies, it should from the outset also include rising powers integral to the global medicines trade and its regulation. The cast of members should encompass the Group of Seven (G7), including the European Union; a handful of (non-G7) industrialized countries that have shown leadership in global regulation, including Australia, Ireland, the Netherlands, and Singapore; and critical rising powers, namely Brazil, China, India, South Africa, Nigeria, and Indonesia. Once established, the coalition should open its doors to any country committed to upholding high domestic health standards and assuming part of the global regulatory burden.

- *Nongovernmental participation.* Full membership in the coalition should be limited to national regulatory agencies, since they represent the public interest. Still, nonstate actors possess unique capacities in global regulation, which the coalition should leverage. For example, firms are best suited to monitor their own supply chains. Likewise, NGOs bring an independent voice to policy debates and can serve as effective watchdogs. The best option would be to institutionalize participation of industry actors and NGOs within the coalition, as observers or affiliate members. Regulators would retain ultimate authority, but the coalition would regularly draw on their input. Criteria for firms should include contributions to drug innovations and a strong commitment to pharmacovigilance—detection, analysis, and prevention of adverse drug effects. Criteria for NGOs should involve evidence-based philanthropic work and a record of consumer advocacy. Limiting firm and NGO involvement to five members apiece would allow leaders to hear diverse opinions without undermining public interest. An alternative option is to establish a parallel network, detached from the coalition, to set standards and undertake activities complementing the coalition's work.

- *Institutional partnerships.* Finally, the coalition should avoid the pitfall of assuming the entire regulatory burden itself. Rather than trying to replace regulatory bodies that are working well, the coalition should aim to steer, shape, or "orchestrate" their work. This can be done through formal or informal partnerships, whereby the coalition either coordinates its activities with organizations that implement programs or realizes common goals by lending financial and political support, such as through grants, office space, joint forums, or high-level endorsements. Such measures might eventually involve regional harmonization efforts (e.g., African Medicines Regulatory Harmonization program) or relevant private standard-setting bodies (e.g., Health Level Seven International, which focuses on electronic health information). Initially, however, coalition leaders should collaborate with organizations that share similar memberships, such as the Summit of Heads of Medicines Regulatory Agencies, a forum for exchanging information. This would minimize policy differences and provide a testing ground for future partnerships.

Building consensus to launch a coalition should not present any major obstacles as the FDA and foreign counterpart agencies are already exploring plans to create a new global regulatory authority. Nonetheless, implementing these policy proposals will require political dexterity. The coalition must provide a clear path to membership for developing countries that initially remain outside the body. One option is to create tiers of membership linked to regulatory capacity, establishing criteria for graduation and mobilizing development assistance to help countries do so. Similarly, nonstate actors will expect a clear and fair set of criteria for their participation. Failing to meet these demands may reduce the strategic role of the coalition and diminish its legitimacy. Moreover, consumer groups may argue that collaboration with the private sector exposes policymakers to regulatory capture, as agencies place private interests above public interests. However, historical lessons from many sectors suggest that regulatory capture is more likely when regulators interact with firms on their own terms and within their own bureaucracies, without the transparency afforded by participation of peer agencies.

These five recommendations are no panacea. Still, they should vastly improve the existing patchwork of disjointed institutions sprawled across the regulatory landscape. More important, they represent a critical first step toward a strategic and nimble network of medicines regulatory authorities, capable of harnessing the strengths of current efforts while also creating new rules to ensure the security of the global supply chain. A global coalition of regulators, buffered by these prescriptions, would enhance consumers' confidence in their medicines, reduce cases of counterfeit and substandard drugs entering the global supply chain, and potentially save taxpayers money by leveraging the resources of other countries and institutions. The stakes are high, given the growing risk to public health. But so, too, are the incentives and opportunities for cooperation, because all countries—and all people—rely on a supply of safe medicine.

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