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Business and Global Health Governance

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Preface

WHO's work in the area of Globalization and Health focuses on assisting countries to assess and act on cross border risks to public health security. Recognising that domestic action alone is not sufficient to ensure health locally the work programme also supports necessary collective action to address cross border risks and improve health outcomes.

In carrying out this work there was an increasing recognition that the existing rules, institutional mechanisms and forms of organization need to evolve to better respond to the emerging challenges of globalization and ensure that globalization benefits those currently left behind in the development process.

Consequently, as part of WHO's research programme on Globalization and Health, global governance for health was identified as an issue that required more detailed analysis to better inform policy makers interested in shaping the future "architecture" for global health.

Working in partnership with the Centre on Global Change and Health at the London School of Hygiene and Tropical Medicine, WHO's Department of Health and Development commissioned a series of discussion papers as a starting point to explore the different dimensions of global governance for health. The papers have been written from varying disciplinary perspectives including international relations, international law, history and public health. We hope these papers will stimulate interest in the central importance of global health governance, and encourage reflection and debate among all those concerned with building a more inclusive and "healthier" form of globalization.

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ABBREVIATIONS

BSE	Bovine Spongiform Encephalitis
CAC	Codex Alimentarius Commission
CEO	Chief Executive Officer
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
CSR	Corporate Social Responsibility
EPA	Environmental Protection Agency (US)
ETAD	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
EC	European Commission
EU	European Union
FAO	Food and Agricultural Organisation of the United Nations
GAIN	Global Alliance for Improved Nutrition
GAVI	Global Alliance for Vaccines and Immunizations
GBC	Global Business Coalition on HIV/AIDS
GHG	Global Health Governance
GIIC	Global Information Infrastructure Commission
IAPO	International Alliance of Patients' Organisations
ICC	International Chamber of Commerce
IFM	Association of Infant Feeding Manufacturers
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
ILSI	International Life Sciences Institute
IP	Intellectual Property
IPC	Intellectual Property Committee
IPR	Intellectual Property Rights
IRP	Institute of Regulatory Policy
ISO	International Organisation for Standardisation
MNC	Multinational Corporation
PPP	Public-Private Partnership
PR	Public Relations
TNC	Transnational Corporation
TRIPS	Trade Related Aspects of Intellectual Property
UK	United Kingdom
UN	United Nations
WEF	World Economic Forum
WHO	World Health Organisation
WTO	World Trade Organisation

BUSINESS AND GLOBAL HEALTH GOVERNANCE

INTRODUCTION AND OVERVIEW

The commercial sector has long played an important role in the health sector. Firms have had a significant direct impact on health through the development, manufacture and sale of their products, for example, from cigarettes to fortified foods to therapeutic and diagnostic equipment, and indirectly through their employment or environmental practices. In many countries the private sector is the leading provider of health care services and makes significant contributions to health care finance. And significantly, the commercial sector plays an active part in health policy-making through, for example, its influence over legislative and regulatory processes at the international, national and sub-national levels. Indeed, the commercial sector cannot be ignored when it comes to thinking about illness, health, health care or health governance.

The advent of globalisation has amplified the impact of the commercial sector on health by extending the reach and scale of global firms and industries, by increasing the concentration of ownership in specific industries, by changing how goods and services are produced, marketed, traded and sold, and in some situations by altering the balance of power between public and commercial sectors and hence the regulatory framework which governs commercial activities and their impact on health. Consequently, developing policies and programmes at any level on any health issue increasingly requires that attention be paid to understanding and shaping the roles and interests of the commercial sector – particularly those that are transnational in scope.

This paper provides an introduction to the relationship between the commercial sector and global health governance. It begins by defining the commercial sector, differentiating among public, non-governmental and commercial organisations, and enumerating the range of commercial entities with an interest in global health. After briefly reviewing the concept of global governance, the paper goes on to describe the commercial sector's involvement in global health governance. In particular, it differentiates between three prominent approaches: (1) establishing private systems of global health governance; (2) influencing public governance; and (3) co-regulation with the public sector. Examples of each of these approaches are provided alongside a discussion of their strengths and limitations and the debate that they often provoke. The final section provides an approach to assessing the governance of these arrangements, as applied to public-private partnerships, and conclusions are offered for advancing public health aims in the context of private health governance.

DEFINING THE COMMERCIAL SECTOR

This paper examines the role of the commercial sector in global health governance (GHG). But what exactly is the commercial sector? This section provides a definition and differentiates the commercial sector from the public sector and civil society. It provides a typology of commercial and commercially-oriented organisations with examples of each in relation to global health. These illustrative examples reveal the tremendous range of

commercial organisations with interests in GHG. These interests play a major role in determining the nature of global health governance and therefore have a significant impact on health outcomes.

It is common to make a distinction between public and private (non-state or non-governmental) actors. Within this distinction, the public refers to state, governmental and intergovernmental organisations (e.g. the Government of Burundi or the World Health Organisation [WHO]), whereas private is a residual category of all remaining organisations and entities. The commercial sector is of the private ilk, but contrasts with the more widely studied and qualitatively different category of private actors falling under the banner of 'civil society' which are distinguished not only by their voluntary but also non-commercial nature.

In contrast, the private commercial sector is characterised by its market-orientation. The commercial sector comprises organisations that seek to make profits for their owners (e.g. firms increasing shareholder value). Profit, or a return on investment, is the central defining feature of the commercial sector. Many firms pursue additional objectives related, for example, to social, environmental or employee concerns; but these are, of necessity, secondary and supportive of the primary objective which concerns profit. In the absence of profit and a return to owners, firms cease to exist.

This overview of the commercial sector will also include a range of organisations that are not-for-profit in their legal status, registered for example, with charitable status, but established to support a commercial firm or industry. These may include business federations, such as the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) or professional organisations. This approach to conceptualising the commercial sector corresponds with that employed by the UN for whom the commercial sector includes "members of the business community and their representatives who may act through not for-profit organizations, such as chambers of commerce or philanthropic foundations."

Similarly, not-for-profit organisations established by companies or wealthy individuals, but run at an arms length from them, are included in this review (e.g. Soros Foundation). This is justified on the grounds that some of these foundations and trusts have injected, not only large quantities of resources, but also the mindset of industry and commerce into global health activities. Indeed, it is arguably the case that many of the global health initiatives (e.g. GAVI, the Global Alliance for Vaccines and Immunisations) launched since the late 1990s would not have garnered significant private sector interest or involvement without the largesse provided to them by the Bill and Melinda Gates Foundation. The Foundation's resources served to incubate the majority of these ventures and, in many cases, also subsidized or underwrote private sector participation. In addition, the unprecedented involvement of global management consultancy firms, such as McKinsey & Company and KPMG, in global public health programmes is a direct result of Gates involvement. Country-level initiatives supported by the Foundation involve such firms in both programme governance and implementation. The co-chair of the Board of the India AIDS Initiative of the Gates Foundation, for example, is filled by a McKinsey executive whilst its membership includes prominent business persons such as the chairman of the giant Tata Group and the head of Infosys.

Further muddying the conceptual map is the growth of hybrid-type organisations, such as public-private partnerships, which are often either legally incorporated as non-profits or housed within public sector organisations – but which are governed by a collective of public and commercial organisations. The Institute for OneWorld Health further blurs the distinction between commercial and public sectors by registering as a tax-exempt 501(c)3 non-profit corporation under US law but calling itself the first non-profit pharmaceutical *company* in the US (OneWorld, 2004). This obfuscation reflects a wider trend towards introducing business practices into public organisations (usually referred to as new public management) and within non-for-profits including public-private partnerships. Many non-for-profit organisations must, therefore, be viewed as an extension of specific or more general commercial interests as far as their involvement in global health is concerned.

CATEGORIES OF COMMERCIAL ORGANISATIONS

This analysis of the commercial sector is mainly limited to the role of global (and international) commercial organisations. This category is itself quite diverse and includes organisations belonging to any of the following nine groups:

* Multi- and transnational corporations with an interest or impact on health. For example, Pfizer the pharmaceutical giant with global sales of almost US$ 40 billion in 2003 and Coca Cola the manufacturer, marketer and distributor of around 400 brands of non-alcoholic beverages in two hundred countries;

* Global cartels in the health sector. Cartels are groups of competitors which collude to eliminate competition or increase leverage on regulatory and policy processes. The existence of a global price fixing cartel for the sale of vitamins between 1989 and 1999 resulted in convictions in the EU and the US of Hoffman-La Roche, BASF, Merck and ten other pharmaceutical firms;

* Business associations, established to promote their members interests, may also have global health sector interests. The International Chamber of Commerce (ICC), for example, makes 'business policy' in a number of areas with an impact on health (e.g. in the areas of precaution, science and risk, and biotechnology among others) (www.iccwbo.org). The World Economic Forum, whose members represent the world's 1000 leading companies, hosts a Global Health Initiative. The Initiative develops and communicates best practice in the area of HIV/AIDS, TB and malaria. It also acts as a business focal point for a range of global public-private partnerships and assists some of them in identifying and selecting private sector board members (www.weforum.org/site/homepublic.nsf/Content/Global+Health+Initiative). The World Self-Medication Industry (www.wsmi.org) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) (www.ifpma.org) represent two prominent business associations with more focussed interests in global health. Many other national business associations also have global health interests. For example, BIO, the biotechnology industry organisation, is primarily an American organisation of over 1000 member companies (some transnational) with interests in health care, bioethics, intellectual property, regulatory and tax issues. BIO

has a number of international affiliates and runs a non-profit, BIO Ventures for Global Health, which enlists its members in the fight against neglected diseases www.bio.org/news/newsitem.asp?id=2004_06060_01;

* Associations of privately employed professionals with an interest in global health. On the one hand these may be organisations of health care providers, such as the International Private Practitioners Association (www.ippaworld.org) or, on the other, professional associations whose practices, interests or norms impact on health. The latter could include varied associations, for example, the Global Alliance for Public Relations (PR) and Communication Management (www.globalpr.org). Yet what, if anything, is the relevance of an alliance of PR professionals to global health? In brief, the Alliance promotes its Global Protocol on Public Relations. This protocol does not require of its adherents active disclosure of clients or funding and has no enforcement mechanism. PR firms may thus spin half-truths or unsubstantiated claims on behalf of their clients (e.g. alcohol, tobacco, food, pharmaceutical etc) but appear as disinterested third parties without a direct interest in the matter. In 2002, the five leading 'healthcare PR' firms earned over US$ 300 million for planning pre-launch media coverage or new drugs, cultivating prescribers, publishing medical journals and supporting patient groups with the aim of influencing health care policy and practice (Burton and Rowell, 2003);

* Non-profit standardising associations which cover global health related domains and are subject to high levels of industry influence. For example, in relation to standards governing a variety of tobacco and tobacco products (e.g. methods for measuring tar and nicotine yield, methods for determining organochlorine pesticide residues, methods for preparation, analysis of genetically modified tobacco, determination of nicotine in environmental tobacco smoke among others), the International Standards Organisation, a non-profit, relies heavily, if not exclusively, on CORESTA which is wholly financed and run by the tobacco industry (Bialous and Yach, 2001);

* Non-profit, issue-specific, industry funded think-tanks, foundations and institutes with interests in global health. This includes organisations such as the Global Business Coalition on HIV/AIDS (www.businessfightsaids.org) as well as the Institute of Regulatory Policy (IRP). Internal documents from tobacco company Philip Morris reveal it provided $US 880,000 to create the IRP in the US 'as a vehicle [to lobby] for the executive order on risk assessment' as part of it campaign to delay the publication of an EPA report on environmental tobacco smoke (as quoted in Muggli et al., 2004);

* Non-profit, 'patient groups' which have been established to advance industry interests. Many of these are national, such as 'Action for Access' set up by Biogen in 1999 to persuade the United Kingdom's (UK) National Health Service to provide interferon beta for multiple sclerosis (Boseley, 1999). Yet others are global in their membership and aims. IAPO (International Alliance of Patients' Organisations), for example, is registered as a charitable foundation in the Netherlands and funded by Pharmaceutical Partners for Better Healthcare, a consortium of about 30 major companies. IAPO has over one hundred member patient organisations and a stated interest in improving patient voice but a more probable agenda of lobbying for policies such as direct to consumer advertising and public/insurance funding of specific treatments (www.patientsorganizations.org). On a more

modest scale, the Global Alliance of Mental Illness Advocacy (GAMIAN) was founded and funded by the pharmaceutical company Bristol-Meyers Squibb (Herxheimer, 2003). The number and range of these industry-sponsored patient groups is growing. Some have short lives as they are formed to influence specific decisions in national, international or global debates whereas others are institutionalised;

* Institutionalised, non-profit, industry-established and -funded, scientific networks with an interest in health issues. For example, the International Life Sciences Institute (ILSI) was established in 1978 by five large food and beverage companies and now has sixteen branches world-wide comprising a total of 250 corporate members. ILSI supports industry-friendly science and attempts to influence regulation at the national, regional and international level. ILSI has been active in areas such as diet, tobacco and alcohol (www.ilsi.org);

* Non-profit, philanthropic organisations which, as stated above, invest significant resources in global health but also influence global priorities and approaches and leverage additional commercial sector involvement. One example is the Bill and Melinda Gates Foundation (www.gatesfoundation.org).

In common with most classification systems, the foregoing suffers from some shortcomings, among them overlap among some categories (e.g. business and professional associations). Nonetheless, the point is that there are many diverse commercial organisations which, in one way or another, have an interest and impact on global health. Yet the above list includes only formal organisations. Informal groups and networks also wield power in GHG. Consequently, a comprehensive list would need to include less formal groups which promote the interests of the commercial sector in the global health arena, for example:

* Loose issue-oriented networks with an interest in global health. The International Health Summit, for example, comprises a group of health sector executives dedicated to enhancing entrepreneurial spirit in health sector organisations by providing a platform for networking and learning experiences for senior decision-makers (www.ihsummit.com). ARISE (Associates for Research into the Science of Enjoyment) promotes the pleasures of 'smoking, alcohol, caffeine and chocolate.' With funding from companies such as British American Tobacco, Coca-Cola, Philip Morris, RJR, Rothmans, Miller Beer, and Kraft among others, Associates, mainly academics, appear to receive payment for publishing articles which promote and advocate consumer freedom in relation to those substances and deride the necessity of public regulation (see for example http://tobaccodocuments.org/usc_tim/2029104023-4024.html); and

* More tightly integrated private policy and regulatory communities. The Intellectual Property Committee, a coterie of 12 Chief Executive Officers (CEO) who are largely responsible for one of the WTO trade agreements, provides one such example (see below for more on this).

Other, novel, representations of a globalising commercial sector with an interest in global health governance can now be increasingly found on the Internet in the guise of virtual service providers (e.g. World Directory of

Holistic Practitioners www.holisticpractitionersnetwork.com/pract_dir_strart.htm), virtual communities and virtual campaigners. While some of these virtual communities are reflections of physical entities, for example the website of the International Public-Private Partnership Initiative hosts a series of private discussion boards for its members (www.ippph.org), others are truly virtual, for example the PharmaMarketing Network (www.pharma-mkting.com). Internet webpages can also serve as fronts for formal commercial organisations. For example, Monbiot (2002a and b) claims that the Bivings Group, a PR firm in the employ of Monsanto, established a website for a non-existent research organisation (Center for Food and Agricultural Research) from which to launch coordinated campaigns against environmentalists, and invented 'phantom citizens' who sent thousands of emails and petitions to select listservers and posted messages on influential notice boards. Globalisation has thus facilitated some firms to establish virtual organisations and campaigners to undertake activities to support their goals.

The commercial sector is highly differentiated with organisations varying in terms of their size, kinds of resources (financial capital, technology, employment and natural resources), level of formalisation, geographical scope, and compliance with the rule of law. In relation to the latter, for example, some firms which generally operate within the law may decide at times that non-compliance will improve profits. For example, on May 13, 2004, the pharmaceutical company Pfizer pleaded guilty to numerous civil and criminal charges for illegally promoting the off-label use of gabapentin under the False Claims Act in New York. It agreed to pay a criminal fine of US$240 million as well as another US$152 million to state and federal healthcare programmes. Evidence was presented which detailed how the company suppressed study results, planted people in medical audiences to ask questions intended to put the drug in positive light, provided generous consultation fees to thought leaders 'in its bid to move gabapentin to so called block-buster status' (Lenzer, 2004). In the same month, GlaxoSmithKline, another major pharmaceutical company, was also in New York courts over allegations of fraud for failing to provide information required by doctors to make informed decisions in relation to the antidepressant paroxetine (Lancet, 2004). Such firms are apparently willing to break the law due the low costs of doing so. As a result of a seven year effort to suppress research evidence challenging the benefits of its blockbuster drug Synthroid, Boots Pharmaceutical company (later Knoll) is estimated to have 'duped' patients into paying an extra US$ 365 million per year. A class action suit which followed was settled out of court for just under US $100 million which was through to represent a fraction of the extra profits made by suppressing the research findings (Shenk, 1999).

By way of reiteration, although the commercial sector comprises those organisations established to realise a profit for their owners, consideration of the role of the commercial sector in GHG requires a wider purview to include those organisations which may be non-profit but serve corporate ends. If this approach is adopted, a vast range of commercial and commercially oriented organisations and networks with an interest in global health

emerge.[1] The activities of these commercial organisations may have impacts on health issues, including how they are governed. These organisations are also likely to have positions in relation to any proposed reforms to how these issues are governed if they impact on company interests.

GLOBALISATION AND THE COMMERCIAL HEALTH SECTOR

> Global corporations are the first secular institutions run by men (and a handful of women) who think and plan on a global scale…a relatively few companies with worldwide connections dominate the four intersecting webs of global commercial activities on which the new world economy largely rests: the global cultural bazaar; the global shopping mall; the global workplace; and the global financial network.
>
> Barnet and Cavanaugh, 1994: 15.

The concept of globalisation is a contested one yet it is widely agreed that the phenomenon is marked by increased global integration – particularly the globalisation of the world economy. The rapid growth of transworld spaces has left an indelible mark on the commercial sector: unleashing and combining resources on an unprecedented scale. Arguably, the commercial sector has also been a driving force behind globalisation. Globalisation and the private sector are intractably entwined and, for many observers, globalisation's economic face is the one that is most familiar – the rise of global brands, global companies and global products.

Although highly clichéd, the present era is characterised by the emergence of global firms in terms of global communications, global markets, brands and products, global production, marketing, advertising and distribution, global information infrastructure (particularly global economic commerce) and global finance among other transworld features. Underpinning these activities are the emergence of a global consumer culture and the increasing commodification of various aspects of social and physical existence including health.

There has been a tremendous growth in the number and scale of global firms. In the health sector, these trends pertain to pharmaceutical and biotechnology companies, medical device firms, health care providers, insurance firms, hospital consortia among others. In some health industries, a phenomenal concentration of ownership has occurred in the past two decades with the pharmaceutical industry providing a prime example. Market share of the top ten companies increased from approximately 1/3 of global sales in 1992 to just over 50% in 2004 (Busfield, 2005). The growth of these firms have resulted from mergers and acquisitions, many cross national in nature. For example, Pfizer, a US company, became market leader after acquiring Warner-Lambert in 2000 and Pharmacia in 2003. Another feature which has marked the pharmaceutical industry has been the staggering growth of strategic alliance building. Between 1997 and 2002, the largest 20 pharmaceutical firms formed approximately 1,500 alliances (Lam, 2004). Globalisation has created a new breed of corporate giant which

[1] Large areas of health with commercial involvement, such as technologies, insurance, service provision, are not covered in this paper due to space constraints.

rivals the size of some national economies and has a wider reach than some intergovernmental organisations.

Yet globalisation also presents a challenge to these global companies: as firms go increasingly global, they have an increasing need for global rules which govern their transactions wherever they operate. These rules serve to minimize uncertainty and lower transaction costs associated with information gathering, negotiation and enforcement among other things (such as barriers to entry for other competing firms). As early as 1998, the Secretary General of International Chamber of Commerce (ICC) indicated that "Business believes that the rules of the game for the market economy, previously laid down almost exclusively by national governments, must be applied globally if they are to be effective" (Cattaui, 1998a). Where possible, business seeks to establish its own rules – as it has been doing through the ICC since 1911. Where this is not possible, it seeks to influence public regulation, through for example the United Nations.

While firms may look to systems of global governance to improve their fortunes, the establishment of these systems raise a series of questions for public health practitioners. First, what exactly is global health governance? Second, how is the commercial sector engaged in GHG? Third, why might the role of the commercial sector in global health be of concern? And what are the impacts of these systems on health? These questions will be addressed in the following sections.

WHY A CONCERN WITH THE COMMERCIAL SECTOR IN GLOBAL HEALTH GOVERNANCE?

There has been a great deal of reflection, debate and acrimony over the respective roles of the state, civil society and the commercial sector as the three main spheres of global social organisation. This section does not rehearse this debate, but indicates how these debates have been reflected in relation to global health governance.

Governance concerns the manner through which a society or organisation 'steers' itself to achieve common goals (Rosenau 1995). Central to the process of steering is the establishment of rules, norms, principles, and decision-making procedures which bring order and structure cooperation. Through a variety of social processes, the governors (sometimes together with those they govern) establish these rules and garner the compliance of those they govern. Governance is thought to be effective if there is a high degree of agreement and compliance with the established rules, norms, institutions, etc. Governance operates from the family to the global level and is sometime formal (e.g. legislation and regulations) and sometimes informal (e.g. norms and etiquette). What is important to remember is that governance does not equal government (neither at the subnational, national or international level). Government provides a form of governance and is typically a very important one. Governance is a broader concept, and is more frequently invoked as a response to the limitations of governments acting alone, or through intergovernmental cooperation, to address complex issues arising from globalization.

James Rosenau (1995) argues that global governance can be conceived of as systems of rule, at all levels, in which the pursuit of goals through the

exercise of control has transnational repercussions. This appears to be a useful definition in that it draws attention to the idea of a society or organization steering itself towards some end (i.e. goal), and that agreed mechanisms and arrangements are devised for attaining these goals (i.e. systems of rule), that control is invoked to encourage and ensure compliance, and that this particular form of governance (i.e. global) has transnational repercussions. Building upon Rosenau's definition of global governance, we might conceive of global health governance in one of two ways:

* Systems of rule at all levels in which the pursuit of health goals through the exercise of control has transnational repercussions; or

* Systems of rule at all levels in which the pursuit of goals (whatever they might be – facilitating or preventing the trafficking of women, development of new irradiation technology for food, etc) through the exercise of control has transnational repercussions affecting health.

Global health governance conceptualized in this broad manner can, therefore, include a wide variety of formal and informal systems which impact on health – including systems established by or dominated by the commercial sector. There are at least seven arguments advanced for why the commercial sector is, and some would argue, ought to be, involved in global health governance.

First, the health impact of many cross- and trans-border flows are beyond the capacity of governments to manage or regulate effectively, acting alone or collectively through intergovernmental organisations (such as the WHO). Examples include the illicit trade of goods and services (and persons), spread of pathogens and antimicrobial resistance, emerging and re-emerging infectious diseases, environmental pollution, information and communication, and population migration. In that the commercial sector often plays some role in these flows and their intensification, the need arises to rethink classical, state-centric public health approaches to dealing with them. In particular, the question increasingly arises as to how to involve the commercial sector in governing cross-border flows in such a way that it can contribute positively to public health goals. In short, globalisation demands responses that involve the private sector.

Second, and following from the first point, new global health challenges have strained existing institutions. On the one hand, driven by ideology, resource scarcity and constraints, as well as spiralling health care costs, governments around the world have embarked on ambitious reform programmes, more often than not altering the balance between the public and private sectors. These typically involve an enlarged role for commercial organisations in health finance, delivery and governance. On the other hand, public sector institutions involved in global health have had to adapt to the changing global environment so as to remain relevant and effective. Many organisations, such as the World Bank and the WHO, have engaged in new and deeper horizontal relationships with the commercial sector as a strategic response and out of a sense of necessity. These relationships between intergovernmental and commercial organisations, which are both formal and informal, represent nascent initiatives to govern global health issues.

Third, as outlined in the preceding section, the commercial sector is simply too large to ignore in most sectors including health. In a world where the majority of the one hundred largest economies in the world are corporations, rather than states, private corporate standards and rules cannot be deemed as inconsequential. Whereas the World Health Organisation's biennial budget for the period 2002-2003 was US$2.2 billion (i.e. just over one billion per year) (WHO, undated), Pfizer, the top selling pharmaceutical company in 2003 had sales in excess of US$39.6 billion which did not include revenues from its over-the-counter, diagnostic and animal health divisions (Sellers, 2004). In the same year, Pfizer spent almost US$2.5 billion on promoting its products (just over the biennium budget of the WHO). Total sales for the top 50 firms (even the smallest of which had sales in excess of US$ one billion) were US$466 billion up from US$296 billion just two years earlier. No intergovernmental organisation and few states can deploy resources on the same scale as pharmaceutical companies in terms of research and development. Other major industries can also operate on a global scale in relation to health issues. For example, on the issue of access to anti-retroviral therapy for HIV/AIDS, Heineken, a global beverage and bottling company, began treatment programmes for its employees, one partner and children at select sites in Africa in 2001, well in advance of efforts by intergovernmental organisations to support more broad-based programmes.

A fourth argument made in favour of a more pronounced role for the commercial sector hinges on the potential contribution that the sector can make to improving global health outcomes and governance. The commercial sector is perceived to have a comparative advantage, and in some cases even a monopoly, in terms of skills, knowledge, expertise, know-how, and manufacturing, distribution, marketing and branding capability in specific domains. There is a sense that GHG might draw more effectively on the know-how and experience of the private sector, and to apply them to the protection and promotion of health worldwide – including governance. This could include in-kind contributions of personnel, product, distribution, advertising, and/or intellectual property for example. Commenting on a partnership between the Vodaphone Group and the UN Foundation, Ted Turner, the Foundation's Chair and major patron, drew specific attention to the technological, mass market and intellectual abilities that the transnational phone company might share with the UN through such projects as the Measles Initiative (UN Foundation, 2004). The Chairman of Pfizer, Inc. William Steere (2001) writes,

> Businesses are eager to participate in a strong global network. As a worldwide community, our ability to share the wealth of technological innovations will enhance human life in the new century. Businesses are ready to stimulate economic growth, improve the overall quality of life, and share technological advances.

Major contributions have certainly been made by industry in global health. According to the International Federation of Pharmaceutical Manufacturers Association (IFPMA), between 1998-2003, ten major pharmaceutical companies which are members of the Partnership for Quality Medical Donations have collectively donated products worth US$2.7 billion, mainly through major global public-private partnerships (IFPMA, 2004). In relation to public-private partnerships, donations of product constitute but one of industry's inputs. Consider, for example, drug development partnerships

where industry might provide goods such as compounds, tools and technologies (e.g. reagents, compound libraries, assays) or equipment as well as services such as participation on governing bodies, personnel inputs for project management, technology services, access to proprietary data and information, functional or scientific expertise. These contributions are increasingly attractive as the commercial sector is generally "ahead of the curve" in relation to new technologies – including those that affect health (e.g. food additives, genetic modification, radiology, etc). Consequently, some argue that the vast resources of the commercial sector can, should be, and increasingly are being harnessed to support GHG.

The foregoing suggests that in relation to governing some global health issues, transnational companies with their global reach may have a comparative advantage over both states and intergovernmental organisations. It is therefore not surprising that firms increasingly govern health issues, at times along side public authorities and at others on their own. These considerations give rise to the fifth reason for thinking about the role of the commercial sector in GHG: it may be more effective and efficient than comparable public efforts at global health governance. This statement is not to suggest that goals will be the same or even equivalent if public and private actors govern the same issue area. For example in relation to mechanisms which govern industry marketing of medicines; industry's guidelines are more concerned that misleading claims will lead to loss of revenue of more scrupulous companies (IFMPA, undated) whereas the WHO guidelines are more fundamentally concerned with patient well-being and cost-efficiency at the population level (WHO, undated).

Where private governance is effective, is consistent with the public's interests, and alleviates the need for public sector governance, it follows that such efforts serve to reduce public sector expenditure. Nonetheless, private governance may be ineffective or have negative consequences for health outcomes, examples of which are provided below. Concerns have led to heated debate and polarised views with calls for scrutiny of emerging mechanisms of private sector governance. What is now required is consideration of the circumstances under which private health governance is appropriate and how to go about identifying when additional safeguards to protect public health are warranted.

To reiterate, interest in the role of the commercial sector arises because:

* the commercial sector is responsible for many transborder flows that may contribute to health threats;
* the public sector cannot effectively regulate these flows on its own;
* the commercial sector is too large and too powerful to ignore;
* the commercial sector has resources which could be harnessed to support global health governance;
* the commercial sector may have a comparative advantage in governance due to its global reach and leverage over firms;
* involving the commercial sector in governance may save resources for the public sector; and
* the mechanisms of governance established by the commercial sector may not be in the public's interest and therefore justify public scrutiny.

While the above list is not exhaustive, it demonstrates why the commercial sector is and ought to be involved in GHG. It also provides a series or reasons to support the view that state-centric analysis of global health governance is simply insufficient to grapple with what is happening as the world becomes increasingly interdependent. The following section provides a conceptual framework for classifying the involvement of the commercial sector in GHG.

THE COMMERCIAL SECTOR AND GLOBAL HEALTH GOVERNANCE

Having defined global health governance in such a broad fashion, it is helpful to distinguish between different kinds of involvement by the commercial sector. While it is beyond the scope of this paper to document in detail all of these varied pathways, it is useful to begin with a conceptual framework which permits categorisation and assessment of the range and scope of these contributions. This paper identifies three main types of governance where the private sector plays an important role: self-regulation; influence on public regulation; and co-regulation. Each one of these areas is looked at in turn together with examples relevant to GHG.

Self-regulation through private rules and standards

Self-regulation concerns efforts by private companies to set and enforce their own rules and policies for operating within a specific domain. For example, rules governing how to design, categorize, produce and handle particular goods and services may be adopted by individual companies, industries or commerce more widely. Equally, such efforts might involve defining rules for relationships among manufacturers in the same industry or between manufacturers, distributors, employees and consumers. These range from the various efforts of the ICC, which sets rules and standards in areas as diverse as nomenclature in trade and investment, commercial law, and banking, but also settles disputes through its international court of arbitration (www.iccwbo.org), to the on-going efforts of hundreds of business associations represented by the Alliance for Global Business to develop standards for e-commerce (AGB, 2002).

Private market standards may be formally adopted, for example, Safety Data Sheets, issued and monitored by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), ensure that member companies divulge essential information on various chemicals to minimise dangers in handling and use (Ronit, 1999), or adhered to informally, such as norms on nomenclature governing commercial contracts, and they may be expressed as statements of principles, guidelines, undertakings, codes, declarations or standards. All belong to the category of private- or soft-law which means that they are voluntary in the sense that they are not traceable to public authority. These rules, regulations and norms are enforced by entities within the market itself (e.g. associations, such as the ETAD, and its individual members) and are often neither monitored nor subject to public verification. The aims of private standards include regulating competition among member companies, dealing with market failures, and suppressing unfair marketing behaviour. Private regulatory initiatives may operate at the sub-national to global level; our interest is where the repercussions are transnational in scope.

One can distinguish between two principal types of self-regulation. On the one hand are those efforts which attempt to regulate what might be termed 'market standards' and, on the other hand, regulation of 'social standards'. In the case of private market standards, aspects of products, process and business practice are subject to governance for the purpose of supporting commerce (for example to reduce transaction costs, increase compatibility between components or processes, or increase confidence in a product). Although there may be social impacts of self-regulatory process which govern market standards, the overriding purpose of market standards is to enable commerce.

There are many thousands of examples of industry self-regulation of market standards and norms including those relevant to global health issues – from advertising and public relations codes of conduct to standards governing the threads on screws used within medical equipment. For example, one can witness the development of global private market standards in the area of electronic health informatics through the work of the Global Information Infrastructure Commission (GIIC). The GIIC is a confederation of CEOs of firms that develop and deploy, operate, rely upon and finance information and communication technology infrastructure facilities. The aim of this private commission is to harmonise global policies through 'business self-regulation.' As early as 1996, based on the work of the Health Information Infrastructure Consortium (a group of made up of 110 US-based and multinational institutions), the GIIC published a paper on Healthcare and Telemedicine (GIIC, 1996). The paper covered areas such as:

* administrative information systems, for example, exchange of electronic unified claims forms and other forms of electronic data interchange for health care administrative transactions and inventorying;
* clinical information systems which include systems for accessing, storing, and transmitting medical information to allow patient records to be accessed instantaneously anywhere in the world as well as clinical decision-making protocols;
* electronic medical claims;
* personal health information systems (targeting consumers/patients directly); and
* distant patient provider consultation through telemedicine.

The paper recommended further development of global rules across all of these areas, and set out the need for worldwide harmonization in vocabulary and nomenclature to facilitate the emergence of global markets for the health information industry. The GIIC provides a good example of a nascent process to establish self-regulation of market standards to facilitate e-commerce which will have important implications for health care.

Global private market standards have been established when industry perceives the need for them due to weak or non-existent public (or private) regulation of market activity or fear of (inter)governmental action. A major empirical analysis of the private standards concluded that "it is more common for globalisation of law (with teeth) to follow globalisation of a new standard of business practice than for globalisation of a new standard of business practice to follow after a new law demands it (Braithwaite and Drahos, 1999).

Mechanisms of global private health governance, whose goals involve the development of market standards, rules or norms, may have both positive and negative health outcomes (either intended or as an unintended consequence). For example, depending on how they are framed, global rules governing transborder electronic movement of patient records could benefit patients who travel internationally for surgery as "medical tourists" but could also be used in such a way as to infringe upon patient confidentiality or increase costs to consumers or insurers through restrictive intellectual property practices. The regulation of tobacco product standards by CORESTA provides a more striking example. Established in 1955 as a research organisation of industry tobacco chemists from around the world, it continues to be dominated by industry. The International Organisation for Standardisation (ISO) relies heavily on CORESTA for research and publication of standards in this area. According to internal tobacco industry documents made publicly accessible in the late 1990s 'there are two international organisations controlled by the industry: CORESTA and ISO…CORESTA which is 100% controlled by the industry…ISO technical committee 126 [tobacco and tobacco products standards] is made of approximately 80% Industry… The best way to work with these two organisations is to do all the technical work within CORESTA and then have it endorsed by ISO' (cited in Bialous and Yach, 2001). Bialous and Yach conclude that, while industry self-regulation in tobacco and tobacco products serves industry commercial interests, from a public health perspective the standards are misleading and damaging. This is where the distinction between the concepts of private 'market' and 'social' standards is useful.

Self-regulation in relation to social standards, rules and norms consists of efforts by business and industry to voluntarily adopt and observe specific practices on the basis of public or social concern rather than in consideration of the functioning of the market per se. Social standards self-regulation is generally undertaken in response to:

- concerns raised by consumers (or public boycotts);
- shareholder activism;
- the threat or the perception of impending public regulation which may be more onerous. For example the Code of Pharmaceutical Marketing Practices was allegedly introduced by the IFPMA to avoid 'surrendering the issue unconditionally to WHO (Ronit and Schneider, 1999); and
- in some instances because it may provide a competitive advantage to leading firms by differentiating them from firms which can not or will not uphold the standards.

The incentives driving self-regulation of social norms are therefore often different to those driving market standards – yet the requirement of a market logic remains.

Initiatives falling under the umbrella of self-regulation of social standards include corporate social responsibility, voluntary codes and reporting initiatives, and some public-private partnerships. Self-regulatory initiatives governing social standards may address issues that are already subject to (often ineffective) national or international statutory regulation. For example, the International Labour Organisation (ILO) has issued standards governing

maternity leave and breastfeeding at work that some countries, such as India, have adopted whereas others, such as Kenya, have not. Research suggests that even those countries which have legislation often do not implement it. Some sections of the baby food industry are lobbying for voluntary, self-regulatory codes in this area (IBFAN, 2004).

In practice, it is sometimes difficult to distinguish between self-regulation of market and social standards as some mechanisms have been established to achieve both goals. For example, in response to a series of food scandals (e.g. BSE, pesticide concerns, rapid introduction of genetically modified foods), EUREPGAP, a consortium of major food companies (producer and retailer), began developing food safety and hygiene standards. While industry claims that the initiative is responsive to consumer fears, others argue that the initiative aimed to pre-empt more onerous public regulation (Lange and Heasman, 2004). It is likely that this self-regulatory project aims to serve not only both of these goals but also to facilitate global markets. According to EUREPGAP, many of its member companies are global and obtain food products from around the world. Consequently, they need a commonly recognised and applied reference standard and therefore one aim of the initiative is to facilitate global trade through technical harmonisation (www.eurep.org/about.html).

Corporate social responsibility

Corporate social responsibility provides an umbrella term for a number of self-regulatory initiatives and industry-promoted measures which are intended to improve the practices of firms and industries so that they operate in a responsible manner in so far as their social impacts are concerned. Among others, there are now a plethora of social reporting (e.g. SOCRATES), investment (e.g. FTSE-for-good), and corporate citizenship initiatives (such as drug donation programmes). Such practices can be traced back to philanthropic efforts of early twentieth century industrialists who supported 'good causes.' John D. Rockefeller, for example, gained prominence through the creation of the International Health Program of the Rockefeller Foundation which sought to control yellow fever and other tropical diseases and established a number of prominent schools of tropical medicine. It may be argued that such efforts were not wholly charitable. Indeed, diseases undermined commercial prospects in many tropical regions and any activity which reduced the risks to workers and investors made business sense.

Defining what constitutes social responsibility remains problematic. Firms' links to tobacco, arms, alcohol and pornography industries may all be targets in relation to corporate social responsibility movements as their products or production processes may negatively affect health. Nonetheless, not everyone will agree that these companies engage in social irresponsibility. Moreover, for other investors this will be a non-issue – investments will be made on the basis of potential return to investment. This is a point which is not lost on the managers of the so-called 'Vice Fund.' The Vice Fund invests primarily in stocks of the alcohol, gaming, tobacco and aerospace/defence industries. Its returns for the year ending 30 June 2004 stood at 33.82% in contrast to the Standard & Poor's 500 index average of 19.11% (Vice Fund, 2004). This example highlights the real trade off which exists between ethical investing and returns to capital which can be difficult to reconcile.

All voluntary self-regulatory initiatives have to ultimately improve financial performance of the firm. In the words of the famous free marketer Thomas Freedman, the only social responsibility of industry is to make a profit for its owners. The CEO of Dow Chemicals reassured his investors that he had not lost sight of this fact. On the 18th anniversary of the infamous Bhopal disaster of 1984, when a leak at the plant of (then Union Carbide) which killed some 8000 persons and resulted in approximately 100,000 permanent injuries, The Dow Chief Executive issued a letter to all employees explaining "Responsibility to our shareholders and to our industry colleagues…make action on Bhopal impossible" (as quoted in Norfolk, 2003). Corporate social responsibility has to be underpinned by a market logic.

Codes of conduct

Voluntary codes of conduct are perhaps the most visible form of self-regulation of social standards. The idea is that companies and industry make public commitments to adhere to a set of standards that they set themselves. Currently voluntary codes cover a variety of corporate practices that have significant impact on important determinants of health. These include, among other practices, workplace and occupational health and safety (which range from worker exposure to pesticide residues to access to on-site clinics), wages and working hours, minimum age of work (i.e. restricting child labour), forced labour, discrimination, freedom of association, right of collective bargaining, equal remuneration, product safety, responsible promotion, advertising, and marketing (e.g. pharmaceuticals and over-the-counter medications, tobacco products, breast-milk substitutes, alcohol), hygiene and food safety, protection of the environment, and human rights.

In the late 1990s, codes of conduct were rapidly multiplying and "competing for the hearts and minds of consumer and corporate managers alike" (Pearson and Seyfang, 2001). Most trans-national and multi-national firms as well as industry sectors have developed their own codes and also purport to abide with the requirements of many additional codes covering various aspects of their operations. Many of these codes are, therefore, global in their reach. For example, all company members of the IFPMA are required to adhere to the Federation's Code of Pharmaceutical Marketing Practices (www.ifpma.org). The world's major tobacco companies have adopted what they claim to be 'globally consistent' International Tobacco Marketing Standards (www.bat.com). Membership of the World Self-Medication Industry requires that Trade Associations abide by a set of conditions and standards among which is the development of voluntary codes of advertising governing marketing of non-prescription medicines directly to consumers (www.wsmi.org/aboutwsmi.htm).

Codes of conduct have been popular with business because, in addition to serving social purposes, they have the potential to serve important business functions – the ultimate aim of which is to increase profits. Codes may improve profitability in any of the following ways:

- demonstrate understanding and responsiveness to societal concerns;
- provide material for public relations and promotion;
- differentiate the firm from its competitors and thereby increase sales;
- respond to concerns of consumers and thereby increase sales;

- respond to the demands of civil society groups and perhaps stave off product boycotts;
- respond to concerns of investors and shareholders and thereby lead to greater investment;
- decrease costs to business. For example, The Global Business Coalition on HIV/AIDS (GBC), an association of hundreds of major firms, promotes a series of workplace policies among and beyond its corporate membership. These codes of best practice operate, at least in part, out of enlightened self-interest from a market perspective. The British mining conglomerate, Anglo American PLC, for example, estimates that 30,000 of its 125,000 employees in South Africa are infected with HIV. It has voluntarily adopted some of the GBC principles, including treatment of 3,000 of its employees. The costs are reported to be offset by sharp decline in mortality and in absenteeism due to illness (GBC, 2004);
- stave off or delay statutory regulation. The tobacco, pharmaceutical, and food safety codes mentioned above were all put forward in an effort to pre-empt what industry feared would be more onerous international conventions both in terms of content and enforcement; and
- provide flexible tools tailored to specific problems instead of blanket regulations which cover all contingencies.

As well as providing a number of benefits to business, voluntary codes might also serve wider purposes. First, they may bring new groups of stakeholders into the regulatory process. For example, casual and temporary labourers, often women, have participated in developing workplace codes of conduct whereas they had not typically been represented in comparable ILO processes. These groups may introduce issues onto the agenda that their colleagues in permanent employment may not have considered as important. Second, voluntary codes may generate better compliance than intergovernmental and national regulation. Experience with many international conventions governing social and economic concerns suggests that although many governments ratify agreements, they often fail to implement their provisions, and can not be held accountable by the international community for failing to do so. With voluntary codes, the theory is that companies will adopt codes so as to gain market share and comply with them so as not to lose the confidence of their consumers/shareholders (e.g. the sanction of adverse publicity). Thirdly, voluntary codes are obviously less costly to the public sector than statutory regulation. There are, however, reasons to remain skeptical of the ability of voluntary codes to adequately govern many global health concerns.

Prakash Sethi, Professor of Management at the Zicklin School of Business, City University of New York, has reviewed a large number of voluntary corporate codes and concludes that “corporate codes of conduct are treated with distain and largely dismissed by knowledgeable and influential opinion leaders among various stakeholder groups, as well as by outside analysts and the public-at-large” (Sethi, 1999). Sethi argues that such scepticism arises because:

- codes tend to enunciate general principles as opposed to specific standards (i.e. quantifiable and measurable indicators);

- codes tend to focus on concerns of Western consumers (e.g. child labour, or pesticide residue on organic fruit) as opposed to concerns of employees (e.g. right to collective bargaining, pesticide exposure);
- codes are rarely linked to internal reward structures, operating procedures, or corporate culture;
- companies typically do not make public the process by which they seek to comply with the code and the findings related to the code;
- reporting of code implementation is often not subject to external scrutiny.

A review of voluntary codes in the chemicals sector has drawn attention to their democratic deficit (i.e. lack of participation of consumer groups and transparency) (Ronit, 1999). An analysis of voluntary codes of pharmaceutical marketing practices, including the IFPMA code referred to above, concluded that they lack transparency and public accountability because consumers are not involved in monitoring and enforcement, omit major areas of concern, and lack timely and effective sanctions (Lexchin and Kawachi, 1996). Similarly, a former Executive Director of WHO argues that self-regulation in the case of tobacco manufacturing and smoke-free policies 'failed miserably' (Yach, 2004). Others argue that adherence to voluntary tobacco marketing codes, relating to restrictions on advertising to youth, for example, have been done in ways that promote the industry (e.g. depicting non smoking teenagers as geeky) (Collin and Gilmore, 2002).

A further problematic aspect of voluntary codes is their often 'aspirational' nature -- whereby they often represent company 'commitment' to stakeholders to undertake certain actions. Undertaking to voluntarily uphold a particular principle is qualitatively distinct from being held accountable under law to ensuring specific rights, for example, of those affected by company operations. As a consequence, such patchwork self-regulation results in 'enclave' social policy which governs select issues and groups of workers at a specific point in their working lives (e.g. policy covers only those workers in a specific plant and only while they hold their jobs). Some fear that these self-regulatory efforts will erode societal commitment to universal rights and entitlements in the process.

In summary, an increasing number of self-regulatory mechanisms are being adopted by the business community as evolving forms of global health governance. Self-regulation is of two varieties: market and social. While both types may facilitate improved global health they may also both potentially have negative consequences. In light of the potential problems with private self-regulation, governance in many domains has remained under the purview of public regulation. Yet as the following section demonstrates, for the commercial sector many of these domains are considered too important to leave to governments and intergovernmental organisations alone.

Commercial sector involvement in Public Global Health Governance

Where the commercial sector is not in a position to self-regulate, it will often seek to influence any relevant public statutory regulation which might impact on its profitability. At the national level, firms and industries will often provide finance to political parties and to political campaigns in the hope that once those parties and politicians are in public office, they will be more responsive to demands that firms may make. American data reveal

that the magnitude of campaign finance doubled in the ten years to 2002. In the run up to the American federal election of 2004, presidential candidates raised over US$1.5 billion with lawyers and legal firms contributing US$138 million and health professionals US$53 million (FEC, 2004). Private organisations will also lobby for or against particular national policies. For example, in 2000, healthcare lobbyists reported spending US $237 million to influence US senators and representatives, the Executive and other federal agencies at the national level (Landers and Seghal, 2004). In the first half of 1998, tobacco companies reportedly spent US$443 million defeating a proposed tobacco control policy in the US (Saloojee and Dagli, 2000).

Industry similarly uses a number of mechanisms to exert its influence in relation to the content and process of the development of global regulation and policy. Recent research has revealed efforts by industry to:

- Delay the introduction of international legal instruments (e.g. conventions, codes, agreements, resolutions). For example, it is alleged that during the 1980s, the IFPMA delayed WHO efforts on a code of pharmaceutical marketing by arguing that it required time to implement its own voluntary code (Richter, 2001);
- Block the adoption of international instrument. For example, the sugar industry, working through the World Sugar Research Organization and International Sugar Organization, provided the main opposition to the international dietary guidelines proposed by WHO in 2003 (Waxman A, 2004);
- Influence the content of international instruments. For example, tobacco companies lobbied at the national and international levels to weaken measures contained in the text of the Framework Convention on Tobacco Control (Waxman H, 2004);
- Challenge the credibility/validity of international instruments. For example, the Association of Infant Feeding Manufacturers (IFM) has argued that a number of World Health Assembly resolutions which aim to interpret and update the International Code of Marketing Breastmilk Substitutes do not conform with the earlier resolution and are hence void (IBFAN, 2004);
- Undermine the legitimacy and capacity of international organisation charged with negotiating international instruments. An enquiry into tobacco industry influence in WHO revealed that an elaborate, well financed, sophisticated and usually invisible global effort had been undertaken by the tobacco industry "to divert attention from public health issues, to reduce budgets for the scientific and policy activities carried out by WHO, to pit other UN agencies against WHO, to convince developing countries that WHO's tobacco control program was a 'first world' agenda carried out at the expense of the developing world, to distort the results of important scientific studies, and to discredit WHO as an institution" (Zeltner et al., 2000);
- Challenging the competence of a UN body to develop norms in a particular domain. For example, the food industry has opposed and tried to circumscribe the extent to which WHO can address the epidemic of obesity by proposing policies and regulations (Waxman H, 2004).

A number of case studies are provided below to illustrate the methods that industry adopts to imprint its interests on global 'public' governance and the implications that this is likely to have for public health.
Susan Sell provides a highly detailed expose of industry influence on the development of statutory rules which are virtually global in scope – those enshrined in the World Trade Organisation (WTO) TRIPS (Trade Related Aspects of Intellectual Property) Agreement (Sell, 2003). The impetus for global governance in intellectual property (IP) arose from the recognition among certain industries that weak IP protection beyond the US resulted in what was perceived by industry as 'piracy' and a significant threat to its returns on investment in research and development (R&D). As a result, the CEOs of 12 US-based TNCs (representing firms in chemicals, information, entertainment, and pharmaceuticals), with an interest in stronger and world-wide protection of IP, established the Intellectual Property Committee (IPC). The Committee was formed in 1986 – one year prior to the launch of the Uruguay Round of trade negotiations which resulted in the establishment of the WTO and the adoption of its agreements.

The Committee operated as an informal network which sought global IP rights through international trade law. The Committee began by linking inadequate global protection of IP to US balance of payment deficits. Based on these economic arguments, superior technical expertise, and presumably as a result of considerable campaign finance and lobbying, the IPC was able to alter the US administration's perceptions of its own interests and was thus able to win support of the US government for its aims. The IPC then sought to convince its industry allies in Canada, Japan and Europe of the logic of its strategy of linking IP to international law and encouraged them to lobby their governments to support efforts to include IP protection in the Uruguay negotiations. In the interim, the IPC hired a trade lawyer to draft an international treaty governing IP. The industry report was adopted by the US administration as 'reflecting its views' and served as the negotiating document in Uruguay. The IPC was able to position one of its key members, the CEO of Pfizer, as an advisor to the American delegation. Although the governments of India and Brazil attempted to stall negotiations and drop IP from the round, economic sanctions imposed by the US administration as well as technical arguments provided by industry lawyers eventually undermined their opposition. As a result, agreement on TRIPS was reached. According to the industry consultant who drafted the treaty, the "IPC got 95% of what it wanted" (Jaques Gorlin as quoted in Sell, 2003).

The TRIPS Agreement has the status of international law. The WTO has responsibility to oversee the implementation of the Agreement and has, by international legal standards, a particularly powerful enforcement mechanism. This case study provides an example of relatively direct participation of industry in global health governance. Indeed given the level of commercial involvement, TRIPS could be viewed as a privatisation of norm-making capacities which are subsequently enacted in the public domain.

The involvement of industry in successfully governing the intellectual property regime from behind the scenes is likely to have profound implications for health. For example, the Agreement obliges countries which had hitherto failed to protect product or process patents to make provisions for doing so. The term on pharmaceutical patents is now twenty years.

Industry argues that TRIPS will therefore ensure that firms continue to invest heavily in R&D to develop innovative therapies. Critics point to the restrictions that are placed on the use of generic drugs and the inevitable increase in the price of pharmaceutical products as well as the barriers to innovation that patenting entails – and the same is true of the fruits of technological progress in other areas which impact health.

In addition to targeting major global treaties, industry also attempts to shape the programmes of intergovernmental organisations. For example, documents released by the tobacco industry as a result of litigation against companies in the USA revealed ongoing efforts by the industry to influence WHO tobacco control programmes (Zeltner et al., 2000). Tobacco companies, their law firms and public relations agencies hid evidence, subverted fact, employed ostensibly independent scientists and experts (secretly in pay) as well as the media and NGO-front organisations to influence the debate on tobacco. The expert enquiry into tobacco industry influence on WHO concluded that industry subversion of WHO tobacco control activities resulted in 'significant harm' but that the extent of which would be difficult to quantify.

Industry also aims to influence the many technical committees of intergovernmental organisations which routinely develop global norms and standards. Analysis of the tobacco industry documents uncovered, for example, evidence of the methods used by tobacco companies and their food company subsidiaries to exert influence on FAO/WHO food and nutrition policies as developed in their respective expert committees (Hirschhorn, 2002). Among other strategies, the documents reveal that:

* Tobacco and food company Philip Morris set up the International Tobacco Regulatory System to track a number of international organisations among which Codes Alimentarious Commission (CAC) and FAO were given priority. Among other things, this 'early warning system' was charged with drafting 'reasonable alternatives [to] new laws and regulations';

* The tobacco industry funded the 'International Council on Smoking Issues'. The Council monitored all international organisations based in Europe. So as to conceal the true identify and purpose of the Council, it used a third-party, public relations firm which would make all requests in its name only;

* Industry 'positioned' experts on various FAO/WHO regulatory committees, using entry afforded by formal NGO relationships with FAO/WHO (i.e. observer, consultative and/or official relations) to conceal industry interests. At these meetings, these experts were afforded full rights to participate in subgroups and working groups. As direct industry representation would be suspect, ostensibly independent experts were proposed but their financial relationship and potential or real conflicts of interest were not revealed. These 'independent' experts served, in industry's words, as its 'lawyers' and 'whole-hearted advocates';

* Industry was able to nominate such experts as a result of close relationships with staff in the FAO/WHO Secretariats. Relations were further strengthened when ILSI managed to place one of its scientists in the WHO Geneva Nutrition programme. The easy movement of experts between private firms, university, international organisations and industry enabled industry

to 'position' experts in regulatory arenas. Hirshhorn argues that positioning is important because 'influence is exerted as much, perhaps more, by personal persuasion as by scientific evidence';
* Industry provided financial support to sympathetic libertarian think tanks and writers to promote anti-regulatory ideology in public settings. For example, Philip Morris paid academics, such as Petr Skarank, though a law firm to disguise the direct relationship, to write papers to undermine WHO's dietary guidelines.

While Hirschhorn cannot marshal evidence to prove that industry was actually able to influence the content of specific policies and regulations, he cites ample evidence that attempts were made in areas as diverse as sugars, pesticide use and residues, transfatty acids, additives and dietary guidelines. More revealing are industry claims that its strategies had indeed been effective. For example in relation to the content of sugar and dietary guidelines adopted by the International Conference on Nutrition held in Rome in 1992.

More covert strategies can be used by industry to influence international regulations. For example, industry-funded groups may position themselves as 'scientific organisations' when entering into scientific debates on norms and standards while failing to disclose their close links and funding from industry. The International Life Sciences Institute (ILSI) illustrates this tactic of concealing commercial interests in research outcomes which inform public regulation. ILSI describes itself as a 'Global Partnership for a Safer, Healthier World.' Its first President, Dr Alex Malaspina, envisioned ILSI as a 'vehicle to do something for the public health – a kind of mini World Health Organisation.' It seeks to employ strategic alliances to bring scientific solutions to important public health issues. In so doing, it collaborates with international health organisations, particularly two programmes at WHO: the International Agency for Research on Cancer (IARC); and its Programme on Chemical Safety (IPCS). ILSI also has special consultative status with the Food and Agriculture Organisation (FAO) of the UN. Eleven ILSI member companies support ILSI's International Organizations Committee (IOC) which is the official conduit for information transfer between the Institute and WHO and FAO. For example in 2001, the IOC coordinated ILSI's participation in a number CAC committees, including the Ad Hoc Codex Intergovernmental Task Force on Biotechnology, Codex Committee on Food Labelling, Codex Committee on Food Hygiene and the Codex Committee on Nutrition and Foods for Special Dietary Uses (ILSI, 2004). ILSI is also active in norm development at the regional level. For example, it manages the 'Food Safety in Europe: Risk Assessment of Chemicals in Food' (FOSIE) project funded by the EC. In other words, ILSI is heavily involved in developing technical norms and standards relevant to global public health.

Although it presents itself as a society of learned scholars working in the public interest, it began as 'a foundation developed primarily to permit companies to pool resources to support research programmes of common interest' (as quoted in James, 2002). Its initial membership consisted of Coca Cola and Pepsi Cola among other transnational food and beverage companies. It first President served simultaneously as a Coca-Cola Vice President. While its code of ethics and organizational standards insists that it does not conduct lobbying activities (www.ilsi.org/misc/CodeAndStandards.pdf) it would appear that it advances

the interests of its sponsors – often failing to disclose its funding sources and deliberately attempting to conceal conflicts of interests. For example, reproduction of correspondence between the editorial office of the journal *Addiction* and ILSI reveal the intentional failure to declare potential conflicts of interest, and attempts to deceive the journal on such conflicts, in relation to a volume on health issues and alcohol published by ILSI and supported by the alcohol industry (Edwards and Savva, 2001). Similarly, ILSI's long association with the tobacco industry, which included membership, was disputed by ILSI (Murphy, 2001), and funding, remained confidential until uncovered by protracted legal proceedings (James, 2002). In relation to the FOSIE project mentioned above, which is concerned with risks from chemicals in the food chain, the food, beverage, chemical and pharmaceutical industries which support ILSI have considerable interests in the outcomes of the project. Through the structure of the organisation, they are able to dominate its steering committee and hence control its scientific focus and manage the way that its findings are interpreted and disseminated (James, 2002).

These illustrative examples demonstrate the interests and range of tactics adopted by the commercial sector to influence public governance of global health issues. With increasing awareness of these strategies, the public sector is in a better position to develop policies and guidelines to protect against conflicts of interest, undue influence, and conferring unfair advantages to certain segments of the market.

Co-regulation

Co-regulation presents a third way between traditional public, statutory regulation and pure private self-regulation. It has arisen, in large part, because of the inadequacies of public and private regulation operating alone. As argued above, public statutory arrangements have been seen as wanting in an era of globalisation as state and intergovernmental capacity for regulation lags behind technological advances made by industry, suffers from jurisdictional constraints (i.e. national law doesn't apply in global space), and is perceived by some as too costly. At the same time, private self-regulation alone is recognised as not always in the public's interest. Hence a case remains for some external public control over self-regulation. Co-regulation may be viewed as public sector involvement in business self-regulation, or as concerted attempts to involve non-state actors in public governance. Others have called it distributive governance in that all concerned actors cooperate to shape norms, develop sanctions for transgression, and condition actor's acceptance of appropriate conduct (Detomasi, 2002). Like private and public governance, these arrangements may be formal or informal.

Co-regulation represents a bargain between public authorities and the private sector. The public and private actors negotiate on an agreed set of policy or regulatory objectives which are results-oriented. Subsequently, the private sector takes responsibility for implementation of the provisions. Monitoring compliance may remain a public responsibility, may lie with the commercial participants, or will be contracted out to a third party – sometimes an interested NGO-cum-watchdog. Indeed, co-regulatory initiatives often involve a mixture of public, private and civil society organisations. The advent of co-regulation is relatively new, and there has

been more formal experimentation with it at the national and regional levels. For example, in the UK the Advertising Standards Authority maintains a range of sanctions against misleading advertising which are backed up by statutory regulations of the Office of Fair Trading. These regulations permit High Court injunctions that would prevent a company using the same or similar advertisements. In other words, statutory support gives teeth to the self-regulating code. The European Union is also experimenting with co-regulation particularly with respect to the Internet, journalism and e-commerce. Two initiatives at the global level with implications for health are presented below.

The Global Compact

The ICC-UN Global Compact may be viewed as a form of co-regulation. In 1998, the ICC publicly called on the UN to develop a global framework of rules as national systems were seen as inadequate to facilitate global commerce (Cattaui, 1998a). According to the ICC President: 'In this process of modernisation and globalisation of rules, ICC is making a positive contribution, both as an advisor and through its own standard setting…Broader efforts should now follow in order to foster rules-based freedom for business, with the WTO assuming a key role' (Maucher, 1998). At the same time, the ICC President warned, 'We want neither to be the secret girlfriend of the WTO nor should the ICC have to enter the World Trade Organisation through the servant's entrance.' Consequently, the ICC established a 'systematic dialogue with the United Nations' in an effort to influence UN decision-making (Cattaui, 1998b). In 1997 the Executive Director of the World Business Council on Sustainable Development co-hosted a meeting with the President of the UN General Assembly to 'examine steps toward establishing terms of reference for business sector participation in the policy setting process of the UN and partnering in the uses of UN development assistance funds' (Korten, 1997). The meeting concluded that 'a framework' for corporate involvement in UN decision-making be worked out under the auspices of the Commission on Sustainable Development. The ICC then conceived the Geneva Business Partnership which enabled 450 business leaders to meet with representatives of intergovernmental organisations so as to determine 'how to establish global rules' (CEO, 1998).

One outcome of the industry effort was a Global Compact into which the ICC entered with the UN in 1999. According to industry, the Compact 'of shared values and principles, will give a human face to the global market' by focussing on human rights, labour standards and environmental practice (Cattaui, 1999). Anti-corruption was added to the agenda in 2004.

The Compact initiative comprises a network of over two thousand companies, six UN organisations, as well as labour and civil society organisations. It is governed by a 17-member Advisory Council which has been touted as the first UN advisory body with both public and private sector representation. Compact participants engage in policy dialogue, learning activities and projects to achieve two goals: (a) to mainstream ten principles (based on pre-existing international norms) into business activities so as to advance responsible corporate behaviour; and (b) to catalyze action in support of the UN. For example, members have used the convening power of the Compact to develop policy recommendations on how to increase impact in the fight against HIV/AIDS by improving workplace HIV/AIDS policies among member companies (Global Compact, n.d.). Members are requested to

publish illustrative examples on how they are enacting the principles of the Compact through concrete business practices on their websites annually.

The Compact's literature stresses that the arrangement is not a regulatory one. It induces corporate change by relying on the enlightened self-interest of members. Others view such networked, horizontal, non-hierarchical, and learning-based approaches as non-conventional forms of regulation. Such approaches, it is argued, will become increasingly prevalent in a globalising world (Ruggie, 2001). Others suggest that co-regulation may provide the UN with greater legitimacy, relevance and authority, and thereby enable it to assume a more influential role as a central node in the emergent and complex arrangements for global governance (Bull et al., 2004).

The Compact has, however, been highly controversial. Critics are concerned that the initiative will enable firms to engage in 'bluewash' – improving their corporate image through association with the UN. After the launch of the Compact, an alliance of civil society organisations opposed to the initiative produced a series of exposés of prominent corporate members who continued to violate Compact principles while at the same time publicising their membership (www.corpwatch.org). Examples included Unilever which was found discharging mercury into the groundwater in India, and Aventis SA whose genetically modified corn approved only for animal consumption was found in human food. Similarly, the practices of Nestlé, an obvious target given reports of persistent violations of the International Code on the Marketing of Breast Milk Substitutes, were reported to contravene a number of principles while the company sought to improve its global reputation through membership in the Compact (Richter, 2004a).

Other critics point to a potentially more damaging aspect of the Compact. By driving a wedge between moderate and more radical or progressive civil society groups, the Compact may undermine efforts to bring about international legally-binding regulation, and in the process erode democratic decision-making and accountability within society. Consequently, a coalition of civil society groups have proposed an alternative 'Citizen's Compact on the United Nations and Corporations' which demands that the UN develop rules which would bind corporate behaviour globally to UN endorsed norms within a legally enforceable framework (CEO, 2000). In response to this proposed strengthening of formal regulation, ICC President Adnan Kassar added what he called an important proviso to ICC's support of the values enshrined in the Compact: 'There must be no suggestion of hedging the Global Compact with formal prescriptive rules. We would resist any tendency for this to happen' (ICC, 2000). In short, the Global Compact demonstrates both tensions over the degree of public sector involvement that the commercial sector is willing to tolerate within co-regulatory arrangements, and broader tensions over the appropriate relationship between the private sector and the UN.

Public-private partnerships

One of the major trends in governance evident in the field of global health is the rise in the number of public-private partnerships (PPP) in recent years. Between 1998 and 2004, over fifty were established (www.ippph.org). These range from product development partnerships (e.g. Medicines for Malaria Venture), to product access partnerships (e.g. International Trachoma Initiative), to advocacy and coordinating initiatives (e.g. Global Partnership to

Stop TB), to initiatives which aim to mobilise additional resources for specific diseases (e.g. Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria). Such partnerships assume different organisational forms: some are new legal entities (e.g. Medicines for Malaria Venture); some are hosted by multilateral organisations (e.g. Roll Back Malaria in WHO); and others are hosted by international NGOs (e.g. Malaria Vaccine Initiative at PATH).

Some observers might characterise the aims of a private sector partner as simply philanthropic; thereby placing partnerships, in the category of corporate social responsibility. Although companies have only provided very modest levels of finance to partnerships, they have provided a range of critical in-kind resources. In return, many partnerships have generated positive PR material for the firms involved and in some cases PPPs have been used to deflect criticism of their business activities. For example, it is argued that the tobacco company Philip Morris (now Altria) uses its ownership of Kraft Foods to improve its image and that this objective was behind a controversial effort to secure Kraft membership in Global Alliance for Improved Nutrition (INFACT, 2002).

Others might place PPPs in the category of vehicles designed to influence public sector governance. Again, there is certainly some truth in the fact that partnerships provide opportunities for business to develop closer contacts with public officials. Yet, some analysts are sceptical of claims that partnerships are used by business to influence the UN. Roy Widdus, for example, questions how the inclusion of one private sector representative on the Board of GAVI can overturn the entire decision-making processes of WHO, UNICEF and the World Bank (Widdus, 2003). Others argue that this reflects a naïve view of how political power is actually wielded, and that partnerships can be used to advance the interests of industry in more subtle ways such as by keeping certain issues off an agenda, or framing the discourse around how certain issues that appear on the agenda (Buse and Harmer, 2004).

For the purpose of this paper, global health partnerships are placed in the category of co-regulation for two reasons. First, partnerships and networks are established as 'hybrid' organisations which are neither pure public nor pure private. There is some attempt to develop systems of rule in which both public and private sectors have a voice in decision-making (although when they assume a legal identity they are often established as not-for-profits or are embedded in public or private hosts). Second, partnerships are not solely established to coordinate action and to influence the actions of their member partners, but to govern substantive issue areas. For example, an analysis of a sample of global health PPPs found that over half self-report the development of technical norms and standards in areas which had earlier been the preserve of national governments or intergovernmental organisations (e.g. drug regimens and protocols) (Buse, 2004a).

If PPPs represent a new, and increasingly common, mechanism through which global health is governed, it begs the question as to how well they are governed and what implications they might have for global health. The results of an analysis of the governance arrangements of seventeen public-private infectious disease partnerships can be summarised as follows (Buse, 2004a):

* The Secretariats of all the partnerships were located either in Geneva or in the US. This could place partners from poorer countries in the global south at a disadvantage in terms of opportunities to participate, suggesting that these global partnerships may not be as global as their names imply.

* Many 'independent' partnerships (i.e. with their own legal identity) and those hosted by NGOs fail to have governments of developing countries as members.

* Commercial partners were almost exclusively northern pharmaceutical companies with very few firms from the south or other industries.

* The governing bodies of hosted partnerships (i.e. housed in NGOs or UN organisations) have curtailed authority as formal authority rests with their host. Moreover, many of these boards failed to have both public and private sector representation.

* Some boards had no representation from southern-based institutions and none of the boards had half of their membership drawn from this group.

* Accountability was problematic in two respects. First, the secretariats of most of the hosted partnerships experienced tensions when attempting to juggle the demands of dual accountability: up the chain of command within their host organisation and horizontally to other member-partner organisations. Second, all of the partnerships adopted a relatively narrow approach to accountability. Accountability was viewed primarily as being responsible to a small number of partners and funding organisations, as opposed to being responsible to all groups affected by decisions of the partnership (a stakeholder approach).

* Transparency, as measured by access to on-line information, was variable but generally inadequate. None of the independent partnerships made available minutes of their governing bodies. Only five of the seventeen published their annual budget.

* Although many of the partnerships developed norms and standards, it appears that only the minority of them had procedures for managing conflicts of interest. Only four undertook assessments of the suitability of commercial firms as partners (e.g. in relation to corporate social responsibility).

* Independent auditing was a common feature of the independent partnerships but not of the hosted ones.

While it may be premature to be overly critical of these nascent social experiments in co-regulation, improvements could be readily made in terms of balancing representation, more proactively managing constituencies, and increasing transparency. In relation to transparency, for example, one could reasonably expect that PPPs make freely available on-line: (1) strategic and annual plans and budgets; and (2) Board meeting agendas, background papers and subsequent decisions; (3) governance arrangements including mandates, processes and membership of decision-making bodies; (4) detailed information on how constituencies are represented and managed; and (5) annual performance reports against stated objectives.

Most importantly, perhaps, what about their impact on public health? Evidence suggests that global health PPPs have had considerable impact in raising awareness, political commitment and resources (often public) for specific communicable diseases, and in accelerating progress, fostering R&D and reducing commodity prices for public sector buyers and consumers (Caines and Buse et al., 2004). A mapping exercise of these partnerships reveals, however, that while the majority are focussed on communicable diseases, few target health systems development or numerous other areas representing considerable Disability-Adjusted Life Years (DALY) losses including maternal health (e.g. obstructed labour, unsafe abortion), depressive and other neuropsychiatric disorders, alcohol dependence, motor vehicle injuries, cancer prevention and treatment, and nutritional disorders (Buse, 2004b). Moreover, most partnerships are product-oriented, place more emphasis on treatment than on prevention, and very few aim to challenge the structural and societal determinants of ill health. This is arguably the case because both private and public sectors seek to pick the low hanging fruit (i.e. easier targets) but also because addressing issues such as non-communicable diseases might threaten commercial interests – although it is arguably the case that innovative partnerships might be forged with companies in the healthy food and lifestyle industries, among others.

As with the Global Compact, health-related PPPs have been subject to considerable controversy. One major apprehension relates to the impact that they may have on public sector organisations. At the global level, concerns have been raised that partnership exposes the UN to undue influence, introduces conflict of interest into decision-making, and undermines accountability (Richter, 2004b). In practice, partnership entails a wide variety of interactions between public and private bodies. For example, possible interactions include *inter alia*:

- joint decision making at the level of a governing body or in relation to norms and standards in technical committees;
- joint advocacy and fund raising;
- private sector donations (financial or in-kind) for activities or publications;
- collaboration on sales or marketing promotions;
- use of seconded personnel from private sector;
- licensing agreements in either direction; and
- use of logos or product endorsement.

Each of these interactions presents different potential risks, ranging from the appearance of compromised neutrality or independence, to actual buying of influence, conflicts of interest, or conferring of unfair advantage on particular firms.

Arguably, the UN has to some extent begun (perhaps belatedly) to protect itself from these risks by, for example, screening companies along social responsibility criteria prior to partnering with them. Many UN organisations have adopted some or all of the following negative criteria which would disqualify a company from partnership: deriving significant revenue (e.g. greater than 10% of total revenues) from the manufacture, advertising, distribution or sale of tobacco, arms and weapons, illicit narcotics, alcohol,

gambling or pornography; involvement in violations of UN sanctions; complicity in human rights abuses; employing or exploiting child labour; or being convicted in the past year for illegal or corrupt activities. Others have established positive criteria which must be met before partnership is agreed; for example, ethical business practices (e.g. active promotion of a code of ethics and existence of an anti-corruption policy) or workplace issues and labour standards (e.g. employee handbook or policy on codes of conduct and labour standards, policies promoting the hiring of minorities and women, non-discrimination policies in respect of employment and occupation etc.). Some UN organisations have also recently introduced procedures to manage potential and real conflicts of interest.

Regarding the accountability critique, UN organisations remain formally accountable to their own governing bodies – not to their partners or partnership boards. At times, as explained above, this vertical accountability results in tensions with partners for being insufficiently accountable to them.

Another area of concern relates to how the proliferation of initiatives further fragments the global health architecture. Health-related PPPs, for example, might be seen as challenging WHO's role and capacity to coordinate health development efforts, undermining its normative role and creating competition for scarce funding. Certainly much of the new funding available for global health in recent years (e.g. Gates Foundation), as well as a great deal of bilateral aid, has flowed to such partnerships – perhaps at the expense of WHO. At the same time, many new partnerships duplicate existing global WHO health programmes, many of these partnerships perform technical functions (which had been performed by WHO), and the proliferation of PPPs renders coordination increasingly challenging.

CONCLUSIONS

This paper provides an overview of the roles of the commercial sector in global health governance. It begins by illustrating the diversity of for-profit and not-for-profit organisations with an interest in health at the global level, along with discussion of the magnitude of the stakes involved (from both a financial and a public health perspective). It argues that a state-centric approach of global health problems and solutions alone is increasingly inadequate. The goals, strategies and resources of the commercial sector need to be more fully explored, and correspondingly their impacts on public health more critically assessed.

Examples of the myriad of ways that the commercial sector might seek to 'steer' global health so as to pursue its own financial, and other, interests is presented. A system of classifying commercial sector involvement in global health governance differentiates between efforts involved in self-, public-, and co-regulation. Self-regulation could be further divided into two types – those based on market and social standards – each driven by different incentives. In relation to the former, essential regulatory functions are performed by the market which sometimes impact on public health. These regulations and norms are diverse and their implications for health and can be positive or negative.

The key point is that public health practitioners need to become more aware of self-regulatory mechanisms which impact upon their sphere of health

concern, and in turn attempt to influence the development of these standards in ways that are health neutral or positive. This is likely to prove to be a challenging endeavour given that market standards evolve quickly, and the networks and organisations which produce them may be reluctant to involve other players, particularly when meeting their demands entail increased costs. However, it should be recognised that this is preferable to a situation where private standards fail to take public health concerns into account, and potentially therefore result in significant and negative health consequences. In such cases, civil society and the mass media could then pressure private actors to take health considerations into appropriate account. Where external pressure does not compel commercial actors to address the health impact effectively, the offending standards become, ipso facto, social standards. Consequently, public health groups should attempt to shift governance from the realm of self- to co-regulation, whereby civil society and the state have some say in how they are governed. Improved transparency and increased scrutiny of private regulation of health is clearly called for and civil society will have a major role to play in ensuring these occur.

Self-regulation of social standards is itself a diverse field with a plethora of initiatives. While at first glance these might appear to present win-win opportunities for commercial and public actors, many have proven controversial as a result of their poor design and management (e.g. codes of conduct without internal rewards or external scrutiny) and because of their potentially negative impact on statutory regulation (e.g. pre-empting public regulation and diluting impetus for public action). A pragmatic response to these criticisms may entail: (a) ensuring public and civil sector organisation involvement in the development of voluntary social standard regulation (so as to ensure that they balance market incentives with safeguards such as credible third party watch-dogs); and (b) simultaneously continuing to develop and implement public regulation where it is warranted. In effect, the idea is to move the instrument away from self-regulation to some form of co-regulation. As noted above, this may prove difficult as private actors may resist public (whether governmental or civil society) involvement. While the threat of public regulation may provide industry with an incentive to reconsider the health impacts of these private arrangements, attempts to develop incentives which will benefit compliant firms may present a more credible and productive approach. For critics, such a strategy is overly sanguine in that it fails to acknowledge the threat of voluntary initiatives to statutory processes and because it may involve interaction with firms with dubious practices (e.g. manufacture or distribution of arms). While policies and criteria to screen companies for practices provide one route to address the latter concern, gaining consensus on what constitutes good or bad corporate behaviour has proven difficult and in some cases elusive. The issue of the impact of voluntary initiatives on statutory regulation is more difficult to deal with. On the one hand, some claim that statutory regulation builds on voluntary initiatives. On the other hand, if the former is not true, it remains the case that it is difficult to understand what drives (and undermines) movements for social change (and clearly this is an area for further research).

Private sector efforts to influence public regulation are neither novel nor avoidable. What is new are revelations about the tactics and extent of efforts used by some corporations to influence decision making within the

intergovernmental system. As a result, multilateral organisations are putting in place policies and procedures to protect themselves from such efforts. What remains to be seen is how effective such measures will prove to be. Research in this area remains highly sensitive and difficult to undertake, not least because the public and private actors involved can be reluctant to cooperate. Perhaps civil society organisations, such as Global Health Watch (www.ghwatch.org), can play a role in this respect, showing that improved transparency and accountability improves the effectiveness of global health governance.

Co-regulation is the newest form of private sector involvement in global health governance, and arguably the most controversial. Early evidence from fledging PPPs suggest that, while they have achieved demonstrable benefits for certain health issues, there remain considerable shortfalls in the quality of their governance along with potentially negative implications for the flow of resources to other public health needs. These challenges with PPPs are slowly gaining attention from donor agencies, public health groups and the partnerships themselves. What remains worrisome for some is the fact that these arrangements appear to have fragmented the civil society movements which might have worked to ameliorate these initiatives or propose alternatives.

Finally, it is worth reemphasising that the purpose of a commercial organisation is to generate profits for its owners or shareholders. All core activities of private firms are thus defined by this profit-earning logic. It would thus be naïve to hope that the public interest and the private pursuit of profit will somehow always coincide. Rather, it is more realistic to recognise that many efforts by the private sector to engage in global health governance can be beneficial to public health. However, trade-offs between profit and public health will often arise. Where these trade-offs arise there are good grounds, from a public health perspective, for some form of co- or public sector regulation (depending on the degree of impact on public health). The key challenge faced by the public health community, either nationally, regionally or globally, is to match the appropriate forms of regulation with the diversity of activities of the commercial sector, in ways that best protect and promote public health.

REFERENCES

AGB (2002) *A global action plan for electronic business – Prepared by business with recommendations for governments*. 3rd Edition. Alliance for Global Business. July 2002.

Barnet RJ, Cavanaugh J (1994) *Global dreams: imperial corporations and the new world order*. New York: Touchstones.

Bialous S, Yach D (2001) Whose standards is it, anyway? How the tobacco industry determines the International Organisation for Standardization (ISO) standards for tobacco and tobacco products. *Tobacco Control.* 10:96-104.

Boseley S (1999) Drug firm asks public to insist NHS buy its product. *The Guardian*. London. September 29.

Braithwaite J, Drahos P (1999) Ratchetting up and driving down global regulatory standards. *Development.* 42(4):109-114.

Bull B, Boas M, McNeill D (2004) Private sector influence in the multilateral system: A changing structure of world governance? *Global Governance.* 10(4):481-498.

Burton B, Rowell A (2003) Unhealthy Spin. *BMJ*. 326: 105-1207.

Busfield J (2005) The globalisation of the pharmaceutical industry. In Lee K, Collin J (eds.) *Global Change and Health*. Milton Keynes: Open University Press.

Buse K. (2004a) 'Governing Public-Private Infectious Disease Partnerships' *Brown Journal of World Affairs*. 2004; 10 (2): 225-242.

Buse K (2004b) *Global Health Partnerships: Mapping a shifting terrain*. London: DFID Health Resource Centre.

Buse K, Harmer A. (2004) "Power to the Partners? The Politics of Public-Private Health Partnerships" *Development*. 47(2):49-56.

Caines K, Buse K, et al. (2004) *Assessing the impact of global health partnerships*. London: DFID Health Resource Centre.

Cattaui M (1999) *Business community takes up Kofi Anna's challenge*. ICC Press Release. 15 March, 1999. Paris: ICC.

Cattaui M (1998a) *Business partnership forged on a global economy*. ICC Press Release. 6 February, 1998. Paris: ICC.

Cattaui M (1998b) *Business and the UN: Common Ground*. ICC Business World. 3 August, 1998. Paris: ICC.

CEO (2000) *Citizen's Compact on the United Nations and Corporations*. http://www.corpwatch.org/article.php?id=992 accessed 15 November 2005

CEO (1998) *The Geneva Business Dialogue. Business, WTO and UN: joining hands to deregulate the global economy?* Corporate European Observatory. http://www.globalpolicy.or/socecon/tncs/maucherhtm accessed 19 February 2005.

Collin J, Gilmore AB (2002) Corporate (Anti)Social (Ir)Responsibility: Transnational tobacco companies and the attempted subversion of global health policy. *Global Social Policy*. 2(3):353-360.

Detomasi D (2002) International institutions and the case of corporate governance: towards a distributive framework? *Global Governance.* 8(4):421-442.

Edwards G, Savva S (2001) ILSI Europe, the drinks industry, and a conflict of interest undeclared. *Addiction.* 96(2):197-202.

FEC (2004) US Federal Election Commission. Contributions as of October 4, 2004 for the 2003/2004 election cycle.

GBC (2004) Why business should make AIDS its business. Multinationals are taking baby steps to control the disease in their workforce. Global Business Coalition on HIV/AIDS. Press Release, 27 July, 2004. www.businessfightsaids.org/news_read.asp?ID=9361&sct=3&PR=0

GIIC (1996) *Healthcare and Telemedicine*. Global Information Infrastructure Commission. www.giic.org/paper/policy/phealth.asp Accessed 9 August 2004.

Global Compact (no date) *HIV/AIDS Everybody's Business.* The Global Compact Learning Forum Series. www.globalcompact.org/NewsDocs/Summit/HIV_AIDS.pdf Accessed 22 February 2005.

Herxheimer A (2003) Relationships between the pharmaceutical industry and patients' organisations. *British Medical Journal*. 26:1208-1210.

Hirschhorn N (2002) *How the tobacco and food industries and their allies tried to exert undue influence over FAO/WHO food and nutrition policies.* Unpublished. New Haven, CT.

IBFAN (2004) *Using international tools to stop corporate malpractice – does it work?* International Baby Food Action Network case studies. Cambridge, UK: Baby Milk Action.

ICC (2000) Business supports Kofi Annan's Global Compact by rejects 'prescriptive rules.' ICC Press Release. 4 May 2000. ICC: Budapest.

IFPMA (2004) *Building Healthier Societies through Partnership*. Geneva: IFPMA.
http://www.ifpma.org/site_docs/Health/Health_Initiatives_Brochure_May04.pdf

IFPMA (undated). *IFPMA code of pharmaceutical marketing practices*. Geneva: International Federation of Pharmaceutical Manufacturers Associations.

http://www.ifpma.org/News/news_market.aspx (accessed 19 February 2005).

ILSI (2004) International Organizations Committee. www.ilsi.org/index.cfm?pubentityidy=87 (accessed on August 2, 2004).

INFACT (2002) Gates Foundation urged to keep Philip Morris out of Nutrition Initiative. Press Release, May 9th, 2002. Oakland, CA: INFACT. www.corpwatch.org/article.php?id=2535 accessed 03/03/05

James JE (2002) Third-party threats to research integrity in public-private partnerships. *Addiction.* 97:1251-1255.

Korten D (1997) The United Nations and the Corporate Agenda. www.igc.org/globalpolicy/reform/korten.htm. Accessed 27 July 2001.

Lancet (2004) Editorial – Is GSK guilty of fraud? *The Lancet*. 363(9425): 1919.

Landers SH, Sehgal AR (2004) Health care lobbying in the United States. *American Journal of Medicine* 116(7):474-7.

Lange T, Heasman M (2004) Diet and nutrition policy: a clash of ideas or investment policy? *Development*. 47(2):64-74.

Lam MD (2004) Dangerous Liaisons. *Pharmaceutical Executive*. 1 May 2004. www.pharmexec.com/pharexec/articleDetail.jsp?id=95090 accessed July 26, 2004.

Lenzer J (2004) Pfizer pleads guilty, but drug sales continue to soar. BMJ 328(7450):1217.

Lexchin J, Kawachi (1996) Voluntary codes of pharmaceutical marketing: controlling promotion or licensing deception? In Davis P (ed.) *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs.* New York: Oxford University Press. Pp 221-135.

Maucher HO (1998) *The Geneva Business Declaration.* ICC Press Release. 24 September 1998. Paris: ICC.

Monbiot G (2002a) The covert biotech war. Published in the Guardian Newspaper, London, 19 November 2002. www.monbiot.com/archives/2002/05/29/corporate-phantoms/ accessed August 2, 2004.

Monbiot G (2002b) Corporate Phantoms. Published in the Guardian Newspaper, London, 29 May 2002. www.monbiot.com/archives/2002/11/19/the-covert-biotech-war/ accessed August 2, 2004.

Muggli ME, Hurt RD, Repace J (2004) 'The tobacco industry's political efforts to derail the EPA report on ETS' *American Journal of Preventive Medicine.* 26(2):167-177.

Murphy P (2001) ILSI responds to March 10 BMJ article. *British Medical Journal.* 322: 576.

Norfolk, L (2003). "What a liability." The Guardian Review, 8 November 2003, London.

OneWorld Health (2004) Collaborations between industry nonprofits at BIO. Press release June 10th, 2004.. www.oneworldhealth.org accessed July 27, 2004.

Pearson R, Seyfang G (2001) New hope or false dawn? Voluntary codes of conduct, labour regulation and social policy in a globalizing world. *Global Social Policy* 1(1):49-78.

Richter J (2004a) *Building on Quicksand: The Global Compact, democratic governance and Nestle.* Geneva: IBFAN-GIFA.

Richter J (2004b) Public-private partnerships for health: A trend with no alternatives? *Development.* 47(2): 43-48.
Richter J (2001) *Holding Corporations Accountable: Corporate conduct, International codes and citizen action.* London: Zed Books.

Ronit K (1999) The good, the bad or the ugly? Practices of self-regulation among dye producers. In Ronit K and Schneider V (eds) *Private Organizations in Global Politics.* London: Routledge.

Ronit K, Schneider V (1999) Global governance through private organizations. *Governance: An International Journal of Policy and Administration.* 12(3):243-266.

Rosenau J (1995) Global governance in the twenty-first century. *Global Governance.* 1(1): 13-43.

Ruggie JG (2001) global_governance.net: The Global Compact as a learning network. *Global Governance.* 7(4):371-378.

Saloojee Y, Dagli E (2000) Tobacco industry tactics for resisting public policy on health. *Bulletin of the World Health Organization.* 78(8):902-910.

Sell S (2003) *Private Power, Public Law: The Globalization of Intellectual Property.* Cambridge: Cambridge University Press.

Sellers LJ (2004) PharmExec 50. *Pharmaceutical Executive.* May; 61-70.

Sethi PS (1999) Codes of conduct for multinational corporations: an idea whose time has come. *Business and Society Review.* 104(3):225-241.

Shenk D (1999) Money + Science = Ethics problems on campus. *The Nation.* March 22, 1999.

Steere W (2001) "The Role of Business" in Koop C.E., Pearson C. and Schwartz M.R. eds. *Critical Issues in Global Health.*San Francisco: Jossey-Bass. pp 399-405

UN Foundation (2004) The Vodafone Group Foundation and United Nations Foundation Announce Landmark Partnership. Press Release. 17 June, 2004, New York.

Vice Fund (2004) Vice Fund performs in top 2 percent based on 1-year total fund returns among 618 multicap core funds with Lipper Analytical Services through June 30, 2004. Press Release, July 19, 2004. www.vicefund.com/docs.PressReleaseVICEX7-19-04.pdf accessed 9 August 004.

Waxman A (2004) The WHO global strategy on diet, physical activity and health: the controversy on sugar. *Development*. 47(2): 75-82.

Waxman HA (2004) Politics of international health in the Bush administration. *Development*. 47(2): 24-28.

WHO (undated). *Proposed programme budget for 2002-2003. Policy and budget for one WHO*. Geneva: WHO.

WHO (undated) *WHO criteria for medicinal drug promotion*. www.who.int/medicines/library/dap/ethical-criteria/criteriamedicinal.pdf (accessed 19 February 2005).

Widdus R (2003) "Public-private partnerships for health require thoughtful evaluation" *Bulletin of the World Health Organization*. 81(4): 235.

Yach D (2004) Politics and Health. *Development*. 47(2):5-10.

Zeltner T, Kessler DA, Martiny A, Randera F (2000) *Tobacco company strategies to undermine tobacco control activities at the World Health Organization*. Report of the Committee of Experts on Tobacco Industry Documents. Geneva: WHO.