In:

Commercialization of Health Care:
Global and Local Dynamics and Policy Responses
edited by
M. Mackintosh and M. Koivusalo.
London: Palgrave, 2005, pp. 170-186 (in press).

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International Collaboration on Medical Device Regulation: Issues, Problems and Stakeholders

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11.1 Introduction

Commercialization of health care around the globe manifests itself in the liberalization of markets and global trade and health care reform measures, including competition and privatization, generating a shift in the balance of power away from the stewardship of the state to free markets. These transformations are especially important for medical devices which carry special risks when unregulated or inappropriately regulated. They may be wrongly classified, dumped on foreign markets where regulatory requirements may be lower, or can even be fraudulent products. The key issue for public health is whether recent trade in medical products, as well as the global and regional harmonization of product and diagnostic standards, have encouraged a widening gap between patients and providers. Conversely, has commercialization produced some tangible (if indirect) benefits to some patient groups and providers?

Two streams of research - the politics of regulation and the delivery of health care are typically undertaken by different research communities with different disciplinary traditions (Baldwin *et al.* 1998: 38-9). Analysts interested in regulation tend to look at the relations between firms and regulators; those interested in the delivery to patients of health care and the use of medical devices look at the local provision of health care. However, in order to fully understand regulatory policy implementation, our analysis needs to be linked to global and regional developments.

Regulation raises complex issues which require highly specialized scientific and technological knowledge and skills that often surpass the capability of

national regulators. The pooling of resources, knowledge and expertise at the global and regional levels is seen as producing the most appropriate regulatory solutions based on the latest state-of-the-art medical technology in a host of different disciplines. While the pooling of resources has benefits, it also carries a heavy price. That price is dependence on the knowledge and expertise of a small number of industry scientists, clinical innovators, and regulatory affairs specialists of multinational companies with little accountability.

The US and the EU have the largest share of global trade, control the largest markets, and are the most important importers and exporters of these products. International and European standards are formulated and agreed upon by medical device experts from EU-based and US companies, national standards organizations, and representatives of national regulators. Understanding their approaches to regulation is thus of importance for the understanding of expected international developments in medical device regulation.

With the widening scope and potential of medical technology, the need for best practices and best available technologies in manufacturing, design controls and marketing is more urgent than ever before. Consequently, global and regional rules, principles and standards have grown quantitatively and qualitatively.

The chapter begins with an overview of the economic significance of medical technologies in the OECD countries and an overview of the medical device industry. This is followed by an analysis of the evolution of medical device regulation, comparing the EU regulatory regime with the global regulatory context, and discussing the implications from a public health perspective.

11.2 Medical devices and medical technology

These two terms are used for many different products and processes. For simplicity's sake, and because EU legal language gives preference to the term 'device', we follow the same usage. Medical devices are often confused with pharmaceuticals but reasoning by analogy can be misleading for three reasons.

First, unlike prescription drugs, medical devices come in different sizes, shapes and forms, are far more heterogeneous

and medical advances (about 4000 per year) which may result from an incrementally altered product as much as from the use of a device in a new medical-surgical procedure. Unlike pharmaceuticals and IVD products, the lifetime of a medical device for exploiting a patent is relatively short (except for medical equipment): three to five years as opposed to five to twenty years for pharmaceuticals. This difference in patenting time and in marketing procedures may explain why innovators of borderline products such as drug-device or device-biologics combination products prefer their product to be classified as medical device rather than as drug or biologics. The differences are considerable in terms of the number of trials, review time, user fees and additional documentation. However, in 2003, the Council of Ministers decided that combination products will no longer be subject to the medical device regime in the future. Instead, they will be reviewed under the EU pharmaceutical regime, with its centralized European and a decentralized national market approval procedure.

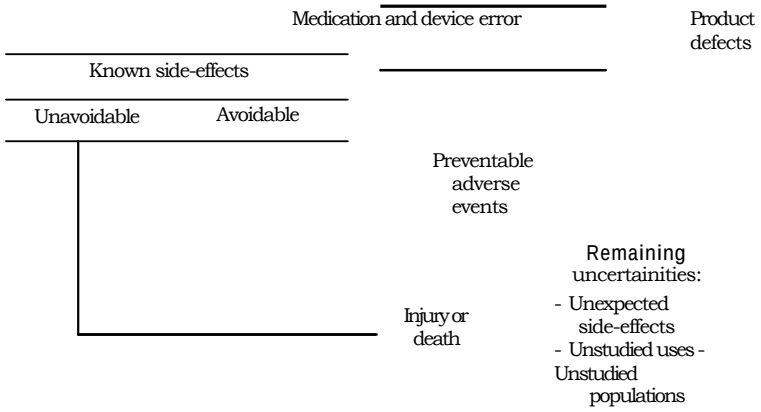
Third, the two regulatory regimes were established at different times. The pharmaceutical regime has evolved over three decades and is embedded in well-established global regulatory practices and protocols.

The institutional arrangements and regulatory mechanisms thus differ for medical devices and pharmaceuticals and involve a distinct group of stakeholders. However, the centrality of the health care system is undisputed. Both product types are unusual consumer products with a potential to harm humans and therefore justify stricter regulatory requirements than average consumer goods.

Why regulation matters

The purpose of regulating medical devices is not only to regulate products, companies and markets, but, above all, to reduce risks to health that arise from their use in clinical practice. While products can be safe, using them on patients may entail serious risks. For this reason, risk analysis and design controls are increasingly critical goals for companies and regulators everywhere.

In the context of commercialization, industry regulation is also important for the development of markets, assessment of cost-effectiveness, and providing patient protection.



Source: Food and Drug Administration 1999.

Figure 11.1: Sources of risk from medical products

interests and priorities and their influence is contingent upon the governmental, economic, political and professional circumstances in each country.

There are five clusters of ideas and practices, concerning quality, safety, performance, clinical evaluation and clinical trials, that constitute the core agenda around which the global, regional and national regulatory discourse, decision-making, and conflict management over the prevention of risks take place. These clusters speak to very different activities and knowledge imperatives in quite different circumstances (Witkin 1998).

Knowledge of medical devices arises typically, but not exclusively, from the medical, natural science and bio-engineering side. In terms of power and influence, the privileged players in regulatory policy are regulators, medical technology industry representatives, scientists and clinical innovators abiding by the scientific rationality of their respective disciplines. In sum, all risks, irrespective of level or source, can lead to adverse events in clinical practice and may harm patients or, more importantly, may lead to injury or death (see Figure 11.1).

11.3 Patenting and intellectual property rights

In theory, patents are barriers to trade; in practice, they are instruments for market dominance and creating inequities

There are two approaches. A lawyer might insist that existing patent law and trademarks fully apply to medical devices and IVD-products. S/he might argue further that the TRIPS agreement obliges all countries to respect each other's patents despite perverse effects. For example, exporters who may os wish to export medical products to the US which were manufactured outside the US but patented there must pay patent royalties to the patent holders, overwhelmingly American and European firms and innovators. Applications for patenting medical products have been increasing in the EU over the last three years (Blatt fur PMZ, 2001-3). Undoubtedly, the payment of royalties for patented medical technology is a hindrance to accessing innovative care in resource-poor countries.

The second approach emphasizes the importance of national patent laws in this context. It can be illustrated by a cursory look at EU patent law which distinguishes between patenting products and patenting medical-surgical procedures (Schulte 2001). While devices fall under EU patent law, and some (though not all) IVD-products under the EU pharmaceutical regime, medical treatments are not patentable (§S PatG). Medicine comprises surgery, diagnosis and therapy and these should be protected against patenting. `Illness must not be commercialized', states §5 PatG. A physician must not be restricted in his/her treatment decisions or diagnoses by patent considerations. By contrast, medical devices and procedures are said to be patentable in the US. According to the WTO TRIPS Agreement, governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than micro-organizations), and biological processes for the product of plants or animals (other than microbiological processes) (www.wto.org/English/thewto-e/what is-e-tif-e-utw-ch.2-e.pdf, accessed 8 July 2004, p. 41).

One frequently asked question is whether the advantages for innovators of

patent protection generate pressures for regulating and classifying medical devices as pharmaceuticals. Keeping in mind the heterogeneous nature of medical devices and the fact that many are obsolete within a few years, reasoning by

tissue engineered products is similar, and they will come under the pharmaceutical regime. Whether efforts to bring therapeutic and surgical procedures onto the patenting agenda is a good thing remains an open question. Certainly such initiatives will find supporters and strong opponents. Given the flexibility of international trade agreements in public health matters, much will depend on the position national policy-makers will adopt.

Health care reform and global harmonization

Two developments impact upon the industry and trade in medical devices. The first crossroads involves the political and institutional transformations under way in the relation of global to regional (especially EU) to domestic regulation. The imperatives of adapting to international and European norms, rules and standards, and the pressures of global harmonization and international competitiveness are well known (Egan 2002: 40-109).

The second crossroads is domestic health care reform. The cost of medical devices has attracted the attention of payers of health care, buyers of medical services, budget cutters in the treasuries, and cost reformers who promote health technology assessment and evidence-based medicine as a cost containment remedy. The actual proportion of public spending on medical devices in the world is hard to pin down. Even OECD data on health care expenditure, which are the best available, provide only a general impression of the proportion of the total health care budget represented by expenditure on medical technologies (Table 11.1).They do not begin to deconstruct public and private spending on medical technology in meaningful ways. Except for a few countries, public spending figures for medical devices are suspiciously low (Eucomed 2000: 28).

The medical device industry

Interest representation in the political arena counts in domestic, transnational and international politics but until recently has been highly segmented. Compared to the power of the pharmaceutical industry, the medical device industry has had limited influence and low political status in most countries, except for the national champions. Over time, the industry slowly overcame segmentation and fragmentation for purposes of interest representation and mediation in the European Union (Altenstetter 1998a, 1998b) and in the US (Duesterberg *et al.* 1994; Bartlett Foote 1992). Collective action of the European and US industry was effectively and successfully co-ordinated and supported by the European Commission, which has energetically promoted product innovation and cutting edge biomedical and technological research to increase the competitiveness of the European industry in the global market (Steg and Thumm 2001). It has a strategic interest in restoring and maintaining the international visibility of European

Table 11.1: Total health care expenditure (THE) and expenditure on medical technologies (EMT) in %

Country	*THE % GDP*	*EMT % THE*
Austria	*8.0*	*7.8*
Belgium	*8.6*	*5.2*
Denmark .	*8.3*	*4.6*
France '	*9.4*	*7.2*
Germany	*10.3*	*7.2*
Hungary	*6.8*	*11.1*
Italy	*8.2*	*6.0*
Netherlands	*8.7*	*8.8*
Norway	*9.4*	*7.7*
Portugal	*7.7*	*7.8*
Slovakia	*6.5*	*7.1*
Spain	*7.0*	*8.1*
Sweden	*7.9*	*10.5*
Switzerland	*10.4*	*4.4*
UK	*6.8*	*4.2*
USA	*12.9*	*6.4*

Note: Total Health Expenditure = total personal expenditure on health + total expenditure on collective services + investment into medical facilities. OECD data on THE may deviate from nationally reported figures, due to differing national definitions. Data adapted by OECD to allow cross-country comparisons.
Source: Eucomed 2000.

The industry is made up of different segments. Multinational corporations have three outlets for exercising pressure and political influence through direct access to regulatory authorities and political decision-makers; membership in trade associations that matter domestically; and in regional and global negotiations. In contrast, small and medium-sized firms, 90-95 per cent of the industry, rely on national trade associations which are members of European (con)federations. Under pressure from domestic health care reforms, as well as fierce international competition for new markets, the US AdvaMed and the European Eucomed have joined forces. Continued success in lobbying and successful requests for hearings is secured by membership in the respective European trade associations and by a permanent presence in Brussels of multinational corporations, including US companies, which small and medium-sized enterprises cannot afford. All leading US corporations are on board.

The world market for medical devices

Medical products, whether authorized for the market in the EU, Japan and the US, or manufactured locally, are sold on all markets around the globe and used in clinical practice.

Table 11.2: World market by region

Americas	56.6% (41.5%US)
Western Europe	21.7%
Eastern Europe	2.6%
Asia/Pacific	16.8%
Middle East/North Africa	1.9%
Africa	0.5%

Source: EBI 2003: 28, data reproduced with permission.

The world market is broken down by region as shown in (Table 11.2).[3] 12 The US, EU and Japan manufacture the bulk of medical devices, invest in 13 R&D, and conduct clinical evaluations and trials. In the European Union, a 14 few countries dominate the export business, led by Germany and followed is by Ireland, Italy and the United Kingdom. However, dependence on export 16 business varies: UK (20 per cent of domestic production), Germany (17 per cent) and Ireland (35 per cent).

Medical devices are used in the high- and medium-income countries more 19 than in the low-income countries. Moreover, their use is greater in the 20 old European Union of the fifteen than in the ten new EU member states. 21 Information about medical devices is scarce, crude and highly commercial and often absorbed in statistical categories reporting on the pharmaceutical and chemical sectors.' Yet the links between wealth, resources and 24 affordability are obvious. The higher the income, the more the countries can afford.

Table 11.3 shows an array of products used in patient care on a daily basis 7 around the world. Half the world's trade in medical devices involves medical equipment. The potential for internationalizing and globalizing risks to health is as serious as for heavy machinery. For example, surgical and medical instruments, heart and hip transplants, breast implants, and diagnostic products raise far more salient regulatory issues than machinery, with dire consequences for life and death, and profits are considerable.

The manufacture of medical products does not generate high numbers of jobs. The industry is relatively small, with more than 15 000 manufacturers employing over 600000 highly skilled and specialized workers world[36] wide who command higher than average salaries. About 5000 manufacturers [37] are located in European countries employing around 351000 persons, with [38] another 350000 in the US (Eucomed, 2001: 4). The bulk of man

Table 11.3: World market by type of device

Device	*Percentage o f total market*	
Bandages & other medical supplies	*8.4*	
Medical X-ray film	*2.6*	
Rubber surgical gloves	*2.6*	
Medical, surgical or laboratory sterilizers	*0.4*	
Wheelchairs	*0.9*	
Contact lenses	*2.6*	
Medical equipment	*49.4*	
Electro-medical		10.7
Syringes, needles & catheters		*12.4*
Dental instruments & appliances		*2.2*
Ophthalmic instruments and		*1.7*
Other instruments and appliances	*22.4*	
Therapy apparatus		4.4
Orthopedic/prosthetic goods		*16.8*
X-ray apparatus		*10.8*
Medical furniture		1.3

Source: EBI 2003: 29, data reproduced with permission.

Table 11.4: Industry leaders

1. Johnson & Johnson (USA)
2. General Electrics (USA)
3. Baxter International (USA)
4. *Tyco* International (USA)
5. Siemens (Germany)
6. Medtronic (USA)
7. Fresenius (Germany)
8. Philips (NQ
9. Becton Dickinson (USA)
10. Abbott Laboratories (USA)
11. 3M (USA)
12. Guidant (USA)
13. Boston Scientific (USA)
14. Gambro (Sweden)
15. Stryker (USA)

Source: EBI 2003: 11. Data reproduced with permission.

operating globally, while 90-95 per cent of all firms are small and medium-sized.The electro-medical equipment sector has long been dominated by Hewlett Packard, Toshiba, Siemens, Philips and GE-Thompson. In the implant sector, Boston Scientific, Guidant and Medtronic supply most implants in the

world and seven or eight global companies control 75-80 per cent of the world market in in vitro diagnostic products. About eight to ten US and 03 European corporations provide a vast spectrum of highly diverse products. 04

Finally, a new industry, the home health care industry, is a fast-growing
industrial sector comprised of a few of the industry leaders mentioned above, among others, selling to regional or national markets. This, too, is character ized by high product segmentation; products range from infusion therapy and home monitoring, to telemedicine and home dialysis, to diabetes management and respiratory devices.
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11.4 EU regulation and medical devices

EU regulation of medical devices has been shaped by three separate but mutually reinforcing developments. First is the internationalization and globalization of production, technology and trade. Second, by accepting the historic project of creating a single European market in 1985, the member states have accepted the delegation of regulatory functions to the EU. However, member states retain full authority over implementation. Third, the European Court of justice has legitimized a new regulatory strategy that allows addressing non-tariff barriers; this is particularly consequential in the social model of health care prevailing in the old EU fifteen member states, but much less in the new EU ten member states.

Historically and cross-nationally, the regulation of medical devices was the responsibility of public health authorities of nation-states. At the EU level pharmaceuticals were regulated prior to the creation of the single European market in 1985 and extended thereafter (Permanand 2002) prior to its overhaul in 2003 (Mossialos *et al.* 2004). By contrast, medical device regulation, which now covers IVD-devices, is entirely embedded in the creation of the single European market and is centrally connected with market building rather than market correction. The EU case study can thus be seen also in the context of regulatory needs of market building and its relationship to health and safety concerns.

The EU regulatory regime for medical devices is complete but continuously evolving along the fundamentals set in place by single market legislation, the *new approach* to technical harmonization. The first EU-level regulatory measure specific to

safety and performance and the issuance of the CE-mark. By contrast, the US model relies on a comparison with currently satisfactory devices as a basis for safety and effectiveness. Unlike the FDA, which retains full control over market approval, the EU approach relies on private organizations - firms, so-called notified bodies and providers - for implementation while domestic public authorities retain oversight functions as a national competency. Public regulatory functions are not privatized and deregulated; yet these functions are separated from health care services functions and organized outside the traditional Ministry of Health, assigned to a quasi-public regulatory agency. In 2002, this process was followed by the UK when medical devices were merged with pharmaceuticals into the new Medicinal and Healthcare Product Regulatory Agency.

In Europe, the regulatory agencies of the `big three' (France, Germany and the UK) are central players and strong competitors for approving devices and diagnostic products for access to the market. They, like their counterparts in other countries, monitor the EU-mandated medical vigilance system designed to monitor unexpected failures and adverse incidents involving medical devices. They can recall medical products from the market, and monitor the safety of human subjects in clinical investigations. Finally, they can audit and inspect manufacturing and health sites. However, in monitoring and enforcing compliance they depend on the co-operation of other players, which is not always forthcoming. State capacities for enforcement and implementation are very uneven and have become more uneven with enlargement. While advocates of regulation push for rules, statutes and procedures, it takes more to turn regulatory goals into effective practice. It takes knowledge, manpower capacities and financial means to monitor postmarket surveillance, which are not always available, even in rich countries.

Of major concern for transition countries are the missing operational capabilities to implement rules and enforce medical vigilance. For the CEE countries after enlargement the key issue is this: how extensively and effectively can they monitor risks, adverse effects and events given their limited resources? The new members face a major challenge in creating national capacities while adapting to the EU regulatory regime, a novel situation in that prior to joining the EU, none of them differentiated between a certification body and a competent authority. In some countries, medical devices were regulated

Policy issues within EU jurisdiction	*Policy issues within sole member state jurisdiction*
• Trade • Commerce • International competitiveness • AIMD, MDD, IVD • Blood safety and other directives • Pharmaceutical regime • Data Protection Directive (95/46/EEC) • Cross-border health care • Professional mobility • Requirements on instructions for use/leaflets • Packaging requirements • Advertisements • EU product licensing through the CE mark • Conformity with standards • Patent protection • Parallel trade • Wholesale distribution • Other potentially applicable EU directives': • Biocidal products • Dangerous substances and preparations • Electromagnetic compatability	• Health care • Health and safety • Professional and lay users • Coverage • Pricing • Reimbursement • Clinical investigation/evaluation • Laws on labelling • Medical institutions & health facilities • Post-market controls & surveillance • Distribution • Installation • Vigilance

Source: Pieced together by author.
" Source: L. Morisset, Medpass, Paris, 2003.

A similar characterization fits the process of standard-setting by the European standardization organizations, CEN and CENELEC. A separate research effort is required to discern who is representing whom in committees convened by the Commission or by CEN or CENELEC, and who from which multinational company serves on which of the numerous working groups dealing with issue-specific matters.

Although the single market legislation was adopted as a package, in the early 1990s a major disagreement flared up concerning about 10 per cent of

medium-risk and high-risk devices. France, with the support of the UK, was able to introduce tougher requirements for evaluation and efficacy of medical devices on clinical outcomes. Political changes can further strengthen public health interests. When Sweden, Finland and Austria joined, the power relationships were redrawn in the Medical Device Expert Group (MDEG) and the pendulum swung in favour of public health. Public health concerns were strengthened in the Treaty of Amsterdam.

Finally, in spite of the EU regulatory measures towards a single market on medical devices, there is no functioning single market in medical devices. This is mostly because conditions for selling, purchasing and using medical devices and IVD-products in European and CEE health care systems differ considerably. Medical devices reimbursement takes four forms:

- Product reimbursement (Fr, Be, Ge, Italy, Spain)
- Physician reimbursement (Fr, Be, Ge, NQ
- Surgical intervention reimbursement (Fr, Be, Ge)
- DRG-like total reimbursement package (Ge, Italy, US)

Each payment type has influence on the medical device market and affects sales volume, market growth and profits. Considerable price differentials and differences in value added tax (VAT) on medical devices exist across the member states. The institutionalization of a regulatory regime on medical devices in the European Union has been a long, drawn-out process over the past decade and is still intimately linked to global harmonization although it remains a distinct regional regime. It was also an exercise in trial and error; learning from the first two directives and from overseas regulators and then, later on, incorporating tougher regulatory requirements.

Developing regulatory requirements can be described as a 'race to the top' while implementation of those requirements qualifies as a 'race to the bottom'. Strong national legal and administrative traditions persist in each member state as well as strong traditions as to how to manage capitalism, government and corporate relationships. Despite the dramatic changes at the international and EU levels, in almost all countries path-dependent regulatory mechanisms remain strong and shielded from major changes in the governance of public affairs.

11.5 The `global approach': universal safety and quality standards

The industry prefers a single regulatory window, which ideally

Why are international or regional regulatory solutions necessary, desirable 02 and beneficial? The approval of an allegedly improved new silicon breast 03 implant by the FDA in October 2003 is welcome. In contrast, the long04 term effects can only be proven in twenty or thirty years. Stents are, but should not be, sold when the damage to patients is greater than the benefits. US-manufactured and CE-marked implants are sold in Europe and elsewhere 07 but have not always had FDA approval. Non-CE-marked devices are also **08** traded. The interested public should have access to information on what 09 medical devices have been approved by which regional regulatory regime, io and made available on which markets, and which potentially harmful or ii counterfeit products are available.

If global harmonization were about optimizing knowledge through epistemic communities (Haas 1992) to discover `best manufacturing practices' and `best medical practices', using 'best available technology' and `best is materials', patients and policy analysts would have nothing to be concerned about. If global harmonization incorporated 'learning', 'pooling resources 17 and knowledge', `exchanging information', `transparency' and 'accountability', there would be even less to be concerned about. What gets into the 'global dossier', however, is a result of a struggle for commercial and professional dominance and trade and profits. Global networks of industry representatives and coalitions of national regulators compete for influence in realizing their own vision of scientific and diagnostic criteria and standards.

Global Harmonization Task Force (GHTF)

In response to trade liberalization since the early 1990s, national regulators from the advanced industrialized countries have worked together through GHTF, a voluntary consortium of regulators and industry representatives (www.ghtf.org). The consortium aims to achieve global harmonization by reducing differences among regulatory systems.

GHTF is composed of a small circle of key players, up to four from medical device regulatory authorities and up to four trade associations (nominated by the most influential multinational companies in specific product sectors). The original impetus for GHTF is said to have come from two US trade associations, the Advanced Technology Association (AdvaMed, previously HIMA) and the National Electrical Manufacturers Association (NEMA). In the late 1980s and early 1990s they began to bring together specialists from 37 around the world. The formal request for the formation of the GHTF came from the FDA (Higson 1997). GHTF mirrors a pattern of geographic representation set by the original founding members: Europe, the US, Canada, Australia and Japan. Each of the three major geographic areas was entitled to eight seats, with observers and advisers from the founding members.

to say. During the 1990s until 2000 the medical device industry met in tandem with GHTF. Thereafter, due to various events beyond the control of the industry (9/11, the Iraq war, SARS), all scheduled meetings were cancelled. The industry has found new forms of communication through e-mail and e-commerce.

GHTF is a relative newcomer to the international standards system. It is playing an important role and bases much of its work on existing ISO and IEC standards and regulatory practices in the EU and the US. GHFT's activities are clearer, more transparent and more accessible than they were in the early 1990s, ending a rather obscure, highly Byzantine style of decision making (Higson 1997). GHTF's chair and four Study Groups (SGs) rotate among the national regulatory authorities of the three geographic areas. The term of office extends to three years or the time period covering two GHTF conferences, whichever is longest.

ISO, CEN/CENELEC and WHO have observer status at the meetings of GHTF. Representatives from South Korea, China, Brazil, Argentina, Cuba, Poland, and later Israel and Switzerland attended the meetings of the SGs as observers, in addition to the representatives of the founding members. The representation of WHO through the Division of Drug, Management and Policies mirrors a legacy of treating medical devices largely as pharmaceuticals. However, the absence of a WHO representative in meetings of the SGs (including SG 2 on Medical Devices Vigilance) is striking.

Beyond GHTF, international collaboration has gone through the signing of bilateral mutual recognition agreements (MRAs) and the development of ISO standards for testing, certification and labeling. An industry insider remarked: `there is ... a confusion of documents...' from the three regulatory regions (Cutler 1999b: 2-3).

MRAs are binding legal instruments and impose rights and obligations 29 on the signatories. The EU has signed medical device MRAs with the US, 30 Canada, Australia and New Zealand, Israel, Japan and Switzerland. Each MRA was negotiated separately and differs from the others in substance and rules. Except for the US and Japanese regulatory regimes, the other countries are closer to the EU approach than to the FDA.

For a good part of the 1990s, the EU and the FDA made little progresstowards resolving their differences. The FDA criticized several features of the EU system: (1) the delegation of regulatory authority to notified bodies outside a public regulatory agency; (2) the sloppy oversight of aftersales

regional rules and instruments, nor is there convergence in national implementation. On the contrary, the variations in practices and activities across the member states are many and significant and may increase in the future.

The lesson from the Global Harmonization Task Force is clear. Once the issues are framed as trade first and public health issues second, it is difficult to reverse provisions harmful to patients and users but exclusively beneficial to trade. What can and should be done to strike a balance between trade and public health interests in the delegations to international and regional negotiations? Unmistakably, public health interests must be present from the beginning to avoid the probability that international agreements will only work for shareholders to the detriment of patients.

Notes

1. The author would like to thank Richard J. Meagher of the CUNY Graduate Center (City University of New York) for his assistance in editing and formatting the earlier versions, Elissa McGowan for editing this reduced version (see www.unrisd.org). My thanks also go the editors for helpful comments.
2. The 1998 IVD directive covers any medical device which is a (i) reagent, reagent product, (ii) calibrator, control material, or test kit, and (iii) instrument, apparatus, equipment, or system whether used alone or in combination, intended by the manufacturer for use in laboratory medicine. All single-use devices such as self-test devices for a pregnancy test or urine test are also included.
3. Data in Tables 11.2-11.4 reproduced with permission of Espicom Inc, 116 Village Blvd, Suite 2000, Princeton Forrestal Village, Princeton, NJ 088640-5799, USA.
4. The most comprehensive market report is *World Medical MarketReport2003*, which draws on a variety of commercial and non-commercial sources such as the African Development Bank (www.afdb.org); Asian Development Bank