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Medical R&D Convention Derailed: Implications For The Global Health System

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Abstract

Potentially game-changing proposals to improve access to medicines have been stalled by the member states of the World Health Organization (WHO). In April 2012, the WHO Consultative Expert Working Group on Research and Development (CEWG) concluded that one way to address market failures in medical research and development (R&D) for diseases affecting the poorest populations was to negotiate a Medical R&D Convention¹ (CEWG, 2012). This could lead to sustainable change within financing, monitoring and coordination of R&D rather than just trying to mend the existing system (Røttingen & Chamas, 2012). To the disappointment of some states and many civil society actors, a recent meeting of the WHO suspended the negotiations (Love, 2012).

While some consider the global economic climate unable to support a convention that would require significant time and funding, we demonstrate that the current global health system has failed once more to address one of the most pressing global health challenges of our time. In this commentary, we show how thwarted attempts to develop an R&D convention have spurred our call for fresh debate on the viability of the very foundations of the current global health system.

Background to the Medical R&D Convention

Discussions on an R&D convention date back 14 years. In 1999, the Neglected Diseases Group (NDG), an independent working group set up by Médecins Sans Frontières (MSF) to address diseases which disproportionately affect poor populations and receive little or no R&D attention, began discussing a hard law approach to change the medical R&D paradigm (Torreele, Usdine, & Chirac, 2004). The WHO acknowledged that “a significant proportion of the world’s population, especially in developing

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¹ The Medical R&D Convention has had many names including biomedical and development, global health, public health and an essential health treaty. There is no clear consensus but for the purposes of this article we chose to use Medical R&D Convention to reflect its goal of specifically addressing market failures in medical R&D.

countries, has yet to derive much benefit from innovations that are commonplace elsewhere” (World Health Organization, 2003). In 2004, the World Health Assembly (WHA) approved the creation of Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) (WHO, 2006).²

Civil society actors publicly challenged the trade framework for R&D (Hubbard & Love, 2004) and the NDG proposed an Essential Health R&D Treaty (Dentico & Ford, 2005; Tallaksen, 2005). CIPRH concluded that the R&D convention proposal needed further work, but agreed that the current drug development system could not respond to global health needs because R&D priorities were steered by commercial incentives (WHO, 2006). The proposal for a convention passed to the Expert Working Group on R&D Financing (EWG) for further analysis. Established by the WHA in 2008 to examine financing and coordination of R&D and proposals for innovative sources of funding, the EWG process marked the beginning of a chain of governance failures which led to this critical global health proposal being shelved.³

Critical Failures in the Global Health System

As the R&D convention proposal moved officially into the state arena, three critical flaws in the global health system became apparent. Firstly, there was evidence that the R&D agenda was being co-opted by the pharmaceutical industry. While civil society worked to defend and explain the proposal that was based on decades of efforts to treat patients with neglected diseases and research into solutions, an R&D convention was controversial. Among the critics were pharmaceutical companies and their allies who considered that the R&D convention’s proposal to de-link medicine prices from R&D costs undermined patents and jeopardized the corporate bottom line (Stevens, 2004).

Evidence of industry co-optation appeared. A storm broke out when the EWG met industry, but not public interest groups. The storm intensified when confidential EWG documents were leaked to industry representatives a month before publishing the report (Mullard, 2010). Several member states, such as Bolivia and Thailand, publicly expressed their disappointment over the process and the outcome of the EWG (Bolivia, 2010; Shashikant, 2010). The EWG recommendations were subsequently rejected by the WHA in 2010 because “there was divergence between the expectations of Member States and the output of the Group” (WHA63.28, 2010). While this rejection was a positive step, the WHA failed to implement a systematic buffer to prevent the risk of industry co-optation. As a result, controversy soon returned, this time in the form of the appointment to the newly created CEWG of an industry representative who had authored a proposal submitted to the discredited EWG (Saez, 2011; WHA63.28, 2010).

Secondly, there was a lack of WHO global health leadership on the R&D convention. This resulted in ambivalence and political power struggles, and eventually led member states to stall their own process. While the CEWG recommended intergovernmental negotiations for an R&D convention (Røttingen & Chamas, 2012), some states were hesitant. The United States, for instance, despite being the single largest funder of neglected diseases research (Hotez, Cohen, Mimura, Yamada, & Hoffmann, 2013), stated it would not “support any proposal that would put in place a new financing mechanism that could be characterized as a globally collected tax” (Carter, 2012). In November 2012, WHO member states convened an open-ended meeting on the CEWG recommendations. At 2 a.m. on the last day, 25 member states worked behind closed doors to draft a resolution for the WHA (PHM, 2013) which would postpone discussions on an R&D convention until 2016 (Love, 2012; WHO, 2012). Despite

² Civil society and some low and middle-income countries (LMICs) actively advocated for the CIPRH. See T. Hoen, *The Global Politics of Pharmaceutical Monopoly Power*, AMB 2009.

³ The Expert Working Group was constituted under resolution WHA 61.21.

strong recommendations not to re-open the R&D convention debate (WHO, 2012), states at the WHO Executive Board (EB) in January 2013 expressed concerns about the draft but were told to “fight it out” at the WHA 2013 (Balasubramaniam, 2013).

The failure of the WHO to fulfill its own recommendation on an R&D convention casts doubt on the ability of the WHO and its member states to work in the best interests of vulnerable populations (KEI, 2013). Despite the WHO’s legitimacy as the directing and coordinating authority in global health, it has continually shied away from providing leadership to promote collective action for global health (Gostin & Mok, 2009). Some view the demand for WHO leadership as a paradox, given that it challenges the principle of state sovereignty entrenched in the current global health structures (Jamison, Frenk, & Knaul, 1998). While the recent shelving of the R&D convention appears to confirm that, it also demonstrates that the CEWG recommendations represent a fundamental challenge to the current global health system.

The final critical flaw of the global health system is its limitation on civil society participation. In stark contrast to the inclusive and transparent process promoted by the CEWG, the intergovernmental process to discuss the CEWG recommendations shut civil society out of both policy and decision-making processes. While discussions at the WHA are open to non-governmental organizations with official relations at the WHO, civil society were excluded from all but the first morning session of the open-ended meeting (Hermann, 2012; New, 2012a, 2012b). Systemic barriers to inclusive processes, transparency and accountability for civil society suggests a system with a serious democratic deficit (Steffek, Kissling, & Nanz, 2007).

Moving to a New Paradigm: A Fresh Debate

The majority of states and global health scholars accept the sovereignty and ultimate responsibility of states in national and global health governance, as set out in the Treaty of Westphalia, 1648 (Ng & Ruger, 2011). However, others claim we are witnessing a non-state-centric post-Westphalian model characterized by broad unstructured participation of a plurality of states and non-state actors working together to develop policy in a non-hierarchical model of governance (Aginam, 2004; Burris, Drahos, & Shearing, 2005). They posit that, out of necessity, international health institutions need to find ways to shed characteristics of state-centricity (Fidler, 2007).

The fate of the R&D convention demonstrates the need to move away from a purely state-centric governance model. The increasing evidence of co-optation of global health by the pharmaceutical industry and the limits on civil society participation demonstrate that the multiple, and often competing and conflicting, interests of states stand in the way of effective global agreements. The process reveals a lack of leadership from the WHO which remains accountable to member states, not populations. A global governance system that enables the WHO to negotiate the multiple and conflicting sovereign interests of member states and that actively resists co-optation of the global health agenda by the private sector would open the way to a more effective leadership role. Such leadership, grounded in social justice and equity, would be able to drive progress towards a global agreement. Meanwhile, public interest and social justice continue to play second fiddle to market-driven priorities.

While this reality may suggest that declarations of a post-Westphalian state are premature (Ricci, 2009), this should not obscure the critical role played by synchronized civil society and academic

voices. The R&D convention only made it so far in the global health system because of the considerable innovative capacity and tireless efforts of civil society actors. Increasingly, states recognize that they need civil society actors to innovate and implement global health policies. Yet, while the landscape may contain many different actors, ultimately decisions are made by powerful states wielding their political and economic power. The systemic defect is that there is no accountability or transparency in decision making either to civil society champions nor to the people who stand to benefit.

Conclusion

We draw two main conclusions. Firstly, the state-centric global health system is continually failing to achieve critical global health advances. Secondly, when the R&D convention comes back onto the negotiation table, actors need to make sure it can rise above the limitations inherent in such a state-centric instrument to avoid relegation to yet another international instrument dependent on “political will” to operate.

This commentary aims to launch a broader debate. One of the authors, for example, is proposing a multicentric global governance for health that would embrace a post-Westphalian nodal governance model where state and non-state actors, including private interests, have clear authority and co-extensive, mutually accountable relationships (Kiddell-Monroe, 2013). We believe this concept can provide a platform to launch a debate which moves beyond attempts to tinker with a failing system (Lee, 2010). To begin an innovative and fresh debate, the key is to accept the existence of systemic global health failures and look beyond the outmoded state-centric model to find innovative ways to address global health needs. A multicentric approach is just one idea; we hope this commentary will stimulate more.

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