

**A Global Medical Research  
and Development Treaty**  
**An answer to global health needs?**

by Andrew Farlow



**IPN WORKING PAPERS ON INTELLECTUAL PROPERTY, INNOVATION AND HEALTH**

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# Executive summary

This paper evaluates the viability of the proposed Medical Research and Development Treaty (MRDT) mechanism that is currently under discussion at the WHO's Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property.

## Implementation issues

After an overview of the genesis and rationale of the MRDT proposal, the paper reviews the many implementation issues that have been overlooked in the supporting literature for the MRDT.

In particular, the MRDT literature takes an overly simplistic approach to the interface of the different components of the R&D process, with no explanation of how different modes of R&D and funding of R&D will coexist, of how the production side of the proposal will work, of how non-patent based R&D will be efficiently exploited, and of how complex underlying IP issues will be handled. No explanation is given for how the transition will be made from the current R&D funding 'system' to the new MRDT 'system', in such a way that current investors – both private and public – do not have their work unfairly expropriated. Unfortunately, this suggests that the MRDT will result in many perverse outcomes and unintended consequences in these areas.

The MRDT hinges around a credit trading mechanism, with signatory countries' credits earned from spending on a wide variety of types of R&D. This thinking is borrowed from the Kyoto Protocol which deals with the very different problem of environmental CO<sub>2</sub> emissions trading – but the MRDT ignores all the differences between R&D and CO<sub>2</sub> emissions, and all of the problems experienced by Kyoto. In particular, the credit trading mechanism is very unlikely to work given the likelihood of multiple non-binding constraints, difficult

measurement and valuation problems, and the inability to formulate a workable way to enforce outcomes. Given that the 'market' for types of innovation and the efficiency with which R&D is done under the MRDT both rely on the efficiency of this credit trading mechanism, this is somewhat unfortunate.

There is also a range of extremely challenging enforcement problems. The data required to discipline errant signatories would be too poor to be useful, and rent-seeking and other forms of inefficient gaming of the system would be impossible to police. It is not clear what credible and enforceable punishments there could be of those deviating from the supposed self-enforcing solution upon which the MRDT relies. The suggestion of using TRIPS and TRIPS-plus as 'punishment' is found to be somewhat impractical. Is it wise to encourage poor countries to support a radical overhaul of the R&D system, for an outcome that is highly unlikely to be enforceable anyway?

## R&D weighting issues

The paper reviews a range of problems in setting weights on countries' spending obligations as visualised in the MRDT. It is hard to visualise a set of permanently fixed weights that is optimal; but a flexible set of weight requires a centralised bureaucracy. A set of weights that is simply proportional to income is a regressive tax; but a set of weights that rises with income gives the rich more voting power in the priority setting mechanism. There is no explanation of how weights might be able to change over time or of how they might respond to unexpected medical emergencies, other than via the centralised bureaucracy. This paper argues that there are other, better, ways to drive priority setting.

## Measurement issues

The paper then reviews the huge range of measurement and valuation limitations that would be faced by the MRDT and those running it. It is difficult to measure performance and the 'value' of R&D activity from looking at spending flows alone. And putting emphasis only on spending measures also encourages waste. The ability of the MRDT's Secretariat to use this data to reward and punish accordingly is therefore limited. Many of the definitions of 'priority' areas would be highly subjective, with legal disputes likely to favour the powerful and rich. It would be difficult to incorporate valuations based on real-time spending flows and valuations based on far-off outcomes (if there were prize components to the MRDT, for example) into the mechanics of reward and punishment via the MRDT. Commercial confidentiality would undermine ability to collect important private sector spending data. There would also be multiple double-counting problems: R&D accounting systems are already struggling to deal with this, and it would be unwise to base the MRDT on such accounting systems. Costs of production (since this does not contribute to R&D) would have to be measured and factored out, and the value of risk-bearing activities measured and factored in; there is no understanding of either of these issues in any of the MRDT literature. Measurement problems exist in mechanisms such as the Kyoto Protocol, but at least there the basic unit of measurement – tons of CO<sub>2</sub> emissions – is the same everywhere in the world; in the current case, converting into a common denominator would be extremely difficult given floating, and sometimes unstable, exchange rates.

## Equity issues and developing country buy-in

The treatment, or lack of treatment, in the MRDT literature of the role of the US is especially perplexing. With the US predominant on just about any measure of R&D, the US would by far and away be the biggest supplier of credits in the credit trading system underpinning the MRDT. The poor in particular would have to be heavy purchasers of US-generated credits, on the basis of no more than the promise that the MRDT will work. It is not clear that the inequities of this

would, or should, be accepted by developing countries given the many unresolved issues – and even faults – that lie behind this promise. The credit trading mechanism requires all nations to join, but it is not clear they all would. With the US such a big supplier of credits, neither is it obvious that the market for credits would be liquid and free of manipulation at all times.

## Efficiency issues

The paper discusses a range of efficiency issues. It has been proposed that special 'intermediaries' could be set up to drive the efficiency of funding flows through the MRDT to avoid the failings of a centralised mechanism. But this paper finds no evidence that such intermediaries would work. Instead there are dangers of protectionist pressures towards local R&D (this largely flows from the inability of the credit trading mechanism to efficiently separate the sources of finance into R&D from the physical locations of the R&D activity), and many potential negative impacts on current incentives and efficiency. There is even a range of perverse incentives on access, given the way many current pressures to increase access are potentially penalised by the MRDT.

The paper also explores the multiple levels of political infeasibility of the MRDT proposal. These include the unwillingness of poor countries to oblige, the inability of key institutions such as the WHO to renegotiate terms already negotiated in prior treaties, the lack of a legal mandate of such organisations to change IP systems, and problems when one of the players – the US – would be so dominant in negotiations. Indeed, the paper concludes that negotiations by key institutions, such as the WHO, may do little more than to reinforce the status quo. Furthermore, the realpolitik of negotiations between countries over spending obligations – with countries seeking the best deal for the amount of R&D they currently fund – instead of leading to a breakthrough in increased support for, and better prioritisation of health R&D, is much more likely to lead to a strengthening of the status quo even as the level of R&D deteriorates. Throughout, the MRDT is found to be full of unintended consequences, and even to contradict the aims of many of those promoting it.

## Priorities now

The paper concludes by discussing the challenges of current global health needs with a list of current innovations, medical and otherwise, that are woefully underused. Reviewing current R&D initiatives and funding flows, it lists a range of issues that will not be resolved by the MRDT. It proposes that there are multiple ways to achieve impact with global health innovations, without complicating, distracting and delaying us from this goal. Given all the recent initiatives to invest in global health, the paper concludes that the real challenge is to turn all of that investment and activity into things that will improve the lives of the poor immediately, and it argues against the grand and bureaucratic and in favour of the simple, direct, and immediate.

## 1

# Introduction

Attention to the health of the poor, especially in developing countries, has never been more intense. After a long period of neglect, research into a range of diseases affecting the poor has been boosted thanks in particular to the efforts of the Bill and Melinda Gates, Rockefeller, and other, Foundations. New organizations such as GAVI and the Global Fund to Fight AIDS, Tuberculosis and Malaria, have injected billions of dollars into vaccination and drug procurement and delivery efforts. Recent analysis has shown that development assistance earmarked for health purposes has climbed from about \$2 billion in 1990 to almost \$12 billion in 2004.<sup>1</sup>

The percent of global health R&D spent on diseases *specifically* targeting the poor is relatively low given the numbers who are poor, but the degree to which the needs of the poor are *uniquely* neglected in R&D is yet to be fully clarified. The poor, or relatively poor, are increasingly being touched by many of the killers of the rich, such as cancer and cardiovascular disease. The poor suffer a disproportionate burden of maternal mortality and mortality dependent on lack of vitamins and micronutrients. Access to basic, off-patent medicines remains extremely low in many parts of the world, particularly in sub-Saharan Africa. Pandemic flu would affect everyone, though provisions for the poor would be least adequate, if existent at all. Addressing these issues has a great deal to do with improving health infrastructure and other determinants of health.

Nevertheless, there are those who claim that the health needs of the poor have been almost entirely neglected in R&D efforts. Some have called for a complete redesign of the R&D paradigm in order to ensure that more effort and resources are dedicated to the diseases of poverty.<sup>2</sup> The latest suggestion is for a Kyoto-style international Medical Research and Development Treaty (MRDT),

through which R&D could be centrally directed towards perceived health priorities.

Proponents of the MRDT claim that many of the problems they identify in the current paradigm could be overcome with their proposal. This paper, then, is an attempt to examine the proposed MRDT as it currently stands, in order to assess its economic and political feasibility. Unfortunately, a close scrutiny of the literature issued in support of the MRDT reveals many contradictions and questionable assumptions.

The first section provides a contextual overview of the genesis and rationale of the MRDT. This is followed by an assessment of the many implementation issues that would arise if the treaty were ever ratified. The third section examines how the different weights of signatory country contributions will be set, which is followed by a section that addresses the problems the MRDT faces in actually measuring the value of different sorts of R&D. The next section examines 'equity' issues surrounding the proposed distribution of R&D between countries, while the final section asks to what extent other approaches might achieve more beneficial outcomes than the MRDT.

Before proceeding, it is worth clarifying the motives of this paper. It is crucially important that we do not mix up a concern for changing priorities with a particular institutional mechanism for doing so. Even very strong agreement on the former does not logically equate in any way to the need to agree on the latter. The issue here is not whether or not priorities should change, of whether or not there should be more or less open source, of public versus private funding, or of whether or not the current status quo is acceptable. We can, and should, discuss the merits and faults of any of these issues. But we need to do this without conflating them with the

MRDT proposal. In correspondence, some have argued that the author should take a stronger stance on some of these issues, such as the role of patents. But this misses the point. The central concern of this paper is whether or not – regardless of one’s views on these issues – the MRDT mechanism is viable.<sup>3</sup> To the extent that it will not work – which is the author’s conclusion – the time and energy devoted to it is lost to alternative efforts, and action is delayed. In this context, though it may suit some to conflate discussion of priority setting with discussion of the MRDT as if it is the only alternative open to us, it is entirely counterproductive to do so.

# About the Global Medical Research and Development Treaty

## The structure of the proposed MRDT

The MRDT would require all countries – rich and poor – to pledge to spend a fixed percent of their Gross Domestic Product (GDP) on medical R&D. Different R&D areas would be targeted as special spending priorities. It is proposed that measured spending would generate credits that would count toward a country's overall obligation.<sup>4</sup> Since some countries have a comparative advantage in performing R&D, the credits would have to be tradable internationally in a way similar to that underlying the Kyoto Protocol for dealing with environmental emissions. Those countries that exceeded their benchmark obligations via domestically-performed R&D would be able to sell credits to those countries that chose not to meet their obligations through domestic R&D. Via a global market for pricing and trading in these credits, and the international flows of resources thus engendered, R&D would, it is proposed, gravitate to those countries that had a comparative advantage in doing it. Thus, the source of finance into medical R&D and not the location of the R&D activity would count towards a country's spending obligations.

Treaties are often no more than wish-lists and statements of aspiration. Clearly, to have any point, the MRDT is, of necessity, far more than this.

In early versions of the MRDT, the notion was to eliminate patents altogether on new drugs (and all medical interventions<sup>5</sup>) so that they could be sold at generic prices immediately after regulatory approval.<sup>6</sup> The R&D of such drugs would be paid for from taxes and tax-like instruments gathered and distributed globally. DiMasi and Grabowski identified the compulsory termination of the patent system as their main concern with the proposal.<sup>7</sup> Maybe in an attempt to allay this

fear, more recent versions have suggested that countries would be allowed to 'experiment' and keep patent protection if they so desire as one of a range of R&D funding mechanisms that would qualify under the MRDT. Some of these mechanisms are as follows:

- Countries could earn credits when they spend on highly priced products flowing from R&D that is based on intellectual property protection – to the degree that such expenditure is judged to create incentives for investments
- By spending on public sector R&D
- On the creation of open source databases such as those of the Human Genome or HapMap projects
- On research explicitly targeted at neglected disease therapies (where not paid for by some other credit-generating activity<sup>8</sup>)
- On projects that involve technology transfer to developing countries and capacity building in such countries
- The preservation and dissemination of traditional medical knowledge
- Direct subsidies
- Expenditure in pursuit of medical prizes
- Subcontracting
- Transfer payments
- Public Private Partnerships/Product Development Partnerships
- Philanthropic expenditures
- Tax credits for companies that invest in R&D

A priority-setting mechanism – and a set of global institutions to run the mechanism – would determine the proportions of global spend that should go on different areas of R&D, even as individual countries could, it is proposed, choose their proportions subject to this global pattern. Thus, there is ‘flexibility,’<sup>9</sup> but always within certain limits. Presumably, the degree to which different kinds of R&D activity would be targeted – and hence the number and marginal value of any credits based on such activity – would be decided in the run up to the setting of the MRDT, and fixed to avoid the risk to investors and sponsors caused by later changes.<sup>10</sup> Thus, priority setting would be dealt with centrally, even if activity is itself decentralized. In other words, the local constraints are to be set globally.

## The MRDT as an alternative trade agreement

The MRDT is also part of an alternative trade framework. It is proposed that the MRDT would supplement or replace trade agreements such as the WTO TRIPS agreement or various TRIPS-plus trade agreements on intellectual property on drug (and all medical innovations) prices, for covered products.

Countries would be allowed to choose to be TRIPS or TRIPS-plus compliant if they so desired even as other countries are allowed to reject TRIPS and TRIPS-plus entirely. As the current draft treaty wording puts it, somewhat presumptuously:

*“Members thus agree to forgo certain WTO TRIPS dispute resolution cases, or bilateral or regional trade sanctions, in areas where compliance with the terms of the Treaty provides an alternative and superior framework for supporting innovation.”<sup>11</sup>*

Similarly, it is asserted (usually implicitly) that if a country rejects TRIPS or TRIPS-plus, and chooses to satisfy *all* of its credits by spending its stipulated proportion of GDP on open source or domestic public R&D, that country would nevertheless be able to get all of its drugs, vaccines, diagnostics and all other medical innovations at non-TRIPS and non-TRIPS-plus terms and at (low) marginal production cost, even if those innovations emanate from and are manufactured in TRIPS or TRIPS-plus compliant countries. So long as a

country meets its obligation for R&D, it would not be subject to any other trade agreements on patents or medical innovation prices.

## The political momentum

A wide range of organisations have voiced support for this proposal, including the International Red Cross, Oxfam, Médecins Sans Frontières, the US-based Consumer Project on Technology (which is the source of most of the supporting material), South Africa’s Treatment Action Campaign, and France’s *Sidaction*. In February 2005, 162 scientists, public health experts, intellectual property specialists, NGOs, academics, members of parliaments, government officials and others, petitioned the WHO to evaluate the proposal, claiming that such an arrangement and its supporting institutions would boost medical innovation and improve access to affordable treatments at the same time.

The proposal was heavily promoted during the deliberations of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) of the WHO between 2004 and 2006. As a result, there is extensive documentation on the CIPRH website.<sup>12</sup> However, the Commission effectively sidelined the proposal in its final report. Recommendation 3.6 simply stated:

*“Recognising the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision.”<sup>13</sup>*

The comments submitted at the request of Commission by F.M. Scherer and R. Nelson, are especially pertinent. While recognising that the treaty proposal had been “endorsed by a stellar constellation of prominent world citizens,” Scherer nevertheless concurred “with Richard Nelson’s scepticism about the feasibility of a new international treaty.” Furthermore:

*“Creating a system that gets the incentives right for developing drugs and medical devices but at the same time ensures widespread diffusion of the resulting*

*technology to low-income nations remains an unsolved problem. Because the devil hides in the details, I don't believe MRDT reaches that goal."*

In late 2005 Kenya formally submitted a resolution to the WHO's Executive Board (WHO EB) asking for the creation of a working group of member states to consider the MRDT. In January 2006 Brazil co-sponsored the resolution.<sup>14</sup> Subsequently, the WHO EB approved a heavily bracketed version of a draft resolution. That draft was debated at the World Health Organization's World Health Assembly (WHA) in late May 2006. In December 2006, the first WHO 'Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property' convened in Geneva, with the MRDT proposal a key item on the agenda.

## Implementation issues

We now turn to examining how a ratified MRDT would be implemented, the problems related to credit trading, how different modes of R&D would co-exist, and the impact of an MRDT on current R&D investment.

### Transition issues

The promotional literature for the MRDT concentrates on the ‘steady state’ of the new system, ignoring the dynamics of transition to that new steady state, and whether or not it will be stable.

Without making any judgments about the inherent value of one system over another, how does one nevertheless deal with the commitments of the ‘old’ system? For ease of exposition, imagine the extreme case where patents are completely replaced by something else (and one clearly sees that the same logic applies along a spectrum). Investors have built up a potentially very long history of sunk investments based on repayment via the ‘old’. How does the MRDT tackle this ‘transition’ problem? More specifically, how does it plan to compensate those investors who will be expropriated during the transition period?

This is much the same situation as is faced when a pay-as-you-go pension system is replaced by a defined benefit pension system. Starting in a steady state mechanism where the pension contributions of this generation pay the pensions of the last generation, if there is a switch toward a system based on this generation paying into its own investments toward future pensions, how do the pensions of the last generation going through the old system get paid? Clearly, this generation has to be taxed (on top of its pension contributions) to make good on the pension obligation ‘owed’ to the last generation going through the ‘old’ system; there is no such thing as a free lunch.

No solution to this transition problem has been proposed by those promoting the MRDT. One can only imagine the instability and uncertainty to investors and sponsors without a solution to this problem in place.

No system is perfect and a prize system should not be judged on the need for a perfect result. However, if there is a prize component to the new MRDT that attempts to pay out based on ‘medical value’ of an innovation, this will need to make adjustment for the date when the treaty came into effect, the R&D funds sunk before the treaty was set up, and the underlying costs of developing innovations (i.e. not just the value of innovation per se). Failure to do this will result in some investors being heavily over-rewarded and others being heavily under-rewarded, generating inefficient outcomes.

### R&D credit trading

Key to the efficient working of the MRDT is an R&D credit trading mechanism, an idea borrowed from other recent treaty mechanisms. If this core component does not work, the whole edifice of the MRDT collapses. From an economic perspective, the problem is one of applying multiple constraints to a problem, some of which may be redundant or reduce the value of the overall result. In general, several aspects of the MRDT proposal do not deal with the likelihood of non-binding constraints.

For example, it is claimed that if countries do more than the minimum required on any particular priority project, they would benefit through sales of the tradable credits thus created. However, the credits and debits in the system must balance globally. If more credits for any particular R&D approach are created at any given demand for them, their price will be driven lower. In

particular, if countries collectively over-do their requirement in a category, the price of credits at the margin must become negative. A country will only over-do its requirement if it believes that others will under-do theirs, leading to a demand for the credits. The notion would be that those with a comparative cost advantage in R&D performed in a particular way would do R&D in that way amongst those countries doing R&D. Those countries that had a comparative cost disadvantage in medical R&D *however such R&D is done* would avoid spending on R&D performed within domestic borders, and would instead buy credits.

Given current patterns of R&D spend (and assuming the credit trading part of the mechanism actually works and the US agrees to join), poor countries would on the whole be large net purchasers of credits. Richer countries, and especially the US, would be the dominant providers of credits to the market. How can we be assured that the credit trading market will be liquid at all times, and free of manipulation? Will the US really be a ‘price-taker’ in many areas of credits?

The Kyoto Protocol is a case in point. Kyoto is supposed to cause firms to reduce emissions of carbon dioxide. The credit trading system is supposed to allow those who find it relatively expensive to cut their emissions of greenhouse gases to instead purchase emission permits, and for those who find it relatively cheap to cut emissions to sell their permits. All this is done via prices of the permits in the trading system. Within a given number of credits, the objective is to minimise the total level of emission. With some caveats, it is in theory possible to make some calculations of the value of emissions created or averted.<sup>15</sup> In practice, because of the gaming of the system, the price of permits for emissions in the 2007–2008 period collapsed from about €30 to about €1. Unfortunately, the language of the market becomes a marketing device to sell the idea.<sup>16</sup>

The ability to ‘experiment’ over R&D approaches appears, at a superficial level, to be market-based – a ‘market’ for types of innovation. However, not only is it based on a centralised mechanism making choices over the proportions of the types of innovation that will be allowed, but the market for types of innovation can only work efficiently if all the price signals in the credit trading mechanism are efficient and stable. If there are

any ‘missing markets’ or inefficiencies in, or gaming of, that trading mechanism – such as would be the case if there were insufficient buyers and sellers of credits generated by particular R&D approaches or breakdowns of belief in the functionality of the system – the efficiency of the mechanism would collapse. Even the expectation of this would create risk and raise the cost of innovation. It is perhaps ironic that a proposal to deal with ‘market failure’ in R&D is based on such an optimistic view of the way markets in R&D credits would work.

In a further complication, for such a mechanism to work efficiently requires the creation of derivatives markets (in the case of CO<sub>2</sub> emissions, on the future price of emission credits). Nobody has yet explained (or even explored) how such markets would be formed in a trading system underlying a MRDT mechanism. Later, we review many of the informational and measurement issues that make the credit trading component even more dubious a concept.

## Coexistence of different modes of R&D spending

MRDT supporters claim that the mechanism would allow – via the credit trading system – ‘competition’ among business models. Open source and patent-based approaches (and hybrids thereof) would ‘compete’ for resources, and the ‘equilibrium’ would involve a ‘mix’. However, a common theme in the critical literature analyzing the MRDT, as noted by Dreyfuss and Orsenigo in their requested submissions to the CIPIH, is how funding mechanisms would coexist.<sup>17</sup> It should be observed that this is not the same issue as the current coexistence of many different kinds of funding, because of the key new component of a centralised priority-setting mechanism and a market in R&D credits.

Hubbard, in a submission to the CIPIH submission, argued that some countries could even go exclusively patent-based and some exclusively open source if they so desired.<sup>18</sup> This extreme case illustrates some of the problems in the thinking. Imagine a small developing country that has satisfied all its obligations by investing in open source research (these countries would supposedly not even have to be doing any open source

research themselves, but could, out of preference, be paying for open source research being performed elsewhere). Who supplies the country with all the at-marginal-production-cost drugs, vaccines, diagnostics and other medical interventions to which it is now entitled? What about separation of this market from others? Do these countries also get to use ‘intermediary’ pieces of technology free of royalty even as the use of the same technology in other countries is policed and may even attract a high licensing fee? How is a monopoly right on a piece of ‘medical technology’ allowed in one country while elsewhere payment for the same piece of technology is from a prize fund with generic manufacture? None of these difficult practical issues have been explored by the promoters of the MRDT.

If the US used mostly a ‘strong-IP’ based approach to pay its obligations to medical R&D<sup>19</sup> and if the products of that activity are internationally traded with countries that use ‘low-IP’ approaches, at what price are they traded? How do the US developers get their ‘strong-IP’ based return and how do the purchasers get their low prices?<sup>20</sup> What if the users use ‘low-IP’ based products too? How is their choice among health interventions made to align with the true marginal value of the different interventions? Again, none of these difficult practical issues have been properly explored.

This undermines another claim – that the proposal allows countries to keep their current strategy for medical R&D if they so desire. For example, if 60 per cent<sup>21</sup> of all current R&D is based on patents and investor return via product prices, but the new priority setting mechanism fixes priority projects such that, say, at most 40 per cent can be paid for in this way, then a country that persisted in basing its figures on a 60 per cent proportion would be penalised unless countries funding other methods of R&D ran these at levels much higher than the global average. If the US – already by far the biggest spender – persisted in sticking to its current approach, the rest of the world would practically have to fund only *other* approaches. Even then, in the limit, the rest of the world might not be big enough.<sup>22</sup>

Incidentally, there is nothing to stop a country that has a comparative disadvantage in medical R&D from adopting a strategy of purchasing *some* of its medical

innovations at a high price so as to satisfy its obligations (with less incentive for disciplining prices on this small part of its requirements), and then (according to the MRDT) claiming all else of its medical needs at marginal production cost.<sup>23</sup>

## Exploitation of open source and public good outcomes

As a specific case of the practical difficulties of dealing with a mixed and complex R&D process, it is not clear how the MRDT would deal with patent-generated research that builds off open source data.<sup>24</sup> The wording of the original treaty proposal referring to data from the qualifying open public goods databases (QOPGD) was that “no patent applications can be submitted that rely upon the data from the QOPGD.”<sup>25</sup> In her CIPIH submission, Dreyfuss drew attention to the case history of HapMap that had dropped the “term and condition” clause that the treaty proposal now included.

The inclusion of the clause in the case of HapMap was, at least in part, based on a fear that someone might try to patent information already in such databases. However, this turned out unfounded since patents are only granted to true inventions.

Furthermore, barring the use of information in the HapMap to develop and patent new products or processes is inefficient. The point of the patent system should be to incentivise the development of new products and processes dependent on information in the HapMap. There is no point having such freely available information if the applications flowing from it are limited. As Dreyfuss puts it:

*“If ‘rely upon the data’ is not meant to bar all uses that would lead to patenting, then the meaning of the expression needs to be clarified. Furthermore, some attention should be given to enforcement. If the idea is to enforce the provision by stripping follow-on researchers of their patent rights, the treaty could wind up chilling research that arguably relies on the QOPGD data, even when that research is not otherwise funded under the terms of the proposal”<sup>26</sup>*

Under such a mixed system, those doing any work funded by treaty mechanisms will of necessity still have

to deal with patents on research inputs. Licensing these inputs will raise the cost of financing these projects. There is no explanation as to how this will be dealt with in the MRDT reward and payment system without making it even more complicated.

In particular, how would any system of exceptions work? Research exemptions would be desirable, but if an exemption is too broad it would only dull the incentive to do commercial research, especially that leading to the development of research tools the use of which would repeatedly fall under the exemption.

Scherer in his submission to CIPIH also worried that another perverse result might be the collapse of various cooperative agreements:

*“I believe an implication of sections 12 and 13 [of the draft treaty] is that, when drug or medical device research is sponsored by public authorities, movement should be encouraged away from granting exclusive rights to profit-seeking organizations in the resulting inventions and/or data. This seems to imply movement away from CRADAs (cooperative research and development agreements) between government laboratories and private companies, and the assignment of patents obtained by university and hospital laboratories under government grant financing to private companies...”<sup>27</sup>*

CRADAs play an important role in helping to commercialise discoveries made in academic labs. They are not without their problems, but at the very least the impact on such agreements of the MRDT should be explored.

Getting the right balance between openness of basic research and maintaining incentives to ensure that possibilities discovered by research are developed and tested to the commercialisation stage is a big challenge under any system of R&D incentives and rewards. There is no evidence that the mechanisms underlying the MRDT would improve this situation, and much to suggest that it would make it worse.

## Treatment of Intellectual Property

As it stands, the MRDT seeks to make medical IP different from other forms of IP. However, unlike tons of

CO2 emissions, the question of what counts as medical research is itself highly contentious, especially when something important might turn on it. For example, a method for making an enzyme can be used for making a food product as well as for making a drug. Who will rule on which patents and what applications of patents are medical and which are not, and what part of what expenditure was truly targeting a medical innovation and what was not? At least a patent with licensing allows the more valued users, and types of use, to identify themselves (including over time) without some global committee having to work this out at one moment in time, and in the face of a great deal of uncertainty and missing information.

If stronger IP is problematic – an underlying premise in some of the MRDT literature – it seems somewhat odd to encourage stronger IP to make up obligations under the treaty. Perversely, the more successful those countries who choose to pay their spending obligations via this route, the more likely they are to have excess credits to sell from other R&D activities. If the whole point is to counterbalance IP pressures, is it not somewhat counterintuitive that stronger IP that generates higher prices is legitimised to generate higher credit value? Imagine the completely counterproductive outcome if part of the intent is to create pressure to lower US drug prices, if higher prices start to earn credits in the credit trading mechanism.

In sum, the MRDT adopts an overly simplistic approach to the interface of the different components of the R&D process. As Scherer comments:

*“Different institutions play a key role, or can do so, at different stages in the process. The levels of uncertainty differ radically among the stages. The incentives that elicit desired behaviour also differ. I believe the draft treaty is too blunt an instrument to deal with these subtleties.”<sup>28</sup>*

## Enforcement

Full compliance of everyone to the terms of the MRDT is required if those who spend on credit-generating R&D are to be sure of getting sufficient returns. Why should investors or sponsors believe this will be the case? The

literature on self-enforcing agreements is not very encouraging in this regard.

The Kyoto Protocol does not exactly inspire us either. To many experts in the field, the Kyoto Protocol (even if focusing attention on the issue of global warming) gives the illusion of dealing with the problem of global warming, whilst most countries largely just ignore it. Why would anybody inflict a period of this sort of behaviour and uncertainty onto global health innovation? And this is an even more complex setting than CO2 emissions.

Hubbard concedes scepticism (in his CIPIH submission) that countries would stick to their obligations.<sup>29</sup> However, he then observes that countries could be regularly evaluated and punished. Those not signing up to the MRDT would face the current system. Those who sign up to the MRDT but violate its rules would also face the 'old system'.

This raises a fresh round of issues. How does one both use a patent-based system as part of an innovation process and as part of a punishment mechanism simultaneously? And what if the default punishment – the 'old' system – is itself a mixed system (part patent-based, part based on many other types of R&D funding mechanisms)? It would be inefficient not to also want that system to sustain innovation however much MRDT supporters think it inferior. Can punishments be done regardless of the impact on investors and sponsors of R&D projects even if they are not personally at fault? Do we punish researchers and sponsors because a government (or other domestic R&D players) misbehaved?

If a country does not meet its spending obligations it will lose the flexibilities allowed it under the MRDT. But, by whose judgment and by what jurisdiction, given the hugely ambivalent nature of much of this? What incentives or penalties could there possibly be to induce a nation engaging in insufficient qualifying expenditure to buy credits, or otherwise to comply? What new trade sanctions will be proposed?

According to Hubbard: "Ultimately, success depends on sufficient power, authority and resources being vested [at the centre] in the treaty institutions."<sup>30</sup> Some might

well balk at this. Others might question a mechanism that requires a radical overhaul of the R&D system, for an outcome that is highly unlikely to be enforceable anyway.

## The lack of a WHO mandate and the realpolitik of treaty negotiations

International treaties are negotiated among sovereign governments and, sometimes, intergovernmental organisations. For example, the WHO can sign some treaties but the WHO is, in turn, controlled by sovereign governments. When negotiating a treaty, a government or intergovernmental organisation, must respect and support the other treaties it has signed, regardless of what it may feel about the exact subject matter at hand.

The countries that will make up the WHO Working Group to prepare for a treaty are almost certainly all signatories of TRIPS. Thus they cannot negotiate a treaty that contravenes TRIPS. If one reads the Doha Declaration carefully, it just says that health is more important than IP. It does not give any quantifiable or objective means to determine in what circumstances health would be more important than IP or, indeed, what it even means for health to be more important than IP. Indeed, some signatories may well argue that the IP system is an important way of stimulating medical R&D, and therefore perfectly within the spirit of Doha, and some will argue that TRIPS has flexibilities to overwrite IP in a state of national medical emergency.<sup>31</sup>

Thus, the Working Group will most likely come up with a draft treaty that simply supports TRIPS and refers to the Doha Declaration. The negotiators will not, for example, be able to make declarations based on the notion that countries can refuse to grant patents for malaria drugs or TB drugs or similar; they would simply not have the 'legal' right to do so, since the WHO does not have a mandate to make proposals for new international IP treaty law. The outcome (after much deliberation, and missed opportunities to reprioritise via other means) will therefore be to strengthen and further institutionalise the status quo.

Another objective of the Treaty is to set a guideline for percent of GNP for supporting health R&D. Since, once again, the negotiators are representatives of sovereign governments, they are not going to put anything on the negotiation table that their own governments cannot do. For example, should the US agree to take part, the US will probably calculate the proportion of GNP that it already puts into health R&D and then, at the very most, propose some number just below that. More likely, it would want to pitch a figure that is lower for strategic reasons.<sup>32</sup> Again, rather than achieving a breakthrough in increased support for, and better prioritisation of, health R&D, these efforts will lead to a strengthening and institutionalisation of the status quo and, even, to reduced levels of R&D. Meanwhile, other ways to apply pressure to change priorities and redirect funding flows will have been squandered.

Observe that in the negotiation phase, different allowed priority weightings will impact heavily upon those who had already invested. It is hard to imagine that there would not be strong rent-seeking behaviour during this phase, especially if design and implementation details are left to this phase. Nobody has even begun to think through the entirely counterproductive drag on efforts to ensure development and access of the poor to much-needed innovation, while those who might otherwise be encouraged to work on these issues, are instead being encouraged to play a rent-seeking game with the WHO and other organizations involved in setting up this new mechanism.

Furthermore, all governments are not equal. Every negotiation provides an opportunity for trading favours or using power. The US will have the greatest power in any treaty negotiations were it ever to agree to take part. Once again, we find that the proposal is counter-productive of its avowed aims.

Given the asymmetry between the size of the current contributors to global medical R&D, the MRDT will be a non-starter if the US simply refuses to ratify it. As Scherer comments in his submission to CIPIH:

*“If the world’s wealthiest nation is so reticent about funding development obligations and joining in treaties concerning global warming and war crimes, it is unrealistic to expect it to ratify MRDT.”<sup>33</sup>*

This alone should make us question the entire logic of distracting the WHO and others from trying to find more practicable solutions.

At a more fundamental level, to what degree are governments currently showing that they care about these issues? Probably with the exception of the NIH, industry and foundations are spending multiples of what most governments are spending on neglected disease research. Whatever one’s views on development assistance, how many governments are spending even 1 per cent of GDP on development assistance, something they have repeatedly promised to do over many years? How many African countries are living up to the Abuja Accord, and spending 15% of their national budgets on health care? Perhaps these facts are more useful indicators of what will most likely happen?

Key to many of the critical analyses of the MRDT is its political infeasibility. We might further add that spending time on it now simply increases the transaction costs of the whole policy process, wastes systems capacity and delays better priority-setting.

## R&D weighting issues

### Setting the weights

It is hard to visualise any system where spending a fixed percent of GDP on health R&D is optimal. Optimality depends on technological opportunities, the medical needs of each country (e.g. an ageing US population has a different R&D need compared to a growing nation with a very young population), the stage of development and economic circumstances of each country, etc. As DiMasi and Grabowski observe:

*“...the agreement would have to be constantly renegotiated, or all of the nations would have to cede authority for this financial obligation to some central authority.”<sup>34</sup>*

Perhaps to allay such fears, at one point it was claimed that the percentages were intended to become floors. However, not *all* countries could at the same time regard their spending obligations as floors; that would create too many credits in the system! Some have argued that the percentages are much more likely to become ceilings. After all, once the spending obligation is met, a country gains entitlements that do not increase the further over the ceiling it goes. And, it is hard to believe that disputes about falling short of the ceiling would be quickly and easily resolvable given the poor quality of much of the data underlying the workings of the mechanism; countries would play games falling short but still claiming entitlements based on the ceiling.

### Fixed or flexible weights?

Will the weights (or rules about how the weights are set) be fixed once and for ever? Or will they have to be constantly renegotiated? The latter will lead to changes in the value of ongoing R&D activity and create uncertainty in the value of the credits flowing from that

activity, risk to investors and sponsors, and raise the costs of doing R&D. As an intuitive example, a country or a company may choose to do a lot of some R&D activity that it is thought is being globally underdone and will generate a valuable credit, only to see a lower price for that credit once the global allowance is changed. If the whole point is to change proportions, why allow negotiations that would make those proportions unstable?

As another practical example of the challenges (and, remember, the issue is not about setting priorities *per se*, but about the practicability of running this through the MRDT), how would one set the priority weighting to deal with SARS or bird flu and consequent risk of pandemic flu? It is easy to imagine the priority afforded to bird and pandemic flu *now*, but had priorities been set five or more years ago within the constraints of a MRDT, it is easy to imagine that it would have been heavily under-prioritized, with it difficult to later reprioritize within the constraints of the MRDT.

It is also unclear how these weights might be *able* to evolve over time, with no mechanism other than a centralized bureaucracy visualized as doing it.

### The size of US spending obligations

If the U.S. ever did sign up to the MRDT, what would be the likely weightings chosen for the US research and development target? Scherer, in his CIPIH submission, did a very rough calculation, based on the proportions being proposed by MRDT advocates, and came up with a figure on the order of \$18bn to \$24bn per year. Against this, the U.S. National Institutes of Health R&D budget alone for 2004 was \$27 billion, roughly half for basic research. Drug companies belonging to PhRMA reported domestic R&D expenditures of \$27 billion in

2003. Then there is US medical school research financed by philanthropic institutions and state funds. Thus, current U.S. expenditures already well exceed the minimum levels that would be prescribed by the MRDT. According to the targets proposed by those promoting the MRDT, \$2.4 billion would be set for priority medical research for the US (10% of the US spend). Scherer comments:

*“But with a bit of creative accounting, I suspect I could manipulate the roughly \$10 billion of annual research and development expended by U.S. biotech firms and other agencies working on HIV and resistant bacteria to satisfy that constraint.”<sup>35</sup>*

Therefore, at current global distribution of R&D spend, the US would of necessity be a huge supplier of credits to the global trading mechanism in such credits, with poorer countries obligated to buy credits from the US. The alternative of poorer countries catching up in their own domestic spending and avoiding buying US-created credits is not likely to be an efficient alternative; this would anyway require the US to cut upwards of half of what it currently does in medical R&D.

## The weighting of drug, and other, prices

How much should drug prices be allowed to contribute to R&D? Scherer discusses the case of the United States also. In 2001, gross margins of the U.S. pharmaceutical industry were on the order of \$58 billion. Those margins induce the drug R&D we see. On the degree to which they do so “reasonable people will disagree – perhaps violently”.<sup>36</sup> What would stop the US, during negotiations, from arguing that these margins induce all the observed US R&D, satisfying the U.S. target, and justifying high US prices? Why would the US accept a lower measure of contribution? Given strong US bargaining power in any treaty negotiations, how would it not obtain a superior valuation of its contribution compared to weaker players? Again, the outcome is counterproductive.

## Measurement issues

The amounts countries are allowed to count towards their obligations and how much they are obliged to buy credits is all dependent on getting a good fix on what they have actually spent on qualifying R&D. If this fix is poor, the credit system will not work as proposed. This is on top of the problems we have already identified with the credit trading mechanism. As Hubbard put it:

*“Each treaty country is required to record its direct and indirect spending on medical R&D and report this to the Treaty Secretariat. The Secretariat is advised on what expenditure qualifies against a country’s obligations by CMI and a number of specialist committees. If the secretariat deems that a country has not met their obligations it advises the WTO that the country’s TRIPS flexibilities under the treaty are void. The Secretariat would also assess the impact of each country’s expenditure on R&D outputs and publish an appraisal of which countries incentive regimes are most effective. A country’s obligations, framed around fraction of GDP, would over time also be linked to R&D outputs, to provide incentives to create the best regime.”<sup>37</sup>*

In sum, spending on each mode of R&D has to be recorded, its impact on R&D valued, this value fed back into the system to work out if countries are living up to their obligations, and punishments and rewards centrally administered on the basis of these evaluations. There are a large range of measurement issues in the process of doing this, the implications of which have been hardly explored, but that would enormously complicate<sup>38</sup> the running of the MRDT and compromise efficiency. The following are just a selection.

### Expenditure flows versus value

If we are serious about measuring value – rather than just requiring the spending of money without regard to

what is achieved with it – this is a much more complex issue than treaty proponents (and indeed many of us) often believe. It is very difficult to measure value in advance. Yet, setting up a committee to do this ex post is also not a panacea. We should be wary of any mechanism built on the notion that these are easy things to evaluate in advance.

Putting emphasis only on spending encourages waste. What if a country invests in costly new research facilities tangentially related to disease research and uses accounting techniques to disproportionately use the cost of doing this to count towards its medical R&D obligations? How is this policed? How does the MRDT deal with drugs (and other innovations) that already exist that can be modified to meet needs that are ‘neglected’ in developing countries, as opposed to totally new R&D campaigns targeting neglected diseases?

### Measuring a mixed and complex process

R&D processes are complex and mixed. Valuation problems happen under mechanisms such as the Kyoto Protocol for carbon dioxide emissions, but there is at least certainty in the fact that a ton of carbon emissions is a ton of carbon emissions wherever it is produced in the world. Those who do lots of basic research will want to use this heavily against their obligations. But how will it efficiently, fairly, and reliably be valued? How *does* one compare the ‘value’ of spending on a bit of basic research versus the purchase of an outcome based on such research?

Definitions of what is ‘open’, what is ‘technology transfer’, and whether priorities have truly been satisfied (so as to put a price on existing credits) would be subjective, and involve legalistic dispute, with this

often favouring the richer players. Given the weight of supposed punishments if falling short, there would be extreme pressure to imaginatively account for what is going on.

Moreover, such an approach would require ongoing violation of commercial confidentiality too, since firms would be forced to reveal what they are doing in real time, since the mechanism would not cope with valuations based partly on outcomes yet to be determined, such as the eventual development of a successful products; investments that have yet to yield any payoff will otherwise fail to be accounted for in the timeframes by which the MRDT evaluates activities.

## Accounting systems

Multiple problems with R&D accounting systems for R&D in general do not encourage us to believe that an entirely new way of doing R&D can be based on such underlying accounting systems.

Each part of a complex R&D process will have to get priced just once to count under the MRDT; in particular, inducements and the actual R&D must not be double-counted. The problem is that in parts of national R&D accounting systems, it is already very difficult to separate out this double-counting.

Furthermore, even if double-counting is avoided, if there are several different ways for spending to be counted, care has to be taken not to allow those being adjudicated to adjust their figures so as to claim in a way that picks off the most favourable method of counting what they are doing.

Any evaluation based on simple accounting of spending flows will also encourage plenty of (wasteful) ways to get around any Secretariat running the scheme. Scherer observes, for example, that “Tax avoidance games, e.g. in the allocation of R&D and the profits therefrom to jurisdictions with the most favourable income tax laws – could also wreak havoc with attempts to attribute R&D financing to the actual sources of incentive.”<sup>39</sup> This is in the context of developed countries. In poorer countries, the quality of accounting systems would be too poor to manage many of the things the MRDT would require of such countries.

We are reassured that “we believe that economic tools and experience exists to implement such structures rigorously and make them flexible enough to respond to government strategies.”<sup>40</sup> It would be helpful if the tools and experiences were listed and some detailed analysis provided so that an objective judgement could be made about this.

## The denominator

Those running the MRDT would have to link a ‘credit’ being recorded in the system to the source of funds and not to the country physically doing the R&D. All expenditure, wherever incurred, would therefore have to be converted into a common denominator in adjudging contributions. Given fluctuating exchange rates, this will not be easy. Nor will it be clear how to adjudge success or failure. Even if a rolling average is used to ‘smooth out’ exchange rate fluctuations, what if exchange rates undergo prolonged periods of rising or falling? This is entirely different from the few credit trading schemes that have been tried previously. The Kyoto Protocol is based on a stable common denominator in the shape of tons of SO<sub>2</sub> or CO<sub>2</sub> which is the same everywhere. Scherer argued in his CIPIH submission that “At the very least, to support the proposal, one ought to have an extensive simulation analysis using numbers gathered from national accounts.”<sup>41</sup> Perhaps unsurprisingly, MRDT promoters have not followed up on this suggestion.

## Cost measurement

Credits earned via prices on drugs and other interventions should only be earned on that part of expenditure that is above the cost of production (i.e. only on the bit available to be spent on R&D). The cost of production of a very expensive-to-produce product should not count towards an R&D credit as much as a product with very low cost of production and high value. Correct calculation of this is also needed to give incentives on affordability. If excess costs of drug production (and R&D spending too) get counted towards MRDT obligations, this weakens the incentive to be efficient on costs. Previously, a country had strong incentive to cut costs; it picked up the advantage in

lower national health bills. Now, without a good secondary mechanism in place, the risk is that part (maybe even, in some cases, all) of higher costs would count towards credits.<sup>42</sup>

Similarly, any prize-based component of a treaty arrangement should take into account differential costs of R&D (intuitively, as a measure of the ‘difficulty’ of generating a unit’s worth of value) and costs of goods, so as to extract the true value of innovation. At one point this was conceded by MRDT advocates and an attempt was made to incorporate it, but the current version of the MRDT just ignores the issue.

Incidentally, higher costs may themselves be a function of uncertainty and of the mechanism being proposed. For example, if uncertainty created by the mechanism interferes with capacity decisions, this will show up in higher prices. Why should this perversely be counted as a credit? What are the counterfactual costs structures to adjust these actual costs so as to create an ‘allowable’ credit?

Marketing costs are just one more cost that would need to be calculated as an allowable expense before working out the value of R&D. How will this be calculated? How will it be allowed to vary across spending categories?

## Putting a measure on the value of risk-bearing activities

There is a huge amount of value that is not picked up in sheer spending flows and may not show up easily in a readily-available price, but is related to the way that different players bear risk. In much public discussion, often the risk bearers are thought of as private players. However, governments, foundations, Product Development Partnerships and others routinely absorb a great deal of risk as part of the way they add value. How is the value of this risk mitigation and risk sharing element to be measured under the MRDT? If a particular player is carrying a great deal of risk, why should that not be counted? The MRDT is next to toothless on this because it only thinks of value in terms of spending flows. What are the dangers that true risk takers and those working to mitigate risks are discriminated against in the mechanism because of the inability of the adjudicators to price in the value of their risk-bearing

activity? The potential distortions this would cause have not yet even been considered.

## In sum, a highly simplistic notion of measurement difficulties

The treatment of measurement issues – and especially the notion that it will be easy – lacks any notion of practical reality, the costs of performing this function, and the risks to all the players if it is done badly. Incidentally, this is not the same as arguing against gathering data and attempting priority setting on the basis of it; the issue here is the use of such a data-gathering exercise and priority-setting in a mechanism to supposedly reward and punish different investors and sponsors, where those rewards and punishments are sensitive to mistakes, the poverty of information on which the system depends, gaming and rent-seeking behaviour, manipulation and even outright fraud, and political manoeuvring.

## 6

## Equity issues and developing country buy-in

The current distribution of global R&D spend is heavily skewed, with the US predominant on just about any measure – public R&D spend, private R&D spend, R&D spend via drugs prices, and so on. Any new treaty-based mechanism either has to start with a distribution of obligations (and credits) that reflects the current ‘distribution’ of contributions towards global R&D, or has to start with some notion of desired distribution where the US is a much smaller contributor than it currently is. In the first case, the US dominates the system. In the second case, there is a huge shift of financial obligations from the US to the rest of the world. Would such an outcome be (or, perhaps, as important, appear to be) equitable?

Incidentally, a hope that it will be the second case – and that the rest of the world will be forced to ‘shoulder its fair share’ of R&D costs – may be driving some supporters in US policy circles, to the naïve acclaim of those promoting the MRDT in those circles.<sup>43</sup>

Were countries all to agree to join a MRDT nevertheless, would mandatory contributions be constant or on a per capita basis? The first is a regressive tax. The latter would see countries with higher incomes getting higher voting power in setting priorities. Was this not a fault we were supposed to be getting away from? Would it not be better to set priorities some other way if our chief interest is to crack the problem of creating R&D with an emphasis on the problems of the developing world?

If the bulk of R&D continues to be done in the US, this represents a huge tax transfer from the poor to the US via the flows through the credit trading mechanism. The promise will be the access to cheap ‘at-cost’ drugs, vaccines and medical innovations. However, given all the faults enumerated in this paper, how politically feasible will it be for relatively poor nations<sup>44</sup> to agree to join

such a mechanism and thus to pay a rich nation – and disproportionately the US – for credits? On the basis of what proof of the promised outcome would they agree en masse?

As DiMasi and Grabowski further observe, many of those countries that currently contribute little to global R&D:

*“...would have little incentive to enter into the national R&D budget treaties proposed...it seems highly implausible that one could get all of these parties, each with their own needs and priorities and with incentives to free ride, to agree to such a framework.”<sup>45</sup>*

How likely is it that the market for credits will therefore work – since it requires all nations to join – such that the market clearing price of credits will be efficient? Again, we find an outcome that is counterproductive of what the promoters of the MRDT claim they are trying to achieve.

## Efficiency issues

Will the proposed MRDT really encourage efficient outcomes, and are there no other ways to drive efficiency? Clearly, no system is perfect and the inefficiencies under an MRDT have to be balanced against the inefficiencies of other approaches. This section briefly surveys some of these challenges.

### Can intermediaries drive efficiency?

Even if they can be measured<sup>46</sup> we will only, in most cases, measure the cost, and not the efficiency or value of R&D flows under the MRDT. How would one therefore discipline efficiency via the MRDT? We are told that there could be “intermediaries experimenting” with different reward systems. As Hubbard and Love put it:

*“Many will also worry that a centralised national drug development agency taking decisions on R&D priorities and allocation of funds (via prizes or grants as discussed above) could easily become bureaucratic and inefficient. As a possible alternative, we propose a competitive financing scheme that would work through R&D investment intermediators.”<sup>47</sup>*

These institutions would, it is proposed, compete to gather funds from countries, make choices how to allocate over different modes of R&D, and somehow (it is never really explained) succeed or fail on the basis of a ‘market’ judgment of their performance. This has never been fully worked through. In the opinion of this author, the notion of ‘competitive intermediaries’ to drive efficiency was introduced at some point to soften the notion of a centralised bureaucratic mechanism, and is not taken seriously enough here to warrant time and space assessing the implications of introducing this new layer of bureaucracy into the scheme.

Nevertheless, what are the incentives of these intermediaries (even if they have the information necessary to make efficient choices, which is highly doubtful)? Given the complexity of the R&D process and the lengths of time needed for investment to show a result (not to mention the role of luck and serendipity), “it is unlikely that individuals or employers will be able to rationally allocate their funds based on the prowess of the organisations that the various R&D intermediaries fund, even if they had sufficient incentive to investigate the possibilities.”<sup>48</sup>

Incidentally, if Hubbard and Love concede that such intermediaries won’t work, will they then concede that “a centralised national drug development agency taking decisions on R&D priorities and allocation of funds” could “easily become bureaucratic and inefficient”?

### Protectionist pressures

At the moment, medical R&D is done in those countries that (on the whole) have a comparative advantage in doing such R&D.<sup>49</sup> There are dangers that if payments are mandated in a Secretariat-run system, there will be protectionist pressures for local R&D. The reasoning is fairly straightforward. Imagine the extreme case of a country that chooses to meet its obligations though local R&D spending, and that will get access to products that are the outcomes of R&D done elsewhere, at marginal production cost. Unless the system is extremely good at adjudicating the value (rather than just the expense) of R&D wherever it is done, a country can both get access to innovations from elsewhere (‘for free’) and carry on with (and even increase) its local R&D. To avoid this, a dollar spent locally should be worth less in the mechanism than a dollar spent abroad if the spend abroad is more efficient for any given dollar spent. It is

not clear how the MRDT will achieve this. Who adjudicates this? On the basis of what information? Even if the ‘true’ value of spending locally could be adjudicated, the incentive to redirect R&D abroad is still weakened, given that access to innovations is supposed to be ‘free’ once the obligation is met; so long as the value of spending locally outweighs the adjudicated inefficiency, the incentive continues to be to spend locally and support one’s local (inefficient) R&D institutions, rather than redirect the spending.

It might be argued that disciplining this could be achieved through the credit trading part of the mechanism. The suggestion is that a country would have an incentive not to waste money on inefficient R&D activities, because a successful R&D program would benefit – via the earning of treaty credits – from the pay-offs associated with licensed patented technologies, rewards from innovation prize funds, etc. It is claimed that even if there is weak domestic pressure to be efficient in spending, and even if monitoring is costly or poor, the relative efficiency of research spent in different parts of the world and under different research regimes would be enforced via the credit trading mechanism. This seems an extremely brave assertion to make. First, no international credit trading system has ever got close to being efficient, such that one could rely on such a system in this way. Second, the assertion could only ever cover certain kinds of innovation anyway, and not, for example, any R&D that is simply evaluated according to the amount spent on it. Third, if it is conceded that once a country has matched its spending obligations it supposedly gets all other medical innovations at marginal production cost, there continues to be less pressure to spend efficiently.

Furthermore, given that non-local spending looks like a tax transfer across countries, what are the political incentives to buy, say, US-generated credits versus spending in politically less sensitive ways such as on domestic activity in order to meet spending obligations, even if this is less efficient?<sup>50</sup>

### Negative impact on industry efficiency

Pro-industry voices would argue that the system as proposed would turn current innovation-based firms

into contract research organizations, but then ignore moral hazard and adverse selection problems that made such firms an optimal (but imperfect) way to handle such problems in the first place.<sup>51</sup> Inability to measure the value of risk-bearing activity – private or otherwise – was discussed above. We can have a debate about the true optimal amount of marketing, and about excessive and unnecessary marketing. Nevertheless, some marketing has to be done. The treaty is not supposed to just support drug R&D, but *all* medical R&D, and some of that requires a major marketing effort to get optimal uptake. The proposal appears to have few incentives to encourage this kind of activity.

### The breadth of the MRDT

The MRDT, unless extremely broad in coverage, risks covering only those aspects of health solutions that involve a product. For example, drugs and vaccines (if ever available) are not the only possible approaches to dealing with HIV. Are credits in HIV prevention going to be tradable internationally? If so, how? In controlling malaria, one can choose from a panoply of interventions, from investing in potential future vaccines to using current drugs, and from bednets to chemical spraying. Maternal mortality is high often for reasons that emphasise poor treatment choices, as well as inadequate access to cheap off-patent drugs, such as magnesium sulphate, calcium, and even aspirin. Should using a cheap intervention count less in the credit trading system than the use of a much more expensive drug? Who judges? Is it done in a case-by-case and country-by-country basis?

This is, of course, a problem faced already, and various proposed mechanisms, and not just the MRDT, run the risk of distorting choices further by favouring one intervention over another. Broadening a treaty, and the remit of its supporting institutions, to try to encompass this problem, would just make its workings even more cumbersome and expensive.

### Perverse incentives on access

Perversely, the MRDT potentially discourages measures aimed at promoting access to medical innovation via lower prices, such as price controls, compulsory licenses,

various 'inventing around' initiatives, diffusion of generics, etc.

For example, a greater use, and higher efficiency, of generics manufacturers will drive down prices but 'harm' contributions towards mandated spending obligations,<sup>52</sup> forcing countries to 'make up the shortfall' with payments into other R&D mechanisms. If successful initiatives to lower prices see countries forced into seeking the purchase of R&D credits, the (marginal) incentive to enact these initiatives is weakened. The chief proposers of the MRDT have not begun to explore the dynamics of the law of such unintended consequences.

## Priorities now

### The need for impact now

There are multiple failures in the current approach to global health. Two-thirds of all African children who die under the age of five could be saved by low cost treatments such as vitamin A supplements, oral re-hydration salts and existing combination-therapy drugs against malaria. More than 40 per cent of Africa's population – 300 million people – have no access to safe water.<sup>53</sup> Without clean water, anti-retroviral treatment for AIDS sufferers is not as effective, and formula milk cannot safely be used to prevent transmission of HIV from mother to child. Better water management can greatly reduce malaria mosquito breeding sites, and spraying inexpensive insecticides inside dwellings has been proven to reduce malaria significantly. Basic vaccinations and drugs are still not getting to a majority

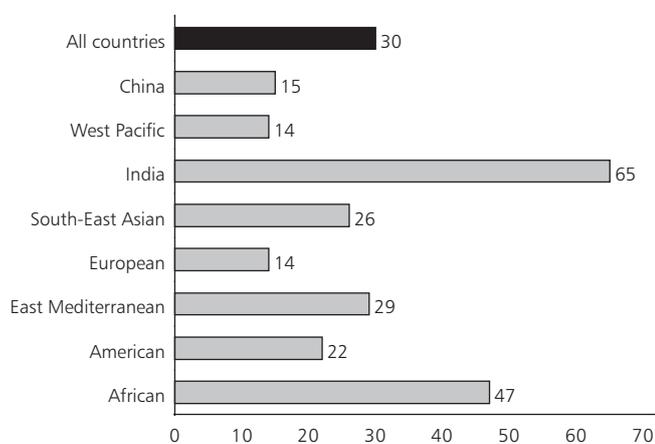
of people in sub-Saharan Africa. A tenth of all the diseases suffered by African children are caused by intestinal worms; these can be treated for 25 US cents per child. Poor nutrition contributes to over half of all deaths associated with infectious diseases in children under five. Maternal mortality runs at almost criminal levels in some countries. Inadequate, often inexpensive, prevention strategies condemn many to disease. None of these issues will be impacted by the efforts surrounding the MRDT.

### The challenges of medical R&D needs now

Even when we turn our attention to medical R&D, the MRDT goes out of its way to defy the principles of Occam's Razor.<sup>54</sup> Roughly, this argues that amongst competing solutions "All things being equal, the simplest solution tends to be the best one." What sense does putting huge effort into establishing an MRDT make when what is really needed is a relatively simple analysis of where the gaps are in diseases and treatments and then applying organization and funding to them? The precedent of organizations such as MMV shows us the power of the simpler – 'obvious' – solution. Unlike the complicated set-up being proposed in the MRDT proposal, MMV works with those laboratories and industry groups that best serve its needs, with heavy emphasis on costs of the end product.<sup>55</sup> There is no need for a grand bureaucratic global mechanism to drive this. The problem is that the simple – even obvious – or cheap often do not hold the same political appeal as the novel, complicated, or big-budget policy item.

After huge increases in recent funding, current R&D efforts are coming under increasing financial constraint. It is not clear how funding into PDPs and the products

Figure 1 **Percentage of WHO regions lacking access to essential medicines**



Source: World Medicines Report, 2004 (WHO)

coming out of such organisations will be sustained.<sup>56</sup> There is still poor understanding of how to support the rapid and wide roll out of new malaria drugs, microbicides, and some of the new generation vaccines. The long-term sustainability of recent initiatives such as GAVI and the International Finance Facility for Immunisation (IFFIm) are open questions. We are still unclear how to create more efficient funding into biotech and what the potential role is of 'innovative developing countries' in enabling access of the poor to inexpensive innovations, and how to encourage such players. Attention to the MRDT does nothing to tackle these pressing issues.

MRDT advocates suggest that the proposal will provide *sustainable* funds to some of these activities, even if the MRDT is only partially applied. They even suggest that it will be a source for PDPs soon. But if so (it is actually not so, and suggesting it is so is dangerous) why not just start working on providing these resources sooner – and for certain? Why instead take such a round about way, introduce huge delays (10–15 years) and then probably a collapse in negotiations, with much uncertainty en route?

## There are other ways to change priorities

It is simply not true that there are no other ways to alter priorities.

For example, diseases such as Chagas disease, which kills 45,000 a year in Latin America,<sup>57</sup> and visceral leishmaniasis, which kills 200,000 a year,<sup>58</sup> receive little global attention even within research priorities on developing world diseases. But even these truly 'neglected' diseases have been targeted by funding to groups such as the Drugs for Neglected Diseases initiative (DNDi) and the non-profit pharmaceutical Institute for OneWorld Health. The issue here is whether funding towards fighting these conditions and boosting the efforts already in place is better through extensions of this activity and increased funding to these sorts of institution, or through something new like the MRDT with all its faults.

If it is argued that funding is already distorted inside the publicly funded regimes away from diseases of the poor,

why is the proposed MRDT a more direct and less lengthy way to enact change than to petition the institutions involved to modify their priorities? Within the field of neglected diseases, one sometimes hears disquiet that research priorities are skewed heavily towards HIV/AIDS, malaria and tuberculosis. To the extent that this is considered important, surely it is more direct, and less likely to lead to lengthy delay, to work directly on this than indirectly and over long horizons via trying to set up a MRDT? A more direct route might be to tackle the priorities of major funders in particular such as the NIH and the European Union.

Similarly, many diseases have a crossover with the developed world – for example, the travellers' market for some vaccines – thus ensuring some market from which to recoup costs. There are few areas where there is *no* incentive currently, and the extent to which there is no incentive there are ways to affect investment.<sup>59</sup> The challenge is how to exploit such situations to the benefit of the poor.

Under the proposal, the very poorest countries will pay very little or nothing. The question then – as now – is whether or not current innovations can be made available to the poor at low or no cost. To the extent they are not now, it is not clear how the MRDT helps. For example, the recent report into the investment case for TB vaccines,<sup>60</sup> essentially ruled out access of the poor to booster vaccine technology on the grounds that such technology will be too expensive. And recent efforts to make pneumococcal vaccines accessible have also stumbled on the cost of such vaccines, to the extent that recent supposed R&D incentives run the risk of simply becoming subsidies of high costs. Making these innovations widely available requires much more attention to cost issues, and to how to make them affordable to the poor in the first place.

There is also the factor of medical infrastructure, with clinics and health personnel in very short supply in many regions of the world. The danger is that attention to the MRDT (and, indeed, various other recent high-profile initiatives) simply distract from tackling these tougher practical problems.

To return to the message at the start of this paper, efforts to change priorities and efforts to promote the MRDT,

with its new bureaucracy and credit trading system, are entirely independent of each other. The concern here is that attention to the MRDT will simply distract attention from some of this better priority-setting, and create yet further delays in tackling these issues. Instead of speeding up action, the efforts of the proponents of the MRDT are likely to work against the outcome we all seek, which is to translate the fruits of medical innovation into life-enhancing benefits for the poorer part of humanity, and to do this soon.

## Notes

1 Schieber, G., Fleisher, L. and Gottret, P., (2006), "Getting Real on Health Financing" *Finance and Development* (December 2006) 43:4, [www.imf.org/external/pubs/ft/fandd/2006/12/schieber.htm#author](http://www.imf.org/external/pubs/ft/fandd/2006/12/schieber.htm#author)

2 Hubbard, T. and Love, J., (2003), "Medicines Without Barriers: From the Human Genome Project to Open Development Models for Medical R&D", *New Scientist* (June 2003), <http://www.newscientist.com/article/mg17823994.100;jsessionid=OOEPBCKKDMA>

3 There have also been endless recent debates on the issues of IP. Nothing fresh on the topic can be added here. Raising the topic yet again, though in the context of the MRDT, will fall into the trap of treating it as a key issue in determining the credentials of the MRDT.

4 "Medical Research and Development Treaty (MRDT): Discussion Draft 4", (February 7, 2005), <http://www.cptech.org/workingdrafts/rndtreaty.html>

5 Much of the promotional material for the MRDT has talked about drug, and sometimes vaccine, patents. As we will see (and as logic dictates) the MRDT would need to cover a much broader notion of medical innovation than this (hence the terms added here).

6 "If a government for example would opt to directly fund research (e.g. by giving grants to research institutions or via a prize fund), it would not have to respect patents on pharmaceuticals, since the country would already have paid its fair share of medical R&D." Hubbard, T., Love, J., (2004), "A New Trade Framework for Global Healthcare R&D" *PloS Biology* (February 2004) 2(2):147–150, <http://biology.plosjournals.org/perlserv/?request=getdocument&doi=10.1371%2Fjournal.pbio.0020052>

7 "Our main concern with HL's proposals centers around the compulsory termination of the patent system, given the strong role that patents have played in encouraging drug R&D and innovation." DiMasi, J.A. and Grabowski, H.G., (2004), "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D" *submission to CIPiH*, p5. <http://www.biag.org/BLAG/images/articles/art10.pdf> p16

8 This phrase follows many of these categories.

9 We find soon that this 'flexibility' is largely a myth.

10 It is not clear to this author that the tradeoff has been fully explored between inflexibly fixed proportions so as to avoid risk but therefore inefficiency if circumstances change, and flexible proportions so as to be able to adapt to changes in underlying variables and the release of information but therefore the risks of 'dynamic inconsistency' (whereby those running the mechanism take advantage of the fact that investors have already sunk their investments).

11 “Medical Research and Development Treaty (MRDT): Discussion Draft 4” (February 7, 2005) <http://www.cptech.org/workingdrafts/rndtreaty.html>

12 [www.who.int/intellectualproperty](http://www.who.int/intellectualproperty)

13 WHO, (2006), “Public Health Innovation and Intellectual Property Rights” p104 [www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf](http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf)

14 Submission to the 59th World Health Assembly from Brazil and Kenya “[Global Framework on] essential health research and development”(27th January 2006)

15 In particular, a large proportion of emissions comes from a limited number of sources, such as power stations, putting a great deal of emphasis on tackling these sources.

16 It has become common in recent global health initiatives to label initiatives as “market-based” even as they defy market principles. The hope is to appeal to politicians who promote their political persona as based on ‘market’ principles.

17 See for example Dreyfuss and Orsenigo in their requested submissions to the CIPIH:

Dreyfuss, R., (2005), “Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty”.

Orsenigo, L., (2005), “Review of CPTech Proposal for an R&D Treaty”, *submission to CIPIH*, <http://www.who.int/intellectualproperty/submissions>

18 Hubbard, T., (2005), “Reply to the comments requested by CIPIH and WHO to the CPTech proposal for a Medical Research and Development Treaty”, *submission to CIPIH*, <http://www.who.int/intellectualproperty/submissions>

19 This is in part a misnomer, since the US already uses many other approaches.

20 It is much worse than this. To give a flavour of the difficulties (and the reader may not easily follow this, but that is the point): If a product (or a portion of a product) is being allowed to earn credits via the high price of the product in a country relying on a strong IP regime, then TRIPS and TRIPS-plus restrictions would be allowed to apply to the product (or a portion of it) and the country in question. Elsewhere, where products (or parts of products) are being priced close to marginal cost because the country concerned has based its R&D credit earning on open source or publicly funded R&D activity, then TRIPS and TRIPS-plus agreements would not apply to those products (or the relevant portion of those products) in those countries. It is actually a bit less straightforward even than this, but this is probably sufficient to give the flavour of the practical challenge.

21 Not a correctly worked out figure, but just for illustration.

22 Even this is presuming that the US would abandon funding its own entire public and open source R&D efforts.

23 Note how this may be very inefficient, and the perverse outcome if there is a pre-stipulated proportion of global R&D allowed to be spent via high drugs prices.

24 R. Dreyfuss, an expert in IP law, drew particular attention to this during the CIPIH consultation process. Dreyfuss, R., (2005), “Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty”

25 Clause 14.1.

26 Dreyfuss, R., (2005), op. cit.

27 Scherer, F.M., (2005), op. cit.

28 Ibid.

29 Hubbard, T., (2005), “Reply to the comments requested by CIPIH and WHO to the CPTech proposal for a Medical Research and Development Treaty”, *submission to CIPIH*, <http://www.who.int/intellectualproperty/submissions>

30 Ibid.

31 It is perfectly possible for this group to overlap with the group arguing in favour of IP, since the Doha Declaration allows the overwriting of IP rights in a state of medical emergency even when relying on IP for innovation incentives.

32 All based on the assumption that the US joins and is not concerned about the consequences to its R&D activities of such a pitch.

33 Scherer, F.M., (2005), “Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty”

34 DiMasi, J.A. and Grabowski, H.G., (2004), “Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D” p5.

35 Scherer, F. M., (2005), Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty

36 Ibid.

37 Hubbard, T., (2005), “Reply to the comments requested by CIPIH and WHO to the CPTech proposal for a Medical Research and Development Treaty”, *submission to CIPIH*, <http://www.who.int/intellectualproperty/submissions>

38 Recent examples include Pfizer’s reformulation of its azithromycin drug, used globally as an antibiotic, so that it could be used against trachoma, a tropical disease, and Abbott’s innovation of heat-stable Kaletra tablets to replace refrigerated capsules so that regions lacking fridges can better use them. One World Health, a highly innovative non-profit organisation, has a portfolio of products based on taking off the shelves of ‘big pharma’ compounds that can be made to have potential impact on the health problems of the poor.

39 Scherer, F. M., (2005), "Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty"

40 Hubbard, T., (2005), "Reply to the comments requested by CIPIH and WHO to the CPtech proposal for a Medical Research and Development Treaty", *submission to CIPIH*, <http://www.who.int/intellectualproperty/submissions/en/>

41 Scherer, F. M., (2005), Submission to CIPIH in response to requests for comments on the Medical Research and Development Treaty

42 In a sense this already happens, but under the MRDT it is actually potentially worse, since there is now an incentive to use higher prices towards meeting an obligation.

43 This is only one way in which realpolitik may intervene to render the outcomes of the actions of MRDT advocates counterproductive to their originally claimed intents.

44 Other than cases where vested interests may see benefit in supporting a mechanism proposing to redirect funds to their R&D facilities.

45 DiMasi, J.A. and Grabowski, H.G., (2004), "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D" p4.

46 Remember that countries will be 'punished' and, if the system is allowed to be flexible, priorities will be reset on the basis of such measurement, however badly done.

47 Hubbard, T. and Love, J., (2004), "A New Trade Framework for Global Healthcare R&D" *PLoS Bio* 2(2):e52 .

48 DiMasi, J.A. and Grabowski, H.G., (2004), "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D" p15.

49 We can debate issues like the consequences of the concentration of R&D into a few large players, issues about the constraints on biotech funding, how much open source should be done, and what are the roles of up-and-coming 'innovative developing countries', and so forth. But, for now, we treat these as out of our remit of interest.

50 Incidentally, this may also explain the interest of some countries in supporting a MRDT; they believe it will support their domestic R&D interests, even if they have not thought through the workings of the proposal in just about every other respect.

51 DiMasi and Grabowski observe (ibid. p10) that "If all R&D activities are treated as inputs purchased by government contract, then some inefficiencies can arise as a result of incentive problems related to what economists have called yardstick competition (Tirole, 1988). Since the effectiveness of R&D activities can be difficult to measure, control and compare (particularly on the research side), some shirking may result (either through reduced effort or the pursuit of what is of purely scientific interest). On the other hand, if contracts have a high degree of specificity, then they may discourage thinking outside

of the box." (Tirole, J., (1988), *The Theory of Industrial Organization*, Cambridge, MA: MIT Press).

52 Unless somehow the value of this activity can be measured and converted into a credit. For example, if a credit can be based on the gain over the hypothetical situation if this action did not take place; though this raises a question about all possible hypothetical acts that might add value.

53 4th World Water Forum, Africa Regional Report, presented by Kordjé Bedoumra, Director of the African Water Facility (2006) <http://www.iisd.ca/download/pdf/sd/ymbvol82num15e.pdf>

54 [http://en.wikipedia.org/wiki/Occam's\\_Razor](http://en.wikipedia.org/wiki/Occam's_Razor). Conversely, another referee suggested that the MRDT had all the hallmarks of a 'Rube Goldberg invention'. Rube Goldberg was a cartoonist who came up with outlandishly complex inventions to do the simplest of things.

55 This is not to say that such groups do not face huge practical challenges.

56 This is not written in an uncritical spirit. One of the issues is also to make sure that some of these alternatives, such as PDPs, are efficient, and that they do not (in the case of vaccines for example) force the uptake of the first product to come along, and harm incentives for better products.

57 WHO, Disease Watch, Chagas Disease, (October 2003), <http://www.who.int/tdr/dw/chagas2003.htm>

58 Shetty, P., (2005), "More creative thinking needed on drug R&D", *SciDev* (May 2005) <http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierReadItem&type=4&itemid=156&language=1&dossier=8>

59 Another line from Scherer's CIPIH submission reads "There can be no doubt that important problems exist in the funding of medical research and development. It is well known in particular that the principal private enterprise approach to drug development provides meager (not zero) incentive for work on so-called tropical diseases. It is unfortunate that the treaty draft does not provide an estimate of how important such neglected diseases are in the panoply of world diseases. In the report issued by the World Bank, "Health, Nutrition and Population Development Goals" (2002), the leading items in a ranking of contributors to the global disease burden in 1999 are HIV/AIDS, perinatal conditions, maternal conditions, childhood diseases, malaria, and tuberculosis. All of these are health problems in the first world too, and, ignoring the special case of mutant strains, there are substantial incentives for the development of effective therapies. Malaria is perhaps the principal exception, but there is a lot of work on it currently. To be sure, some diseases occur primarily in the third world, but the magnitude of the problem that is uniquely without solution ought to be brought into sharper perspective."

60 "Tuberculosis Vaccines: The Case for Investment," BIO Ventures for Global Health, October 2006, <http://www.bvgh.org/resources/market/TBBC.asp>.

# A Global Medical Research and Development Treaty

## An answer to global health needs?

by Andrew Farlow

In the past few years, billions of dollars have been committed by philanthropists and governments to the development of new drugs for the diseases of poverty. Nevertheless, some still argue that too little is being spent on the development of such medicines and have called for radical changes to be made to the global system of R&D.

The latest suggestion is for a binding, 'Kyoto-style' international Medical Research and Development Treaty (MRDT), through which R&D would be centrally directed towards perceived health priorities.

This proposal has gained a great deal of political traction, and a variant of the treaty is currently under discussion amongst members of the World Health Organisation in Geneva.

However, a close scrutiny of the literature issued in support of the treaty reveals it to be full of contradictions and questionable assumptions.

The MRDT, if ratified, would face all kinds of implementation challenges, few of which have been addressed by its proponents. In particular, the efficiency of the MRDT relies heavily on a credit trading mechanism, with credits earned from spending on a wide variety of types of R&D. The thinking is borrowed from the literature on carbon dioxide

emissions trading, but the MRDT ignores all the differences between R&D and CO<sub>2</sub> emissions, and all of the problems experienced by Kyoto.

Neither is it clear how the MRDT would assign true value for medical inventions, or how self-interested gaming and free-riding could be avoided. It is not clear how the level of a country's spending obligations would be set and evaluated, making it extremely difficult to police and enforce the MRDT.

These, and other shortcomings identified in this paper, mean that the MRDT could have the opposite effect to that intended resulting in more risk, less efficiency and less innovation. Worse, the complexity of the MRDT is likely to divert resources and attention from more simple solutions that actually stand a chance of improving the health of the poor immediately, instead of at an unspecified time in the far-distant future.

