Providing Global Public Goods: Non-State Actors, States and the WHO facing the Challenge of Neglected Diseases

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Abstract
Knowledge is a classical public good: there is no rivalry in consumption and – once the good is provided – nobody can be excluded from consumption. In modern societies, however, the transformation of “pure” knowledge into the development of marketable products, basically works through private actors. In many domains, like in the production of medicines, the production of technical knowledge is expensive and those who invest it do so in the anticipation of a reasonable rate of return. The protection of intellectual property rights and the grant of monopoly rights for exclusive economic use of an intervention for a determined period has been a compromise solution through which societies combined the access to knowledge with the chance to refinance the costs of innovation.

A patented product can only become a public good, if society guarantees access to this good (e.g. through a comprehensive health system) and, what is usually the case, patented medicines can be produced cheaply and without restrictions. This constellation has led to conflicts about access to medicines broadly debated in the global health governance discourse. In the case of neglected diseases, the situation is different, as the “neglect” is expressed in the lack of existing knowledge. These diseases are not seen as a public problem in rich countries, poor countries lack the financial resources and research capacities to create the knowledge necessary for effective treatment and pharmaceutical producers do not see any effective monetary demand which could raise expectation for a reasonable return on their investments.

Since the 1990s, however, the global concern for neglected diseases and the lack of knowledge related to their treatment and prevention has greatly increased. This paper will look at the institutional changes at the background of these processes and tries to understand, whether a global public has developed which takes over responsibility in the transnational space for providing global public goods related to (formerly?) neglected diseases. I will focus in particular on the interaction between global society forces and international state actors, primarily WHO, in (1) the foundation and management of public-private partnerships, (2) the process of transnational norm building, (3) the development towards the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and (4) the discourse on alternative incentives (e.g. prizes) for the production of knowledge.

Talking about responsible decision-making of a global public and power-relations which allow an implementation of global rules in the transnational space of fighting neglected diseases, links, the World Health Organization, “the directing and co-ordinating authority on international health work” (WHO constitution) to the forces of a growing global society.
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Introduction

“Neglected diseases” are diseases on which expenditures on R&D had been small due to a lack of private incentives as affected persons or countries have low (if any) purchasing power in health.

The famous 10/90 gap (roughly: 10% of worldwide expenditure on health research and development is devoted to the problems that primarily affect the poorest 90% of the world's population) is traced back by the Global Forum for Health Research to 1990, when the Commission on Health Research for Development estimated that only about 5% of the world's resources for health research (which totalled US$ 30 billion in 1986) were being applied to the health problems of low- and middle-income countries, where 93% of the world's preventable deaths occurred. (www.globalforumhealth.org/layout/set/print/About/10-90-gap). A very recent article uses a quite different term of comparison: with less than 1/10,000th “of the costs of producing and maintaining a nuclear arsenal the 11 nuclear powers could eliminate most of their neglected diseases and engage in joint neglected disease research and development efforts” (Hotez 2010: 1). These data give an idea about the inequity of effort in global health research and health expenditures, but, of course, they can be questioned if they are taken at face value. ¹ In section 1 I will look a bit deeper into the issues related to the definition of neglected diseases.

In general, it can be expected – and has been supported by the report of the Commission on the Social Determinants of Health (CSDH) – that this neglect of investing resources into fighting the respective diseases, reflects processes of exclusion which also negatively affect human development in other forms: It has been frequently shown that those diseases which are most neglected in terms of the research and development of medicines are those which predominantly occur in poor areas with not only a lack of medical care, but with various conditions of poverty related to all the dimensions of basic needs (low income, lack of access to sanitation and clean water, lack of access to adequate housing and education). Fundamentally, it seems to be more adequate to talk of “diseases of poverty” than of “tropical neglected diseases”.

On the other hand, since the 1990s, activities to fight neglected diseases have grown considerably: A large number of research-oriented public-private partnerships (PPPs) have been founded, much more financial resources have been invested in this field, and with the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) and the CSDH, WHO has pursued a policy to support the capacity to fight neglected diseases, in particular in the context of the “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”. Recently, WHO published a report which observed important improvements in this field (WHO 2009).

There can be no doubt that the neglect of research on widely distributed diseases because of a lack of effective monetary demand is an important infringement of the human 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (International Covenant on Economic, Social and Cultural Rights (ICESCR) Art. 12.1), which includes ‘The prevention, treatment and control of epidemic, endemic, occupational and other diseases’ as well as ‘the creation of conditions which would assure to all medical service and medical attention in

¹ One has to take into account that there is even no broadly accepted definition of “neglected diseases” in terms of specific diseases; if one uses a very restricted definition (see e.g. Stevens 2004: only three diseases and related to deaths instead of disease burden), results may be quite different.
the event of sickness’ (Art. 12.2) (http://www.unhchr.ch/html/menu3/b/a_cescr.htm). The Committee on Economic, Social and Cultural Rights (CESCR), which was established to carry out the monitoring functions assigned to ECOSOC in the Covenant, in 2000 adopted a 20-page document on ‘The right to the highest attainable standard of health’.2 This General Comment obliges State parties ‘… to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs’ and ‘to ensure equitable distribution of all health facilities, goods and services’. The discourse on neglected diseases suggests that we also need a reference to “essential medical research” as without research & development there are no “essential drugs to be provided”.

This would imply that the continuous improvement of medicines and vaccines in all relevant medical fields – i.e. including the formerly neglected diseases – is seen as a global public good. If we assume that the problem of universal access to existing medicines might be solved by a combination of health systems development and differential pricing for medicines (including the option to issue compulsory licenses) supported through pressure from a globalizing civil society (Hein 2010, Moon 2010), the questions still remain of how priorities for research & development should be set and which mechanisms would assure their implementation.

In this paper I will pursue this issue by dealing with the following problems:

(a) What exactly are neglected diseases? What characterizes their neglectedness? Why do we frequently found the combination “neglected tropical diseases”? Are we primarily talking about neglected diseases or neglected people?

(b) What does it change to the problem, if we consider knowledge on neglected diseases Global Public Good (GPG)? Who determines which knowledge is created? Who is setting incentives for research in neglected diseases? Who is looking for the public interest in global society when research is a global affair, but state regulation is limited to national spaces. Is there an emerging global public? Is it reasonable to expect stable compromises between incentives for private profits (IPRs) and norm-based interventions for guaranteeing the delivery of the public good?

(c) Why has there been an increasing global interest in this field, considering the fact that (most) “neglected diseases” are not particularly threatening for rich countries? Is there a growing fear of other diseases spreading like HIV/AIDS? Or that infectious diseases in general might again be a growing problem in rich countries? Is their a growing political threat from uncontrolled, impoverished? Or do ethical aspects and increasing advocative action due to global social integration play a growing role?

(d) How can we assess the progress reached on these diseases in the last two decades? Is there a chance for inter-/transnational actors to guarantee through collective action the provision of prevention, medicines and treatment according to contemporary medical standards, i.e. the supply as a global public good? What is the role of global civil society, public-private partnerships and other global health initiatives? Has WHO initiated a process (CIPIH+CSDH; Intergovernmental Working Group on Public Health, Innovation and Intellectual Property; Global Strategy and Plan of Action) which is based on the necessary normative authority (formal legitimacy plus broad normative acceptance) to guarantee the provision of a GPG?

(e) Though it is ethically difficult to declare research on particular diseases or medical problems “non-essential”, there is a need to develop criteria other than expected monetary returns for discussing priorities of medical research. A prize system has been proposed as an alternative (or complement) to the patent system, to give more weight to human needs.

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What is a “neglected disease”? Dimensions of “neglectedness”

The simplest and at least most unequivocal way to define “neglected diseases” certainly is by making a list. Then, the criteria for inclusion or exclusion of specific diseases are of vital importance, while other more flexible criteria are not taken into consideration. WHO focuses on 13 tropical diseases.

Zacher and Keefe (2008) present an Appendix (A), which distinguishes between diseases prevalent in both, “developed and developing regions” and those only prevalent in developing regions (Table 3) and furthermore, diseases with effective vaccines and drugs, diseases with effective vaccines, but no drugs; diseases with effective drugs but no vaccines and diseases with neither effective vaccines nor drugs (Table 4). Implicitly these distinctions refer to “neglect” in terms of a lack of successful pharmaceutical research.

The review PloS (Public Library of Science) Neglected Tropical Diseases gives detailed references about which topics they include in the PloS NTD Series, i.e. which they consider relevant for the NTD topic (http://www.plosntds.org/static/scope.action, the PloS NTD “Journal Scope”). This includes a similar, but somewhat more detailed list of diseases as the WHO brochure, and refers to various social and political aspects linked to the attribute “neglected” and summarized in the definition given on the same web-page: The NTDs are defined as a group of poverty-promoting chronic infectious diseases, which primarily occur in rural areas and poor urban areas of low-income and middle-income countries. They are poverty-promoting because of their impact on child health and development, pregnancy, and worker productivity, as well as their stigmatizing features.

These definitions might be useful to circumscribe a particular type of diseases hitting in particular poor people in poor countries, but they tend to be tautological, including one main proposition already in the definition (the neglect of NTDs tends to increase poverty) and passing over the distinction between “neglected people” and “neglected diseases”. The final report of CIPIH discusses the typology of diseases introduced by the Commission on Macroeconomics and Health (CMH):

“Type I diseases” are incident in both rich and poor countries, with large numbers of vulnerable population in each…. Many vaccines for Type 1 diseases have been developed in the past 20 years but have not been widely introduced into poor countries because of cost.

Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries…HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in poor countries.

Type III diseases are those that are overwhelmingly or exclusively incident in the developing countries,…Such diseases receive extremely little R&D, and essentially no commercially based R&D in rich countries…

Type II diseases are often termed neglected diseases and Type III diseases very neglected diseases. …Our remit is to cover the range of diseases and conditions that currently affect developing countries, from Type I to Type III, taking into account of those that will increase in importance in coming decades. The criterion should be diseases or conditions of significant public health importance in developing countries for which an adequate treatment does not exist whatsoever, of because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable.” (CIPIH 2006: 25f.; original emphasis)

According to WHO 2009, the World Health Organization focuses on the following 13 diseases: Buruli ulcer; Chagas disease; dengue/ dengue haemorrhagic fever; dracunculiasis (guinea-worm); Human African trypanosomiasis; Leishmaniasis; Leprosy; Lymphatic filariasis; Onchocerciasis; Schistosomiasis; soil-transmitted helminthiasis; Trachoma; zoonotic diseases. Further diseases are proposed for “an expanded list”.
In this paper, I will focus on the “capability to treat a specific disease” as a global public good for health. This means, a disease is neglected if investments in the development of these capabilities are disproportionately small compared to the burden of that disease measured in (global) disability-adjusted life years (DALY’s) lost. A broad-based research group published around 2000 a number of articles on the situation of drug development for neglected diseases, looking not only on existing drugs but also on the progress levels reached at the developments of new drugs (Trouiller et al. 2001; Trouiller et al. 2002). They stated that “substantial advances in molecular biology and pathophysiology … are not translated into new products directed at the needs of patients” (Trouiller et al. 2002: 2190). In this article the authors also calculated for groups of diseases and the period between 1975 and 1999 the number of new chemical entities per DALY (for typical chronic diseases between 1.25 and 1.44, while for tropical diseases the ratio is 0.1. The ration for drug sales (in mio. US$) by DALY is 307 for non-infectious respiratory diseases, but only 3 for the average of tropical diseases (op.cit.: 2189).

There is no use restricting the use of the term “neglected diseases” to tropical diseases, in particular as most of the so-called tropical diseases are not restricted to the tropics because of bio-climatic characteristics (Malaria has been endemic in the Netherlands and North-Western Germany until the 19th century; Labisch 2002; the Chagas disease and Trachoma are endemic in many non-tropical countries; and quite a number of “neglected diseases” are spreading in the US (Hotez 2009). I also do not include the problematique of access to existing medicines which has led to quite different conflicts and political compromises and certainly has been an aspect of the neglect of the poor people concerning medical care but not of the neglect of diseases.

(2) Intellectual property rights link knowledge production to monetary demand but not to human needs: How can research on neglected diseases be delivered as a GPG?

Although the issue of neglected diseases is frequently touched in publications on IPRs and access to medicines, most analyses concentrate on the links between the patent-based monopoly prices and the capacity of poor countries (or global governance actors) to pay for treatment.

‘Universal access to essential medicines’ appears as a norm of growing importance in the IPR conflicts since the turn of the Millennium. Related to existing medicines (result of R&D due to large markets in High Income Countries)\(^4\). The field of neglected diseases is linked to the globalization of a profit-based system of pharmaceutical R&D, but not directly to the operation of IPRs.\(^5\) A public innovation system also would have to worry about R&D costs, but it would not assess the need for research in terms of demand in monetary terms.

In the high-income countries medicines have been basically developed and provided for treatment combining both models: Basic medical knowledge is developed through publicly funded research producing universally accessible results, while research & development for medicines is carried out by private companies, which are able to refinance costs due to monopoly rights based on patents. Depending on the concrete features of national health systems (and due to the relative negligibility of production costs of medicines compared to the costs of R&D) most

\(^4\) In 1977, WHO introduced its “model list on essential medicines” in order to improve the access to lower-priced generics in developing countries – at that time contested by various conflicts with transnational pharmaceutical companies (TNPCs). Since the mid-1990s, basically related to ARVs, new groups and coalitions of actors, however, have helped to bring the ‘access to essential medicines’ norm into the centre of global health conflicts

\(^5\) This paper is part of a preparation of a research project, which will ask to what extent and how far transnational networks have stimulated and stirred this process, whether the discursive power of civil society organisations have been able to improve the substance and meaning of this norm, whether is has proven to be effective to implement at least one dimension of the human right to the “highest attainable standard of physical and mental health”, and, finally, whether its informal character has helped in the process of norm implementation. (see Hein 2010)
essential medicines can be treated in these countries as public goods. And – what is important concerning the challenge of neglected diseases – research focuses basically on those diseases which are considered to affect a society most seriously.

This is different in the case of diseases which primarily affect poor countries: Neither do these countries have the option to direct significant public research to these diseases (due to a lack of research capacities and a lack of financial resources) nor can sufficient monetary demand be expected for medicines if they were successfully developed by private corporations. An interesting aspect of the whole issue consists in the fact that the typically “neglected tropical diseases” stay neglected even if they occur with a considerable impact in rich countries. (see Norman et al. 2010; on various infections in the US see Hotez 2009: 2).

Thus, in the logics of a profit- (and patent-) based system of drug development, the problem is not to explain why private pharmaceutical corporations invest little in R&D to develop medicines against this kind of diseases, i.e. why they became neglected, but actually why this should have changed. The stories about available medicines against the sleeping sickness (Human African Trypanosomiasis) illustrate the lack of interest of the industry and are frequently told: Melarsoprol contains an arsenic compound which results in the death of 4 to 8% of the patients treated; Eflornithine was introduced in 1977 against Trypanosoma, then taken from the market for lack of profitability and later reintroduced to remove unwanted facial hair (Masocha; http://www.scienceboard.net/community/perspectives.178.html). Now the drug is manufactured and distributed freely by Sanofi-Avensis in association with WHO and MSF.

There can be no doubts about a significant human need for R&D for neglected diseases (about a billion people hit by them) and the implications of the ESC human rights on “Essential Health R&D” (see Hotez & Pécoul 2010). also concerning the importance of international cooperation (ICESCR, Art. 11) and in recent years a growing discourse on “extraterritorial obligations” has developed. The question of implementing human rights norms like the ‘right to health’ (to use the short form) has not only been a difficult task because of its huge dimensions but also because of a lack of political determination; to some degree the dimensions of the challenge were in fact used as a legitimization of the second point.

In this context, the distinction between primary and secondary (or subsidiary) norms is important. Primary norms are those norms laid down in binding international legal instruments, while secondary norms are those designed to make sure that primary norms are in fact observed. In a world of sovereign nation states this is not an easy task and it took the UN International Law Commission (ILC) about 45 years to produce in 2001 “Draft articles on Responsibility of States for internationally wrongful acts”. In many cases, the determination of “wrongfulness” demands an authoritative interpretation of the international law concerned, which is a central part of the somewhat broader concept of secondary norms by Herbert Hart (1973: 115ff.)8. Concerning ESC human rights, this has been done by the CECSR in the form of various “General Comments”, regarding health, it is the General Comment No. 14 quoted above. The conception of secondary norms also provides a link to the concept of global public goods: The provision of essential

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6 The term “essential health R&D” has been introduced in November 2005 by Kenya into political debates at WHO on measures to follow-up the Report of the Commission on Intellectual Property Rights, Innovation and Public Health. The term alludes to the concept of “essential medicines” as used by WHO in its “Model List on Essential Medicines” (see n. 4), to which the ‘General Comment No. 14’ (document E/C.12/2000/4) makes reference.

7 Extra-territorial obligations: In the case of civil and political rights, these obligations refer basically to the conditions under which military force might be used to force compliance. In the case of ESC rights, however, the situation is much more complex as it implies a transfer of resources without the existence of institutions to make binding decisions on the level and character of resource transfers. Furthermore, as has been argued in the human rights discourse (Windfuhr 2005), it should oblige member states not to take over international obligations which might have adverse effects on the realization of ESC rights.

8 See also Fn 48, in Bodansky & Crook (2002: 779).
health R&D on neglected diseases is in fact an important precondition for an adequate medical service and medical attention to patients of neglected diseases. Thus, it would be interesting to consider the advances which have been reported in this field under the perspective of a *global public good (GPG)*, i.e. the public forces which reliably and sustainably deliver relevant R&D (basically medicines) as a public good:

The discourse on GPGs is explicitly based on the assumption that there is no global state has appeared, which could be in a position to authoritatively decide to provide research on neglected diseases. This makes it useful to have a closer look on the arguments proposed by Inge Kaul and Pedro Conceição (2006: 14) on the production path of GPGs.

![Production path of global public goods](image)

Public research institutes do some work on neglected diseases, but the missing link has been the lack of commercial interest of transnational pharmaceutical corporations (TNPCs). So we need to explain, how it has been possible to convince firms that research in R&D of so far neglected diseases is worthwhile and, in addition, to convince governments to agree to invest negotiating
interests and – at least in principle – financial resources in research institutions which concentrate on “essential health research”. The actors identified by Kaul and Conceição are those normally seen as the main actors in global governance, so we will basically have to analyse the more concrete forms in which they interacted in the issue of neglected diseases. We will have to discuss (a) what have been the most important intermediate public goods (e.g. human-rights-norms; cooperation in global health security; political security in regions hit by neglected diseases) and (b) what are the constellations which might result in a long-term stable (and improving) delivery of essential R&D for “diseases of the poor”.

There are a few comments to be added to the GPG figure:

(1) The assumption “that the good follows a ‘summation’ aggregation technology” concerning the aggregation of national public goods to shape the delivery of a global public good, does not hold in the case of scientific knowledge. Though in some areas (though not in pharmaceutical research) national or local innovation systems might still dominate R&D processes, this is definitely not the case in the development of new medicines (accept of course in the area of traditional medicine, see Aginam 2005: 95f.)

(2) A clearer differentiation between specific types of actors (private-for-profit; private-not-for-profit/ civil society; state actors) is important. This is particularly important concerning the authority of international public actors, in particular concerning decisions obliging nation states to accept agreed regulations and/or financial obligations.

(3) The impacts of non-state actors in global governance have reached a level, which implies a significant change in the provision of GPGs. Certainly, non-state-actors cannot legitimately use force to implement a norm, but they have various means to put pressure on legislatures and governments. Possibly, the element of sovereignty might have been overestimated. Legal norms do not really prevail if they are not matched by a broad acceptance within the population. In international law, the pressure by civil society organisations might even be instrumental in the implementation (see the role of “blaming and shaming” in human rights). An important question in global governance is whether this assumption can be turned around: If a norm is solidly anchored among all relevant actors, it might possibly be more effectively implemented than many international legal norms.

(4) The role of the media seems to be underestimated in Kaul’s GPG concept (as actually it is in many analyses of global governance). It seems that frequently the media are just considered to be magnifiers of positions taken by other actors. Here, this point will not be treated in more detail, but it plays a central role in explaining public support for specific demands in global health.

Incentives for producing a public good (and thus also a GPG) will – by definition – not primarily be provided through the market. And furthermore, a stable provision of such a good requires a stable public support. In global politics, at first sight, a strong international regime seems to be a pre-condition for that. In global health governance (GHG), however, we could observe, that actually a very chaotic structure of rapidly growing and diversifying actors (encompassing states only as, in most cases less powerful, political partners of Civil Society networks) could successfully withstand the powerful opposition in one the strongest international regimes in existence, the WTO and making strong WTO members as well as TNPCs accept the norm of “universal access to essential medicines” – at least with respect to ARV (Wogart et al. 2009). Acceptance was signalled by the Doha Declaration as the most important document, but it was implemented not by a coherent integrated mechanism, but by a broad range of different measures (differential pricing; refraining from TRIPS complaints concerning the use of TRIPS flexibilities in trade with first-line ARVs; cooperation of TNPCs in access-oriented public-private partnerships; financial support for poor countries).
This experience points to a situation, where a complex plurality of supporting actors can be a chance for a stable implementation of norms, operating (in principle) similarly to an open, non-oligarchic market (Fidler 2007; Hein 2008, Kickbusch 2009). A large number of states, a number of intergovernmental organizations competing with WHO, many CSOs; large and small foundations; international organizations of bilateral cooperation; International Business Organisations and a number of powerful TNPCs have created a field of political interaction which has proven surprisingly stable. This broad interaction of close to antagonistic actors resulted in norm-building (and implementing) processes, based on a general acceptance of human rights. Getting at an “equilibrium” between demand for a GPG, the provision of the necessary investment and a mechanism of distribution (guaranteeing access + incentives) probably depends on the development of strong norms as an alternative and/or a complementary force to formal international law. Following this reasoning, norm-building appears to be the most important intermediate public good to support the delivery of research on neglected diseases as a GPG.

Thus, there remains the “traditional” means of “blaming and shaming” which should, according to the UN Human Rights System be set off by reactions of other states towards reports of the not-complying countries. Again: States can be blamed, if they do not undertake every possible action to provide essential medicines, but not if they do not invest in R&D if the necessary technological capabilities are missing. Only: question of extra-territorial obligations: Blaming&shaming not against local states, but rich states concerning their global responsibilities. The effectiveness of “blaming and shaming” has been considerably strengthened by the growth of a global civil society linked to greatly increased importance of mass media in international communications.

Building on research in the field of the access norm, the second part of the paper will look more closely at what has happened in the field of neglected diseases. Concerning incentives for R&D, basically two strategic options have played a significant role: Subsidizing R&D of TNPC according to politically agreed global needs in global public-private partnerships (GPPP), where quite often the WHO was the initiator), and strengthening R&D systems in developing countries (CIPIH; Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property). In addition: Support of biomedical research on these diseases, resources for treatment with available medicines. However, a third option has accompanied this discourse during all the last decade: substituting other incentives for the patent system at least in areas where the patent systems obviously does not fulfill its regulation role, the most important alternative proposal being a prize system (see more in the conclusion)

3. Transnational Norm-Building, Non-State Actors and Implementation in Global Health

Transnational Norm-Building refers to a basically discursive process to set up binding standards of behaviour which in our context are related to the human right to the highest attainable standard of mental and physical health which has been linked in a large number of transnational discourses (i.e. not only between official delegates to the WHA) to the demand for a significant increase of research on neglected diseases in order to improve the chances of treatment of these diseases and to reduce their impact in terms of DALYs lost. This would be an intermediate public good, demanding concrete measures to stimulate R&D in this field and to be sanctioned primarily by blaming and shaming, and to a certain degree by holding countries or IGOs accountable in the case of a larger disease outbreak or in discourses on poverty or – in the more and more probable – case that the Millennium Development Goals will not be reached by 2015. Neglected diseases are directly involved in goal 4 (reduce child mortality) in goal 6 (combat
HIV/AIDS, malaria and other diseases), but as “diseases of poverty” also related to goal 1 (eradicate extreme poverty and hunger).

Basically, there have been three rather separate discourses on the interrelationship between private actors and transnational norm-building which are significant for my argument

(a) the role of CSOs in global-norm-building:
(b) market-related norm-building by private economic actors
(c) transnational norms and ‘corporate social responsibility’

3.1 CSOs in global norm-building: Contestation in the name of human rights (or social development) and participation in norm-building processes

A large number of publications analyze the role of CSO in contesting specific global governance processes, in most cases defending the interests of underprivileged people and/or environmental protection against dominant interests prevailing e.g. through institutions of international economic governance (see e.g. O’Brien et.al. 2000; Tarrow 2005, Brand et.al. 2008). A more active role in norm-building has been a focus in a number of publications of a group of authors around Kathryn Sikkink (Keck/Sikkink 1998; Finnemore/Sikkink 1998; Khagram/Riker/Sikkink 2002). In the Hein/Kohlmorgen article we used the Finnemore/Sikkink concept of the “norm-life cycle” as an analytical starting-point for reconstructing the norm-building process concerning access to essential medicines.

Many publications on private actors in global norm-building focus on forms of self-regulation among private enterprises, many standards in international business from ISO norms via environmental standards of tourism enterprises to the self-regulation of drug promotion are based (see e.g. Braithwaite/Drahos 2000, Appelbaum 2001; Schneider/Ronit 1999, Ronit/Schneider 1999, 2000). In the case of access to medicines, there are no norm-building or standard-setting private institutions, but one can observe the successive development of a consensus that pharmaceutical corporations have to respond to evolving global norm, and have to offer ARVs at much lower prices at least to patients in low-income countries. The International Federation of Pharmaceutical Manufacturers and Association (IFPMA), which at first heavily fought against any compromise in the TRIPS field, finally expressed their full support to the results of the paragraph 6 negotiations (following the Doha Declaration of 2001, see fn. 10) on a revision of the TRIPS agreement (concerning the possibility of countries technically unable to produce generics to issue compulsory licenses for production in third countries) and boasted itself of having played the decisive role in reducing prices of ARVs.

CSOs in general are not playing a comparatively active public role in campaigning for more resources for neglected diseases. It is a topic which is always used to criticize the TNPCs and sometimes to criticize specific interests of TNPCs in partnerships. There are a number of CSOs which cooperate directly in GPPPs, but the only large CSO for which the work against neglected diseases is a central topic, are the MSF and die Drugs for Neglected Diseases Initiative (DNDi, see below). Advocative action is broadly directed to support activities in this field, but conflicts are not playing a very central role: It is a broadly accepted norm among all types of actors that more has to be done for drug development in this field.

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9 See e.g. the table of contents and the titles quoted in Tarrow/Acostavalle (1999), a bibliographic guide on transnational movements and advocacy groups.
3.2 Market-related norm-building by private economic actors

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3.3 Transnational norms and ‘corporate social responsibility

In contrast to market-related norm-building, the growing importance of the Corporate Social Responsibility (CSR) concept plays a significant role in the implementation. The global activities of CSOs, their reference to core human rights, and the successful framing of the issue in major industrialized societies - including the impact on public opinion and the reaction of politicians - have exerted a strong pressure on TNPCs. Pharmaceutical companies cannot deny that the industry as a whole is highly profitable. They had to show corporate social responsibility and to contribute to the fight for ‘better health for all’. To offer effective cooperation to improve access, at least to ARVs, and to reach some results in the field of neglected diseases, were indispensable elements in a strategy to defend (or better reestablish) the image of the industry (‘good practice in pharmaceutical industry’, see DFID 2005). The Global Compact between industry, civil society, and state actors, initiated by UN General Secretary Kofi Annan in 1999, was explicitly set up for this purpose (Kell/Ruggie 1999). The participation in and support of GPPPs (like in the Accelerating Access Initiative (AAI), see below) is obviously seen as an appropriate strategy: the voluntary character of these activities and the potential to keep control on GPPP activities are central aspects in this regard. Another instrument which is accepted by the pharmaceutical industry is differential pricing.

Whatever TNPCs were offering to cooperate in the field of access to drugs in poor countries, the basic objective has always been to prevent any weakening of internationally accepted IPR rules as a basis for securing profitability. In comments on the CIPIH report, the International Federation of Pharmaceutical Manufacturers’ Associations (IFPMA) rejects all critical comments on strong patents laws (Noehrenberg 2006). For them, defending TRIPS regulations in their integrity has had absolute priority; thus, to take off pressure towards making concessions in the field of compulsory licensing (and realizing that they might loose support by US politics, their mainstay in international affairs), they were rather early ready to support a move towards

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10 I can only refer in this form to the importance of the Doha Declaration on the TRIPS Agreement and Public Health made during the WTO Doha Ministerial Conference in November 2001, stressing that the ‘TRIPS Agreement does not and should not prevent Members from taking measures to protect public health’ and accepting the use of compulsory licenses if member governments deemed that to be necessary.
universal access by entering access-oriented partnerships. On the other hand, there are no ideological barriers against cooperation in concrete projects; IFPMA’s Health Partnerships Directory lists for partnerships where TNPCs are cooperating with DNDi in the field of R&D for neglected diseases.

4 Global Public-Private Partnerships

In the discourse on neglected diseases, there was no one single conflict or case which might have caused an eruption of criticism against TNPC practices. Partnerships developed as part of the more general development of GHG in a period when (a) the transmission of infectious diseases from poor to rich countries was seen again as a serious threat, (b) development cooperation began to refocus from structural adjustment and austerity to poverty reduction strategies and (c) cooperation between public institutions (in particular of the United Nations) and private corporations was widely praised, in particular through the so-called Global Compact negotiated between UN General Secretary Kofi Annan and the International Chamber of Commerce in 1999.

Partnerships between pharmaceutical corporations, WHO, and governments in the field of development cooperation and tropical diseases are nothing totally new to the age of Global Health Governance. Since 1961 Bayer HealthCare has supported a family planning programme in cooperation with bi- and multilateral organizations, among others, UNFPA, the World Bank and WHO. The most important multilateral organization working since 1975 is the Special Programme for Research and Training in Tropical Diseases (short: TDR), a joint programme of UNDP, the World Bank, WHO and UNICEF, which cooperated with pharmaceutical companies as well as with public research agencies in some developing countries in the development of specific drugs against tropical diseases (Manderson et al. 2009; WHO/TDR 2007).

A few GPPPs were founded between 1985 and 1992 (8 of the more than 200 documented by IFPMA and still existing in 2010), then 9 between 1994 and 1997, before in the following years a boom started (13 in 1998 and 1999 and 87 from 2000 to 2004. An important number of them, though not the majority, were product development partnerships, others had the goal to ease the access to specific drugs Under Director General Gro Harlem Brundtland, WHO promoted large PPPs in the fields of drug development and the coordination of the fight against specific neglected diseases, like Roll Back Malaria, the Medicines for Malaria Venture; the Stop TB Partnership and GAVI, the Global Alliance for Vaccines and Immunization with a strong financial role of the Gates Foundation and with its secretariat with UNICEF.

We can observe two tendencies which turned out to be complementary: On the one hand, the more the right to health is becoming a central political and moral issue, the more the pharmaceutical corporations are coming under pressure to rise up to their corporate responsibility and to contribute themselves to the fight for a “better health for all”. The Global Compact between industry, civil society and state actors, initiated by UN General Secretary Kofi Annan in 1999, was explicitly set up for this purpose, we find an increasing engagement of TNPCs in this field and a resulting upswing of GPPP activities since 2000. On the other hand, the financially difficult position of WHO (and the refusal of important member states to increase WHO’s budget) made it necessary to look for more flexible agreements with a stronger position of private actors that at the early times of the TDR:

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11 Around the mid-1990s the US became the site of something like a scare of becoming victims of new diseases (like HIV/AIDS, outbreaks of some other infections, Ebola), being driven by publications like Richard Preston’s Hot Zone, Laurie Garrett’s The Coming Plague or the film Outbreak, all appearing in 1994 and 1995.
In fact, from the perspective of TNPCs nothing seems to be better suited than a strategy of global public-private partnerships (GPPPs). Besides showing their readiness to cooperate in the development of new medicines and vaccines for the typical diseases of the poor and marginalized parts of the global population, they could react to the reproaches of CSOs related to IPRs by proving flexible in supplying poor patients with drugs (without giving up their position on IPR). The global activities of civil society organizations, their reference to core human rights and the successful framing of the issue in major industrialized societies, including the impact on public opinion and the reaction of politicians has exerted a strong pressure on TNPCs. They had to show corporate social responsibility: To offer an effective cooperation to improve access at least to ARVs and to reach some results in the field of neglected diseases, were indispensable elements in a strategy to defend (or better re-establish) the image of the industry (cf. DFID 2005: good practice in pharmaceutical industry). Early examples are the Mectizan Donation Programme (medizine against riverblindness) and various other similar programmes (among others involving drugs against malaria). The most important programme in the case of HIV/AIDS is the Accelerating Access Initiative, a GPPP involving five UN agencies (UNAIDS, WHO, World Bank, UNICEF und UNFPA) and five pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, GSK, Gilead Sciences, Merck Co, and Hoffmann – LaRoche), working together with national governments. It is the largest such endeavour of the industry to cooperate in providing access to HIV-treatment.

Many of the GPPPs have been criticized by civil society actors ((HAI 2000) and often by public health specialists as well – for example for linking humanitarian actions to specific interests of the firms involved, for not offering reliable and transparent solutions to the problem of access and medical service (see e.g. Bartesch/ Hein 2003; (Huckel-Schneider 1999)). On the other hand, there is no doubt that the rise of GPPPs reflects the acceptance that pharmaceutical R&D and the access to patented drugs constitute a public issue to be negotiated. The role of GPPPs fits into the general picture of an increasing complexity of GHG: Though it is difficult to assess "how these initiatives affect the health and the conditions of those they are meant to help" (Health Action International), they have constituted another field of activities characterized by a broad involvement of various types of actors in Global Health Governance thus strengthening the general acceptance of a universal right to health. In addition to GPPPs, there are a number of other political initiatives in which the industry is involved like the Global Health Initiative of the Global Economic Forum (Davos) or the Global Compact referred to before.

Whatever TNPCs were offering as forms of cooperation in the fields of developing new drugs for neglected diseases and to improve access to drugs in poor countries, the basic objective has always been to prevent any weakening of internationally accepted IPR rules as a basis for securing profitability. This is also reflected in Eric Noehrenberg’s comments on the CIPIH report, in which he rejects all critical comments on the implication of strong patents (see also: Noehrenberg 2006).

However, we could also observe the development of a totally new phenomenon in pharmaceutical research: In 2003 MSF founded of a non-profit firm to develop new drugs, which of course also cooperates with pharmaceutical enterprises but in the context of an integrated enterprise oriented exclusively to the need for discovering new drugs on neglected diseases (“Drugs for Neglected Diseases Initiative”, DNDI)/ Workshop on “Access to Medicines and the Financing of Innovation in Health Care”. Washington/ December 4, 2003 (cf. ip-health). DNDI started with one specific project, but already two years after the foundation they have developed 20 projects - 10 in the discovery phase, 4 in preclinical development and 6 in the clinical phase. Seven cooperate in DNDi: five public sector institutions – the Oswaldo Cruz Foundation from Brazil, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Ministry of Health of Malaysia and France’s Pasteur Institute; one humanitarian organisation, Médecins sans Frontières (MSF); and one international research organisation, the UNDP/World
Bank/WHO’s Special Programme for Research and Training in Tropical Diseases (TDR), which acts as a permanent observer to the initiative. It has been shown that research-oriented GPPPs have mobilized a significant amount of resources for research on “neglected diseases” – so that some of these diseases can no longer be called “neglected” according to the definition given above. There are some promising advances in drug development (Manderson et al. 2009). On the other hand, though it can be shown that some of these partnerships have been founded following academic and political discourses on public needs and decisions taken by the WHA (e.g. those on Malaria and Tuberculosis), GPPPs in general are not linked to an institutionalized process of assessing research needs which are not indicated by market opportunities. Huckel Schneider refers on the one hand to the “leadership role played by large states and prominent private donors (2009: 113), on the other hand to the important role of strong epistemic communities with experts presenting themselves as authorities in their specific fields of knowledge with a strong belief in technical solutions (2009: 115f.). Thus, if GPPPs succeed in producing GPGs, those are extremely linked to solving specific problem and not really coordinated to work for “neglected people”. So far, positive synergies between GPPPs as global health initiatives have been quite limited (WHO Maximizing Positive Synergies Collaborative Group 2009).

The GPPP model resulted from voluntary cross-border collective action to respond to the problem of neglected diseases (and to do that in a way that corresponded to specific actor interests). Available analysis has thrown some light on typical structures of GPPPs, the role of interest groups (TNPCs, IFPMA) and IGOs and (to a lesser degree) governments in their foundation and operation, and the shortcomings with respect to questions of legitimacy and accountability (Huckel Schneider 2009; Buse & Harmer 2007). However, little research has been done concerning the norm-building process defining the need for public action for “neglected diseases”. This is reflected in the lack of a clear definition (see above) and in the lack of interaction among the various GPPPs.

In order to get an idea of the potential impact of a more focused norm on effective self-coordination of diverse actors, I will start the following section with a short overview about the implementation of the access norm, i.e. “universal access to essential medicines”.

5 “Essential medical R&D” as a norm: From CIPIH to the ‘Plan of Action on Public Health, Innovation and Intellectual Property’ (James Love and WHO)

5.1 Success of the access norm

Since 2001 we can observe a successful move towards a universal access to ARVs (see t’Hoen 2009, Hein 2010), supported by the Doha Declaration of 2001, but basically through a convergence of different activities on the access norm, taking into account the self-interests of the corresponding actors (e.g. a combination of the use of generics, differential pricing by TNPCs, use of various subsidizing mechanisms). Two further issues, however, are important as criteria for a successful implementation of the access norm (1) Is the norm really stable, independent of fluctuations in public interest and political pressure? and (2) While developing countries and most CSOs have always insisted that not only access to medicines for HIV/AIDS or a limited group of diseases (including Tuberculosis and Malaria and/or tropical diseases in

12 See: dndi.org (About DNDi; research portfolio; accessed June 25, 2006); also: interview with Karim Laoubdia, MSF.
general) is at stake, but access to all essential medicines, which is far from being explicitly accepted by all stakeholders.

(1) There are a number of indications for a broad acceptance of the norm: Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines were submitted to the UN General Assembly in 2008 (Khosla/Hunt 2009), based on a broad participation of various stakeholder groups. In 2008, an Access to Medicine Index (Menou/Hornstein/Lipton-McCombie 2008) has been published on behalf of the Access to Medicine Foundation with a broad-based support of the pharmaceutical industry, WHO, bilateral development agencies and CSOs (church-based organizations, but also Oxfam) (see also Access to Medicine Index-Webside, [www.atmindex.org/about/collaborative_governance](http://www.atmindex.org/about/collaborative_governance)). Furthermore, CSO activities in this field have not been reduced and are integrated into well operating networks. One indication of that is the continuously strong internet presence of ip-health (an e-mail list on intellectual property rights and health), in which every day new documents on IPRs and access to medicines are distributed (including statements of CSOs in this field).

(2) In conflicts about the Doha Declaration and the negotiations on §6, the pharmaceutical industries and some industrialized countries tried to insist on restrictive interpretations of the TRIPS flexibilities, but could not prevent a final agreement that allowed compulsory licensing for export to countries not capable of producing needed medicines irrespective of specific illnesses and did not include a narrow determination of eligible countries. In spite of strategies by TNPCs to constrain the use of compulsory licenses (CL), during recent years this instrument has played an increasing role in developing countries policies to improve access to medicines. In many, probably the majority of cases the intention to issue a CL (or an effectively issued CL) were revoked later-on, after the patent-holding company has agree to supply the medicine at a price rebate or even to provide a voluntary licence to the respective country (and frequently also threatened a request to the USTR to put the country on its “Special 301 Priority Watch List” as a candidate for US trade sanctions). Though most of the declared intentions to issue compulsory licenses still are related to medicines against HIV/AIDS (basically to so-called newer second-line ARVs where originator companies are rather reluctant to offer significant price rebates, in particular in middle-income countries), the scope of diseases is expanding in particular towards non-infectious diseases like cancer and heart diseases. There seems to be no clear difference of reaction towards such declarations in terms of the diseases involved.

Seen from the perspective of norm stability and norm inclusiveness, the intellectual property system – i.e. the currently dominant system for R&D intensive industries to refinance their costs of developing a product – continues to be a factor obstructing universal access to essential medicines in a highly unequal global society. If it is correct that the implementation of this norm has been significantly gaining strength during the last decade, this necessarily implied a changing attitude by pharmaceutical companies (possibly supported by one or the other form of financial subsidy) towards voluntarily selling medicines at specific places and/or to specific patients at greatly reduced prices. “Voluntarily” could take three different forms: Either as a response to an internalization of this norm into the business ethics of TNPCs, or as a reaction to external pressure by civil society or by political institutions, or, finally, in a negotiated form in

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13 These Guidelines, however, were not accepted by pharmaceutical companies, see e.g. for GlaxoSmithKline: ‘The “right to health” is an important issue, though not well defined, especially as it relates to non-state actors. Therefore we do not accept the suggestion - implicit in the development of this Report - that GSK’s programme and ongoing commitment is in any way required by international legal norms, whether in the human rights or other areas. Given the lack of legal obligation on companies relating to the right to health it is not clear to us how the Ombudsman recommended in the Report could operate.’ (GlaxoSmithKline Statement in Response to Paul Hunt’s Report on GSK (A/HRC/11/12/Add.2) June 2009).

14 Least developed countries are eligible to use the mechanism without any restrictions; any other country must submit a notification to the TRIPS Council that it has insufficient or no manufacturing capacity for the ‘product(s) in question’.
some type of public-private partnership. Obviously, all three forms have played a certain role. In order to get a clearer idea of the mechanisms through which social norms are accepted by private business, the immense material on IPR conflicts (easily accessible through ip-health) and on access PPPs should be more systematically analyzed.

5.2. Essential Health R&D based on an international regime

In modern societies, if there are normative conflicts between various forms of regulations in different but interdependent sectors, it is the role of the state to deal with these conflicts. In a relatively wealthy society, health systems could bridge the gap between high prices of medicines supported by IPRs and a broad access by patients. Therefore, if a health system is really comprehensive, there are no “neglected diseases”, as also poorer people should be able to use expensive patented medicines – instead there is a problem of “orphan drugs” for rare diseases, which face a similar problem, i.e. the total aggregate demand even at high prices is not sufficient to pay for the R&D costs.

In systems of global governance many factors like the readiness for a comparable resource transfer, conflicting interests of sovereign states, the necessary degree of mutual trust etc. are missing. The rationality of international organizations points to negotiate a regime to create the necessary conditions for supporting the access to medicines norm or to develop normative criteria for creating incentives for research on neglected diseases. However, taking into account the huge differences of interests, of identities, principles, resources, it seems quite difficult to reach such a regime, even though people might agree on the general target.

New initiatives to develop alternative forms to fund research on medicines important to poor countries like James Love’s\textsuperscript{15} proposal to negotiate a Medical R&D Treaty under the auspices of the WHO means an attempt to shift the focus of setting rules on IPRs in the field of essential medicines to the WHO. This can be seen as an attempt to define criteria (and necessarily institutional forms) to make political decisions about global research priorities – which will only be acceptable to TNPCs (and high-income countries supporting them), if this form of political/social control is limited to a clearly definable sector of health research (the frequent use of “neglected tropical diseases” could also be a step towards such a delimitation). One interesting question in relation to a medical R&D Treaty would be whether there is a possibility to reach a platform of cooperation linking research done on neglected diseases in GPPPs to a WHO-based treaty on medical research, i.e. between organizations favoured by pharmaceutical corporations and a new piece of international law so far rather rejected by them.

After the Doha Declaration and the intensifying discourse to IPRs and access to medicines on the one hand, the poverty and neglected-disease focus stressed by the MDGs on the other hand, the WHO organized a broad-based international expert commission, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). Following the publication of the report of this Commission (CIPIH/WHO 2006), a consensus began to emerge on the need for changes in the global system of innovation for medicines and for health research more generally. While the GPPP system basically uses the technical “hardware” (in the sense used by Fidler 2007) of TNPCs for pursuing research on new drugs and creates new “software” in the form of alliances between organizations, now the hardware (strengthening innovation systems in low and middle income countries for research on neglected diseases) also is under discussion.

\textsuperscript{15} James Love is the director of Knowledge Ecology International (KEI; formerly, the Consumer Project on Technology (CPTech), the most important US consumer protection organization.)
This led to the establishment of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) under the auspices of the WHO. The Group, open to all interested member-states, and including civil society actors, was mandated to draw up a global strategy and plan of action. Its aim is to provide a medium-term framework to secure an enhanced and sustainable basis for needs-driven, essential health R&D relevant to diseases that disproportionately affect developing countries by proposing clear objectives and priorities for research and development and estimating funding needs in this area. This global strategy and parts of the plan of action were adopted in a resolution passed at the World Health Assembly in May 2008 (WHA 61.21).

The aims of this strategy are (Art. 13) “to promote new thinking on innovation and access to medicines” and to “…provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries.” The new formulation of the mission of TDR anticipated this strategy: “We have a twofold mission: (1) Research and development into new and improved approaches on diseases of poverty. (2) Empowering and building research capacity in the countries where the diseases are prevalent. In 2007, we launched a new vision: ‘An effective global research effort on infectious diseases of poverty, in which disease endemic countries play a pivotal role.’” (http://apps.who.int/tdr/svc/about/about-tdr; accessed 02-05-2011).

In January 2009, the Executive Board discussed the completed plan of action, including the costing of implementation, estimated at about US$ 149 bio. between 2009 and 2015 (national and international spending); this is supposed to increase the percentage of R&D for ‘diseases which disproportionately affect developing countries’ from currently 3% to then 12%. The 2009 WHA “noted” the funding needs, and established a WHO Expert Working Group on R&D Financing (EWG). The perspective of negotiating a “Medical R&D Treaty” remained vague, primarily opposed by the pharmaceutical industry. It remains quite doubtful whether the additional resources mobilized will come even close to the sum calculated by the WHO Executive Board, taking into account that they are supposed to cover the years from 2009 onwards, while the first report by the EWG was discussed and dismissed at the WHA in May 2010. A new Expert Working Group has been appointed, but is already contested by a number of WHO members because one member of the Group is recused for being too close to industry.

5.3. Civil Society Pressure is essential

Thus, the negotiation process at WHO has integrated itself into the multi-faceted support for the norm “universal access to essential medicines” as an element of the right to health without moving a step forward towards developing anything close to an international regime on health R&D. Actually taking into account the diversity of interests between stakeholders, the chance to develop something like a treaty bridging the gap between IPRs and global health needs seem to be scarce. The flexibility of an informal political norm to some degree accepted and internalized by all stakeholders seems to be closer fitting into a world characterized by a globalizing society and a fragmented structure of global governance.

This, however, points again to the difference between civil society involvement in the access campaign and in the realization of a system of “essential health R&D”, in particular for securing the development of medicines for neglected diseases. Considering the amount of financial

16 For example, Medicines Sans Frontiers (MSF), Knowledge Ecology Institute, Third World Network, Drugs for Neglected Diseases initiative (DNDi), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).
resources which are supposed to be mobilized basically by high-income countries, it could well be that the deadlock around the Expert Working Group is not really seen as a political catastrophe by this latter group of WHO members – as long as pressure put on them by CSO campaigns will not reach a certain level.

6 Conclusions

In this paper I tried to answer the question, whether a global public has developed which takes over responsibility in the transnational space for providing global public goods related to (formerly?) neglected diseases. The answer is “not yet”. There are two lines of development which have had an important impact on institutional change in global health governance: (1) the development of a rather chaotic field of GPPPs and other global health initiatives which has used the flexibility provided by these institutional forms to bring together rather conflictive interests of different groups of actors linked by a broad agreement on the secondary (or subsidiary) norm that more R&D on neglected diseases is essential for realizing primary human rights norms in health – with some positive results but without an institutional integration which would allow a systematic assessment of research needs for “essential health R&D”; (2) a negotiating process pursued by WHO and supported by CSOs which could lead to such an institutional integration, but has been stalled in quite intransparent conflicts on financing the system.

Non-state actors (note: that includes for-profit actors) are crucial at all stages in the process of building and implementing secondary norms to Human Rights. There is a lot of evidence for this statement in the case of access to medicines, especially linked to HIV/AIDS. Certainly, this case has a specific character, as the disaccord between the availability of drugs and the suffering of millions of AIDS victims has been so obvious – and the disease has been perceived as a major health threat in all rich countries and as a much publicized political threat to stability and security in developing countries. The case for overcoming the neglect of R&D regarding the “diseases of the poor” is related to the same field of incentives for research on drugs. But the concrete issues are different: For neglected diseases, there are no available drugs to which all people in need, independent of their ability to pay, ought to have access, but the anticipated lack of effective monetary demand has stopped research at a point where profits are at stake.

In contrast to the demands around the access norm, public mobilization for a system of essential health R&D has been modest though the importance of increasing resources for neglected diseases is accepted by a broad group of actors involved. There seems to be an inverse relation between public mobilization and the development of highly institutionalized systems of guaranteeing global public goods on a broader basis than fighting for access to medicines in a much publicized setting. More research on the dynamics of public mobilization on global governance issues is necessary.

Since the late 1990s, the public discourse on access to medicines and the role of patents has always been accompanied by a – mostly very technical – discussion on alternative incentives for investment in R&D. The substitution of patents by prize system, i.e. prizes paid by governments to successful developers, sounds promising, as it would allow the government (or an international institution) to decide politically about priorities for medical R&D. Prices for drugs would not be kept high as the successful developer will not receive monopoly rights, but will receive a prize to refinance his development costs. Generic producers could enter the market and create competition without doing financial harm to the original developed who has received the prize. In order to achieve this, prizes paid have to be quite high and will have to be paid for through taxes. Furthermore, there will be large incentives for firms to try to influence government decisions on prizes.
There is no space and time here for discussing all the arguments (see Fisher & Syed 2009). There is, however, one obvious problem with shifting from one incentive system to another: its huge complexity will make it rather improbable to happen. Politically feasible are only gradual changes, which on the other hand are full of intricacies. This should make it preferable to pursue the establishment of an international regime on essential health R&D following the Global Strategy and Plan of Action negotiated at the WHO. Conflicts between nation states on financing the regime and on securing its effectiveness cannot be avoided – but a system with an active participation of non-state actors (for political pressure, for finance, for expertise and for participatory discourses on priorities) will have higher degrees of freedom (flexibility) than a pure intergovernmental system. Binding non-state actors more actively into the WHO decision-making system (e.g. through a Committee C, in which they are formally represented), might be a way forward to form a global public which creates a transnational link between local and global political perspectives (Kickbusch et al. 2010).

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