Round Table

A role for public–private partnerships in controlling neglected diseases?

Robert G. Ridley[1]

Public–private partnerships mean different things to different people, depending on the values of the individuals and organizations concerned. They raise numerous political, social, public health, economic and commercial issues. Partnerships formed to promote product research, development and access, however, can only work effectively if the collaborating organizations have a common goal, however their values may differ.

In developed economies, members of the public and private sectors are continually discussing shared concerns, often through well-defined structures. Despite tension, a *modus operandi* has emerged whereby legislative, market and societal forces can operate to accommodate the needs of both sectors. This can result in a sustainable balance of power and flow of resources and rewards while generating wealth that leads to progress in health.

In many developing economies, however, a sustainable balance of this kind does not exist. It is widely believed that in addition to national inputs, external resources will be required if health is to be improved. External resources can come through donor governments, international organizations, philanthropic foundations, nongovernmental organizations and the private for-profit sector. The underlying question about investment for health in developing countries is: who has what responsibilities and obligations? Closely related is the issue of the power of developing countries in relation to that of other stakeholders in defining the goals, values and mechanisms of the partnerships.

The situation today is perhaps more promising than ever before in terms of the political will to mobilize resources to reduce global health inequities. Public–private partnerships are increasingly being explored as a mechanism to meet the needs involved, and this has given rise to much debate. In addition to the general questions above, the following more specific ones arise. First, regarding appropriateness: when, if at all, are public–private partnerships necessary and desirable? Second, regarding trust: can goals be clearly distinguished from values as an aid to dialogue? Should differences in values ever preclude cooperation or partnership? How best can trust be generated when potential stakeholders differ sharply on values? Third, regarding risks and benefits: what are they for each party involved in a public–private partnership? What operational value can each contribute to such a partnership? What special role can it play? ■

[1] Chief Scientific Officer, Medicines for Malaria Venture, ICC Building, 20 route de Pré-Bois, 1215 Geneva 15, Switzerland (email: ridleyr@mmv.org).

Round Table Discussion

A donor perspective

Julian Lob-Levyt[1]

Public–private partnerships in health have to be seen in wider economic and political contexts, usually set by domestic agendas in the West. These agendas have frequently been driven by ideology, but more recently the debate has centred on exploring new ways of funding and improving the performance of traditional public sector activities. In the UK and elsewhere, examples include partial privatization of state infrastructure such as rail transportation, private financing initiatives for the construction of hospitals, and the private management of poorly performing schools. Inevitably, similar thinking has entered the health and development field.

Classically, development funding has been seen either as a public good or as a philanthropic endeavour. Support has been channelled through governments to public health systems and care, or through nongovernmental organizations that operate in a similar framework. Some of the great achievements in public health, such as the development of vaccines for polio and other diseases, have been based on public funding. Drugs developed with private funding have been made widely available as international public goods.

In recent times public funding for research and development (R&D) concerned with diseases of the developing world has declined, as has overall official development assistance. Development assistance for health, however, has actually increased in real terms by as much as 3% per annum.

As a response to these changes, public–private partnerships in the population and health sector have expanded in recent years. This has been partly to mobilize additional resources, and partly to build a new political framework for working with the private

[1] Chief Health and Population Adviser, Department for International Development (DFID), 94 Victoria Street, London SW1E 5JL, England (email: Lob-Levyt@dfid.gov.uk).

sector on traditional public service provision. But more important than either is the recognition that health and development are part of the globalization agenda. They now hit the radar screens of world leaders, the G8 discussions in Okinawa and Genoa being the most recent example.

The three main focuses of collaboration are products, outcomes, and activities within countries.

Regarding products, efforts are being made to increase investment in new drugs and vaccines, in the face of decreased emphasis on R&D for diseases of importance to the poor. Public funding, tax credits, current and advance purchase funds are among the incentives being developed. Examples include the Medicines for Malaria Venture (MMV), a partnership which brings together the pharmaceutical industry with its expertise in drug development and the public sector with its expertise in science and fieldwork. The mission MMV has set for itself is to discover, develop and commercialize antimalarial drugs at prices that are affordable to the populations worst hit by the disease, at the rate of one new product every five years. Another example would be the international negotiations around the differential pricing of drugs to increase their affordability in poor countries, such as those currently under way in the European Commission Trade Directorate.

Regarding outcome-focused partnerships, efforts such as polio eradication or filariasis control are good examples. They often involve industry and private philanthropy. A large-scale innovative example is the Global Alliance for Vaccines and Immunization (GAVI).

Activities within countries include the social marketing of commodities such as condoms and insecticide-treated bednets and, more generally, using private sector mechanisms to provide public goods. Contractual arrangements for providing health services fall within this type of partnership. An important partnership under way in the UK involves GlaxoSmithKline, the University of Liverpool, WHO and the Department for International Development (DFID), which have joined forces to develop an effective, safe and affordable drug, Lapdap, for treating drug-resistant malaria in Africa.

These new partnerships present a fundamental challenge to the way we do business. Governments are increasingly engaged with development, but increasingly within a framework governed by issues of world trade, such as trade barriers, pricing and intellectual property. The United Nations likewise is challenged to take into account these new ways of working, and reform itself to meet the new agendas of the post-cold-war era.

Perhaps more important is the question of how an adequate voice is given to developing country governments in these new partnerships and discussions. The recently announced Global Health Fund to tackle HIV/AIDS, tuberculosis and malaria must be judged on how it handles this issue, and how it supports national priorities and nationally led processes, rather than undermine long-term development efforts. These new partnerships naturally want to avoid the bureaucracy and inefficiency of the "old style" UN, but there is increasing concern about lack of accountability and who is setting priorities.

Finally, we urgently need research to determine whether a public–private partnership really is a more effective or efficient vehicle than others for tackling poverty and inequality. Evidence from the UK is mixed at best. ■

Thinking boldly

Jeffrey Sachs[1]

Donor assistance in the order of US$ 20 billion or so per year may be required for sub-Saharan Africa if the vicious cycle of impoverishment and disease is to be broken. The vast bulk of increased assistance will have to come from governments, but these donations must engage both the public and the private sectors at various levels. Within countries, the design and implementation of country-led strategies to control the key diseases such as AIDS, malaria and tuberculosis, and to reform their health sectors more generally, will have to engage civil society on a broad level. National plans should be worked out on the assumption that the actual delivery of health services will involve not only state-run facilities but community organizations, private physicians and local and multinational businesses. The public sector, backed by large-scale international donor support, will have to fund the bulk of the efforts, but the funds will flow through a myriad of public, private, and not-for-profit institutions. The new Global Fund to fight HIV/AIDS, malaria and TB should make it a core strategy to insist that national programmes engage these relevant sectors in the design and implementation of Fund-supported activities.

At the international level too, the private sector will enter the expanded effort at disease control in a number of ways. First, large-scale donor support for disease control will have to be combined with new strategies for assuring access to essential medicines and research and development (R&D) efforts targeted at the disease burdens of the impoverished countries. This will require international donors, member governments of the World Trade Organization, and the private pharmaceutical industry to work in new ways. There have been many attempts to square the circle by lowering drug prices for the poor while maintaining or increasing incentives for R&D. The following is one possible approach.

The world community could agree that the essential drugs needed in the world's poorest countries, as identified by WHO, should be available

[1] Director of the Center for International Development, 79 John F. Kennedy Street, Cambridge, MA 02138, USA (email: jeffrey_sachs@harvard.edu).

to those countries (or to donors on behalf of those countries) at marginal production cost, rather than patent-protected prices. One way to do that would be to establish the norm that production licences would be made available to all qualifying drug producers, including generics producers, for the production of such drugs that are still under patent. The patent-holders would, at the same time, be assured of royalty payments for all licensed production of their products. Those royalty payments would be covered by the international donor community, for example as part of drug procurement by the new Global Fund.

This licensing-and-royalty system should also apply for any new medicines and vaccines that are brought to market in the future as the result of current R&D. An optimal royalty scheme, designed to spur R&D for neglected diseases, would set a high *prospective* royalty for currently neglected diseases with a high disease burden (such as malaria), and much lower prospective royalties for diseases (such as cardiovascular conditions) that already command a large market in the high-income countries. In this way, R&D incentives would be introduced where there is currently little or no perceived market.

Prospective royalty payments are an example of a "pull" or market-based incentive mechanism for spurring R&D. Economic theory and experience teach that such pull mechanisms should be combined with "push" mechanisms, in which the public sector directly spurs R&D by subsidizing research in basic and applied sciences directed at the targeted diseases. The Medicines for Malaria Venture (MMV) is a powerful example of such a push mechanism in action. If MMV and similar ventures were funded at a much higher rate, and combined with new pull mechanisms, the international community would finally create a much-needed system for spurring R&D in currently neglected areas.

In addition to targeted support for R&D through prospective royalties and direct financing of R&D, the international community should think boldly about fostering long-term institutional capacity in health sciences in the developing world. The National Institutes of Health, for example, have been central in building academic centres around the United States, and to a smaller extent abroad, through peer-reviewed competitive financing of academic institutions and research projects. Donors should combine to fund a global competitive process for the support of academic centres and research teams in developing countries, in order to sow the seeds of scientific breakthroughs for decades to come.

If wisdom prevails in the international community we are on the verge of a greatly stepped up effort of disease control and public health in the poorest countries. Public–private partnerships are at the heart of this change and they should be understood as involving the efforts, needs and interests of all parts of society, both globally and locally. ■

Values and benefits

Desmond Johns[1]

Since the health problems in question are usually far away from the resources that could solve them, a bridging mechanism is certainly needed. It is for finding and transferring such resources that innovative partnerships hold most promise, especially where they involve the multinational pharmaceutical industry working on neglected diseases such as tuberculosis and malaria. Such partnerships will therefore be the focus of these comments.

Experience has shown that the success of partnerships depends largely on the extent to which a clash of cultures can be avoided. While it should not be seen as a religion, public health is nevertheless essentially value-driven. Public health goals and the strategies to attain them have therefore to be compatible with this culture of values. Rob Ridley touches on this point by suggesting that if the emphasis is placed on goals rather than values, there can be common ground for dialogue which would otherwise not exist (*1*). This approach could expand the circle of interlocutors beyond the most like-minded, and facilitate a process by which common interests could be defined and mutual trust built up. Even then, however, if partnerships are to be successful, shared goals must to a significant extent reflect and be supported by shared values. Thus it has been considered worth exploring alliances for health with, for example, the pharmaceutical industry and the food industry but not with the arms industry or the tobacco industry.

This is evident in what is arguably the gold standard for partnerships of this nature, the Mectizan Donation Programme for the treatment of onchocerciasis (*2*), but it is sadly absent from others that are less admirable but more widely reported (*3, 4*). Clearly, it is not helpful to portray either product research or market development as altruism (*5*). Fortunately, the right signals appear to have reached the boardrooms, as evidenced by the recent willingness of companies to make substantial, transparent and often open-ended commitments, proving that the desired level of generosity requires neither their own impoverishment nor the abandonment of the profit motive.[a] After all, public health advocates recognize the importance of ongoing research and development, and some understand economics too, and are therefore aware of the benefits that would accrue to all sides if products

[1] Counsellor, Health, Permanent Mission of the Republic of South Africa to the United Nations Office at Geneva and other International Organizations in Switzerland, 65 rue du Rhône, 1204 Geneva, Switzerland (email: desmond.johns@ties.itu.ch).

[a] Including Pfizer's donation of azithromycin within the International Trachoma Initiative and fluconazole within its Diflucan donation programme, SmithKline Beecham's (now GlaxoSmithKline) Albendazole donation programme for lymphatic filariasis, Boehringer Ingelheim's nevirapine donation programme, the collaboration within the MMV, and the many offers that have been made and continue to be made within and outside the Accelerating Access Initiative.

destined for poor markets were priced closer to the marginal costs of production.

Space constraints prevent further consideration of this important issue, but these comments would be incomplete if they were not to include some speculation on what partnerships could achieve in the near future. The main possibilities seem to be the following: greatly increased access to existing drugs and vaccines, and faster development of much needed new ones. Some of the mechanisms that will lead to this improved situation include reduced prices, pooled procurement through competitive bidding, local manufacture, strengthened health systems and a more realistic funding base for health care. Fuller agreement on a fundamental issue will need to be secured within and between societies: how to balance economic and public health demands, bearing in mind that sooner or later all of us will have the opportunity to see it from a patient's point of view.

In conclusion, while this contribution reflects the personal views of the author, the South African Government is on record as having expressed its desire to be a part of the future described above. ■

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2. **Kale OO**. Review of disease specific corporate drug donation programmes for the control of communicable diseases. *Médecins Sans Frontières and World Health Organization Conference on Drugs for Communicable Diseases – Stimulating Development and Securing Availability*. Paris, October 1999 (unpublished paper).
3. **Stephens J**. As drug testing spreads, profit and lives hang in the balance. The body hunters: testing amid an epidemic. *Washington Post*, 17 December 2000.
4. **Stephens J**. Doctors say drug trial's approval was backdated. *Washington Post*, 16 January 2001.
5. **Shretta R et al**. Sustainability, affordability, and equity of corporate drug donations. The case of Malarone. *Lancet,* 2000, **355**: 1718–1720.

A landscape in rapid transition

Tim Evans[1]

The product development landscape for important diseases in developing countries is in rapid transition. Unacceptably empty pipelines are complemented by new scientific and technological possibilities. These two phenomena have led many people from industry, academia, civil society, government, multilateral organizations and philanthropy to seek support from one another in attempting to bridge the health product divide. During the last five years innovative initiatives for tackling AIDS, malaria and tuberculosis have won the confidence of public and private investors as frameworks within which to carry out drug, vaccine and microbicide development. I see the following four questions arising from this exciting trend.

[1] Director, Health Equity, Rockefeller Foundation, 420 Fifth Avenue, New York, NY 10018–2702, USA (email: TEvans@rockfound.org).

First, are public–private partnerships meeting an institutional need? The challenge of providing drugs and vaccines for diseases of poverty is not new. Indeed, it attracts considerable energies from a variety of concerned public and private sector institutions, and has done so for many years. In the aggregate, however, these credible efforts are insufficient to support viable health product pipelines for diseases of poverty. Too much investment in products with small prospective returns will not be tolerated by private sector shareholders, and public institutions often lack the degree of freedom necessary to manage product development successfully. It is these obstacles to mustering and managing resources on the scale needed that have led to the emergence of public–private partnerships. Although sceptics argue that these partnerships are taking away resources from other credible efforts, a zero-sum interpretation is misleading as the partnerships have mobilized 'new' resources and anyway often channel funds through their respective partners.

Second, can public–private partnerships do it alone? The grand vision and boundless energy of these new product development efforts might lead one to suppose that they could negotiate the path and deliver an AIDS vaccine or a TB drug without other support. But in reality they face a set of common challenges that can be more appropriately managed through other institutional arrangements. Among these challenges are guidelines for the management of intellectual property, the availability of good clinical trial facilities and the ability to clear regulatory hurdles. Independent efforts that are sensitive to the needs of public–private partnerships but better able than them to meet challenges of this kind will be an important complement to the work of accelerating the development of new products to fight the diseases of the poor.

Third, can public–private partnerships accomplish their mission? They have a legitimate place and a credible purpose, but are they up to it? So far, no public–private partnership has produced a product. The long and expensive road to product development — usually in the order of decades and hundreds of millions of dollars — means we won't know for a long time. We do know that the odds are low for a successful vaccine or drug for a specific compound entering the drug development pipeline. As such, partnerships will have to be skilful in maintaining investor and public confidence when promising products end up in the graveyard or, worse still, are found to have a net negative health effect on those participating in clinical trials.

Fourth and finally, how many public–private partnerships are enough? With the spate of new ones, the question of how many can be accommodated, or are necessary, arises. If one looks at the long list of diseases found in poor countries for which the product development pipelines are dry, it is clear that much remains to be done. This perception is tempered by the complaint that a proliferation of independent entities is producing a feeling of

anarchy, initiative fatigue and duplicated efforts. Might efficiencies be gained from partnerships managing more than one product portfolio, e.g. for TB and malaria, or would such mergers jeopardize the identity, focus and single-mindedness that are needed for success?

These questions should not be seen as obstacles to the activities of existing or future partnerships. On the contrary, more active discussion of these and other important issues will help to bring about a healthier transformation of the global health product development landscape. ■

Reversing failure

Harvey E. Bale[1]

Partnerships in global health care involving government institutions and industry — particularly research-oriented pharmaceutical industry — are relevant to at least three challenges: development of new medicines for certain diseases such as malaria; expanded access to medicines; and improved quality of medicines. This last includes tackling the serious problem of counterfeit drugs. These brief comments will be confined to the first two challenges. However, it should be noted that far too little public effort is being made to solve the serious problem of substandard and counterfeit medicines in developing countries. This is a growing threat to the use of (largely generic) medicines in Africa and other low-income regions. Much greater coordinated international attention to the problem of counterfeiting is called for.

The value and urgency of industry–government partnerships exists firstly where there is economic and social failure on the part of state institutions, especially where access to health care and medicines is concerned; secondly where neither government nor industry can succeed on its own (for instance, in global immunization programmes or tackling the HIV/AIDS pandemic); and thirdly where there is insufficient incentive for industry to act alone.

WHO notes that a third of the world's population lacks access to quality medicines (*1*). Of critical importance here is the fact that, with the exception of AIDS drugs, the most urgent and extensive need is almost entirely for the older, off-patent medicines. While HIV/AIDS receives much attention today, many more people suffer and die from diseases such as malaria, tuberculosis, acute respiratory infections, diarrhoeal diseases, measles and polio. For these, effective curative and preventive treatments have been available cheaply for decades, but hundreds of millions of people continue to lack access to them. Partnerships between industry and the public sector to deliver medicines for these diseases through donations and other schemes can make an immensely important contribution to reversing this failure.

People often ask: "Why does the pharmaceutical industry care about public–private partnerships for health?" There are four main answers. First, because companies are managed and directed by people who share society's basic social values and concerns. Second, because employees of pharmaceutical companies, like bright people in all walks of life, are motivated by ideals that extend well beyond their companies' bottom line. Third, because they have every interest in meeting the high expectations of shareholders and the public for the role of private companies in public life. Fourth, on a commercial level, it is a fact that healthier people are healthier future customers.

To partnerships for developing new medicines for diseases such as malaria, under the current Medicines for Malaria Venture (MMV), industry brings unique expertise: extensive research knowledge; chemical discovery and development experience, including clinical development; and a business approach free of political and academic considerations that can distort and ruin drug development projects.

It may also be necessary to consider other partnership mechanisms, perhaps similar to incentives contained in various orphan drug and paediatric regulatory laws that exist in several developed countries. These would need to offer 'transferable benefits' so that companies might be encouraged to develop medicines for certain developing country populations. However, no incentives can overcome critical scientific barriers to breakthroughs such as HIV/AIDS or malaria vaccines — and public authorities need to exercise caution to avoid seeking partnerships that overreach what is scientifically possible.

In the final analysis, partnerships are vital for progress on a number of public health challenges. This means that national and international public institutions and governments will need to step up substantially their political and financial commitments to them. Some governments will also have to recognize more clearly the vital role that incentives, including those related to intellectual property, play in delivering new solutions. Finally, some stakeholders will have to shed their mistrust of the private sector's legitimate role in helping certain (failing) public sector activities fulfil their function through new partnerships. An outmoded ideological stance may jeopardize the health of millions of people, and come to be seen as increasingly irrelevant. ■

1. **Brundtland GH**. Speech at the WHO/Public Interest NGO Pharmaceuticals Roundtable, 3rd Meeting, 1 May 2000 (available at http://www.who.int/director-general/speeches/2000/20000501_ngo.html).

[1] Director General, International Federation of Pharmaceutical Manufacturers Associations, 30 rue de St-Jean, 1211 Geneva 13, Switzerland (email: h.bale@ifpma.org).

Partnerships need principles

Jonathan D. Quick[1]

Public–private partnerships are becoming increasingly common in many fields, including health. For WHO, the critical objective of any partnership should be a health gain for the population WHO serves. In the field of medicines this could mean improved access, quality and use for existing products, and expanded research and development for new ones that are needed.

The potential of public–private partnerships in the pharmaceutical sector is considerable. The pharmaceutical industry plays a major role in research and development for new medicines. It represents a vital source of expertise in good manufacturing practices and the distribution of medicines, in both developing and industrialized countries. Public sector entities such as national governments and the World Health Organization are accountable to different constituencies, and have different responsibilities from those of private companies. Hence, certain principles must apply if both kinds of organization are to play their part effectively in a partnership (*1*).

First, the focus of the endeavour should be appropriate. Not all areas of public–private interaction are. For instance, normative functions such as setting regulatory standards for pharmaceutical products may use information and views from the private sector, but the regulatory decision-making process should be ring-fenced to remain independent, and not undertaken in partnership.

Second, the nature of each partner's involvement should be subject to certain expectations and conditions. For example, a public–private partnership for research and development of a new product must have a firewall between the overall management of the project and the scientific evaluation of the results. The freedom to publish both positive and negative results is vital to the scientific integrity of such a partnership.

Third, each partner must maintain full independence in policy matters and in areas of endeavour outside the focus of the partnership. For WHO this means, among other things, continuing to speak out and to take action on matters of public health policy, even where WHO's views may differ from those of its partners. Recent examples have included WHO's efforts to inform countries about the public health implications for access to essential medicines of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (*2, 3*).

Public–private partnerships can harness private expertise, creativity, and resources for the public good. Much can be achieved through well-conceived and effectively implemented partnerships. To avoid any untoward effects of such partnerships, a principled approach is needed to ensure that the focus of the partnership is appropriate, that the involvement of each partner is subject to certain expectations, and that each partner maintains independence in policy matters and endeavours outside the partnership. ■

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2. **Brundtland GH.** Remarks to the Ambassadors of African Unity, Geneva, Switzerland, 12 March 2001 (available at http://www.who.int/director-general/speeches/2001/english/20010312_oauambassadorsl.en.html).
3. Globalization, TRIPS and access to pharmaceuticals. *WHO Policy Perspective on Medicines, No. 3*. Geneva, World Health Organization, 2001 (unpublished document, available on request from the author).

[1] Director, Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland (email: quickj@who.int).

Market enticements are not enough

James Orbinski[1]

In theory, public–private partnerships begin to tackle both market failure and what has to date been public policy failure in the area of drugs for neglected diseases. They are a hopeful experiment but their potential is as yet unproven. While the creation of a new medicine or vaccine for a neglected disease cannot be seen as a bad outcome, it can only be seen as a good one if equitable access for all those who need it is achieved. The effectiveness of public–private partnerships will lie in a clear and unambiguous commitment to a social vision that is translated into intellectual property rights, and manufacturing and procurement policies that guarantee equitable access to any new medicine or vaccine by all those who need it — including those who cannot pay for it. This is a needs-based objective that can use enticement and subsidies to channel the profitability requirements of market forces, but will not rely on these alone. Within these partnerships, potentially competing public and private sector interests, roles and responsibilities must be carefully managed. This can only be achieved through open, transparent, accountable and representative governance structures. The aim of those structures must be to pursue effectiveness in drug or vaccine research and development (R&D), and at the same time to insist that a social vision is translated into equitable access to new, effective and field-relevant therapies for the people who need them.

Existing public–private partnerships target neglected diseases for which there is both enormous unmet need in the South and a potentially lucrative market in the North (for example, northern markets

[1] Chairman, Drugs For Neglected Diseases Working Group, Munk Center for International Studies, University of Toronto, 1 Devonshire Place, Toronto, Canada M5S–3K7 (email: james.orbinkski@utoronto.ca).

for new tuberculosis drugs, the travellers' market for antimalarials, and northern markets for an HIV/AIDS vaccine). They do not and probably will not target the "most" neglected diseases. For these diseases, effectively no consumer purchasing power exists or is likely to exist, despite the needs of patients for effective treatments. Leishmaniaisis, trypanosomiasis and Buruli ulcer are but a few examples of the "most" neglected diseases. For these, public intervention must be marshalled, to meet a social need that is unlikely ever to be met through market forces — with or without "push/pull enticements".

Future access to effective medicines for both neglected and the "most" neglected diseases cannot simply rely on good intentions or strong enticements to existing market forces. New drugs and vaccines, together with technology transfer and capacity-building in the South, must be complementary goals for public–private partnerships. While such partnerships can help to reduce the vacuum in R&D in developing countries, they are unlikely to fill it. Only strong national policies and a concerted international commitment to R&D — perhaps through an international treaty on this objective — can fill this vacuum for both neglected and the "most" neglected diseases.

Charity and philanthropy have been key and welcome driving forces behind most public–private partnerships. While helpful and catalytic, though, they are not a substitute for good and responsible government in the North and in the South. Even with a clear vision and mission, public–private partnerships cannot displace the responsibility of government to ensure and promote people's right to equitable access to health care, and to set the health agenda both nationally and globally. Public-private partnerships, their stakeholders and national citizens must insist that governments and intergovernmental institutions fulfil their responsibility in properly funding and directing needs-based R&D. Governments still have a duty to ensure that appropriate resources and capacity exist in independent national and intergovernmental institutions to set, drive, monitor and critically evaluate the national and global health agenda. This is a minimum requirement, and goes far beyond the disease-specific initiatives which typify most new public–private partnerships. ■