Chapter **9**

Prospects for win-win international rapprochement of regulation

by

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I. Introduction

This paper argues that opportunities can be seized at many levels: ***a)*** to harmonize between governments on minimum regulatory outcomes; *b)* to harmonize privately specification standards (here called "default input standards''); *c)* to nurture a proliferation of competing optional input standards; *d)* to increase levels of mutual recognition of input standards; and ***e)*** to strengthen parliamentary oversight and NGO participation in all of these international activities. It will be argued that bargaining forums such as the OECD, the EC, APEC, and the GATT can be used to nurture rapprochement toward regulation that is simultaneously more efficient, more effective and more democratic. Certain ironies of internationalising regulation lead to the conclusion that there is no inevitability about having to trade off a more effective international regulatory order and a more costly one, a more harmonized order and a less democratic one.

11. Race to the bottom or race to the top?

Most of the time, most nations in the modern world do not write their own business regulatory **laws.** Increasingly, the parliaments of the contemporary world are law takers rather than law makers. Europeans have given this feature of modernity a name – "the democratic deficit". But the democratic deficit is not a just a European phenomenon. Indeed, the peoples of Europe have a capacity for democratic control over regulation that is second only to that of the United States. Other OECD nations such as Australia and even Japan are much more law takers compared to the European law makers.

By this I mean, for example, that Australia does not really write the laws that regulate the safety of commercial airlines in Australia. Mostly, it takes standards devised in the North, perhaps by the US Federal Aviation Administration after the FAA has engaged in processes of consultation with firms like Boeing and some major international players. Sometimes the law taking occurs because smaller nations simply are not big

Glossary of terms and acronyms for Chapter 9

APEC: Asia Pacific Economic Cooperation.

ASEAN: Association of South East Asian Nations.

Default Standards: When the precise input standards required to achieve regulatory outcomes are optional, default standards are those which apply when none of the other input options are chosen. The default input standards are a safe harbour for anyone who wants to be sure that they meet agreed regulatory outcomes.

Harmonization: Standardization of regulation in identical form.

ICH International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Input Standards: Specification standards; standards that specify inputs required to achieve regulatory outcomes.

ISO: International Standards Organisation.

Mutual Recognition: Acceptance of diverse regulatory inputs as means of meeting common goals or outcomes.

NGO: Non-Government Organisation.

Rapprochement: Reduction of regulatory differences between levels of government.

Outcome Standards: Performance standards for regulation.

TRIPS: Trade-Related Aspects of Intellectual Property Rights.

WHO; World Health Organisation.

enough markets to dictate in any realistic way the terms of its imports. Often, even if they could, they choose not to put up their costs by imposing special requirements at odds with those settled in the centres of economic power. Often they model their regulatory laws on those of the centre simply because they can't be bothered with the transaction costs of even finding out if they might be better off with different laws. Or they don't have the analytic skills to **manage** this with any but a selected few ***of*** the regulatory standards that flow from the centre of the world economy. In areas such as food, telecommunications and intellectual property, standard setting by international organisations is well accepted. In these areas, governments voluntarily cede a lot of their law-making capacity to international deliberative forums in which they have some small voice.

The traditional national adversaries in business regulatory debates tend to have strong views about an internationalisation that they see as progressively eroding their influence at home. National environmental or consumer groups may complain about how internationalisation tends to drag national standards down to a lowest common denominator. Their story is that consumers and the environment will lose out in a race to the bottom, with international competition that delivers most jobs to the locales where

regulation is weakest. National business groups, in contrast, tend to argue that if you put a bunch of national business regulators together, the most likely view to prevail is the most risk averse, since regulators are not rewarded for being risk takers, only punished for it when a crisis occurs somewhere in the world. So they say you will get a race to the top, rather than a race to the bottom. Often the fear of national business associations outside the United States is that internationalisation will foster highly legalistic or formal styles of regulation that they characterise as American.

Such views of traditional national regulatory adversaries about the inevitability of either a race to the bottom or a race to the top are simplistic and wrong. There are regulatory domains in the world system where one can discern a tendency for an international race to the bottom, others where one can see something of a race to the top, others where one can see a convergence to the middle. Indeed. one can identify an area like the regulation of banks where there was something of a race to the bottom during the first half of the 1980s as governments scrambled to offer the most attractive environments to finance capital. Then one saw the G-10 realise that everyone could be losers unless this downward spiral was reversed. And it was reversed as prudential standards for banks throughout the OECD were upgraded during the second half of the 1980s (Kapstein, 1989). Following the ravaging of so many developing countries by BCCI, we are likely to see a general upward movement in regulatory stringency outside the OECD during the 1990s.

So the first worry we must clear away in the debate about regulatory internationalisation is that there is any inevitability about the direction of the effects that this will have on the stringency of regulation. There is no such inevitability. Internationalisation can push regulatory stringency up, down or sideways. It usually does all three at once within any large set of standards. The management challenge is to design deliberative international institutions that improve the quality of standards – their efficiency and decency – regardless of stringency going sometimes up, sometimes down.

The plan of this paper is first to argue the case for rapprochement, then the case against it, then to plot a strategy that secures the advantages of rapprochement while avoiding its disadvantages.

111. The case for rapprochement

Whether international regulatory rapprochement occurs through harmonization, mutual recognition or convergence, there is the potential for three kinds of advantages to be secured: eliminating duplicative inefficiencies, reducing non-tariff barriers to trade, and reducing free-riding on efforts to tackle international problems.

A) Eliminating duplicative inefficiencies

When different nations impose different regulatory requirements on products, there are duplicative inefficiencies in the manufacture, storage and labelling of these products. So, if the regulations of some nations require driving on the left side of the road and

others the right, international auto manufacturers reduce their efficiency by having to maintain different production runs for left- and right-hand drive vehicles. In the new world of just-in-time management of stocks, there are costs in separate storage and in non-substitutability across inventories. There are also information costs for consumers. In **a** perfectly harmonized world of automobile standards, Australian consumers would be able to benefit from the enormous research Consumers' Union undertakes in the United States on car performance. But in the world in which we live, the information generated by consumer testing associations in different countries is mostly non-transferable. All of these regulation-driven duplications rcducc the efficiency of the world economy. Duplicative inefficiencies arise with the regulation of services as well as products. It can be an enormously inefficient use of the time of a world-class doctor, lawyer or architect to be required to study for exams before she can practice in a new country.

B) Reducing non-tariff barriers to trade

If some nations impose royaltics on blank tapes to compensate copyright owners and others do not, this disrupts the free flow of goods across national borders. Governments that enforce such an intellectual property regulation will have to check imports from a nation that does not enforce it to ensure that the royalty is collected at the customs barrier. The delays and administrative costs associated with this process, especially if they are administered with intentional inefficiency, can cause the exporter to abandon that market, thus reducing competitive efficiencies in the importing nation.

The worst inefficiencies arise when national regulations are used as non-tariff barriers. Resistance to regulatory rapprochement in the automobile industry has very much been about national governments defending idiosyncratic national or regional standards, not because they benefit consumers, but because they confer some structural advantage upon a national producer. If a European auto-maker has pioneered headlight technology that doubles the field of illumination, then that auto-maker's national government can impose a severe cost disadvantage on foreign competitors by lobbying for a European standard to expand the field of illumination required for headlights.

C) Reducing free-riding on efforts to tackle international problems

The world faces a tragedy of **its** international commons. No one could argue that the tightening of environmental regulation that occurred in OECD countries during the second half of the twentieth century was unnecessary. Equally, no one could dispute that the old communist nations were free riders on international efforts to restore planet earth's precarious futurc. An objective of international rapprochement is to counter such national free riding on the solving of international problems. In areas like environmental protection where regulatory costs can be enormous, temptations to attract investment by waiving environmental standards are profound, especially for poorer nations.

Such free-rider problems can be addressed, however, by appropriate institutions of regulatory rapprochement. The world has prevailed against enormous national temptations to cheat in solving problems like the slave trade and the atmospheric testing of

nuclear weapons Narrowly economistic thinking is an obstacle to progress in solving such problems. In the economic analysis, the free rider problem reduces to an enforcement problem. How do you change the pay-offs of nations that are tempted to cheat on the rest of the world? The empirical evidence suggests that international institutions do not effect change mainly by enforcement but much more by persuading states to re-evaluate their interests (Chayes and Chayes, 1991). In the Harvard studies of international environmental institutions, "monitoring environmental quality and national policy measures was a far more influential institutional activity than was direct enforcement" (Levy, Keohane and Haas, 1992). This is why international institutions like the OECD, that have no "teeth", can, either in spite of this or because of it, have important effects on regulatory rapprochement.

> *In cases where a laggard state's lack of concern was due to a misunderstanding of its own interests, normative pronouncements (to reduce transborder air pollution or to stop destroying the ozone layer) accompanied by collaborative scientific reviews sometimes contributed to a shift from low to high concern. The collaborative reviews of scientific evidence under the Vienna convention and Montreal protocol on protecting the ozone layer clearly played a major role in the increased concern of several governments for the problem of stratospheric ozone depletion.*
> (Levy, Keohane and Haas, 1992)

In the very worst cases of rent-seeking states, the prospects for achieving change by enforcement seem especially remote because the sums required to change payoffs would be so enormous. Consider the Malaysian state of Sarawak, for example, which, according to Porter and Brown, "now exports 58 per cent of the world's tropical timber" (Porter and Brown, 1991). "Timber concessions totalling 3 million acres and worth $22.5 billion were given to relatives and friends of the chief minister of Sarawak, and the minister of the environment is the owner of more than 750 000 acres of timber concessions" (Porter and Brown, 1991). International institutions have some small prospects of unseating such state rent seeking through fomenting international political pressure at multiple levels – the Malaysian government, regional groupings such as ASEAN, and locally in Sarawak through the activism of environmental NGOs. Prospects of doing so by orchestrating multi-billion dollar payoffs seem absolutely remote.

In short, it is possible for international regulatory rapprochement to tackle some of the problems of states free-riding on efforts to tackle international problems. Agenda-setting within international institutions such as the OECD can help secure this advantage of regulatory rapprochement, just as it can help reduce duplicative inefficiencies and regulatory barriers to free trade.

IV. The case against rapprochement

A) Erosion of sovereignty

All OECD member states subscribe to a belief in a popular sovereignty wherein elected leaders are accountable to the people for government decisions. From this demo-

cratic perspective. the idea of empowering non-elected international bureaucrats with responsibility for regulatory decisions is unappealing. There is no doubt that the impressive regulatory rapprochement that has occurred in Europe in recent years has involved a ''democratic deficit". Both parliamentary sovereignty and direct popular sovereignty have been eroded at the hands of non-elected employees of the European Commission in Brussels. While it is true that this has happened, later I will argue that regulatory rapprochement might be accomplished with a democratic surplus rather than a democratic deficit. The European trends are certainly toward reducing the democratic deficit, by, for example, strengthening the authority of the European Parliament.

B) Stultification of regulatory innovation

Regulation is like any other economic activity in that its efficiency depends on innovation and entrepreneurship to lead responsive adaptations to changing environments. The regulation of regulation therefore risks a stultification of regulatory innovation. International harmonization poses the greatest risk here. The sheer consensus-building demands of international harmonization can be so great that no one wants to break the mould once it is set. Worse than that, consensus can take so long that the problem has changed fundamentally from the one that existed at the beginning of the consensus-building process. So we can have yesterday's solution to today's problem that no one will have the energy to change tomorrow. Delay, inflexibility and the death of innovation is a formula for regulation that is high in cost and low in effectiveness.

C) Reduced efficiencies through preventing firms from shopping for lowest-cost regulation

This disadvantage of rapprochement is in a sense the obverse of the advantage of eliminating free-riding on efforts to solve international problems. When firms gravitate toward the states with the weakest regulatory standards, they free ride, and they create incentives for lowest common denominator regulation. On the other hand, when they gravitate toward states with low regulatory costs, they create incentives for states to regulate efficiently. Even within states, I have been an advocate of giving firms a variety of regulatory options, all of which meet certain minimum standards, so that firms can choose the regulatory package that is most efficient for them. **A** simple example is the US Mine Safety and Health Act of 1977 which defines standards for seven optional techniques for mine roof support, but then goes on to allow firms to tailor-make their own roof control plans with technologies not covered in the law but which produce outcomes equal or better to those specified in the law (Braithwaite, 1985). **A** single perfectly harmonized set of international standards might eliminate shopping for lowest cost standards at the same time as it eliminates free riding on the greater responsibility of others.

V. The objectives of win-win rapprochement

Having argued for the three key advantages of international regulatory rapprochement and the three key disadvantages, the challenge is now to discover how to deliver the advantages while escaping the disadvantages. With sharp regulatory analysis, creative design of international and national regulatory institutions and strategic agenda-setting by international agencies, this is a challenge that can be met.

Specifying the policy objectives more precisely, we can aspire, through international regulatory rapprochement, to:

A. Reduce duplicative inefficiencies;
B. Reduce non-tariff barriers to trade;
C. Reduce free riding on efforts to tackle international problems;
D. Increase popular sovereignty over the regulatory process;
E. Increase regulatory innovation; and
F. Increase the capacity of firms to shop for lowest-cost regulation.

VI. Delivering on the objectives

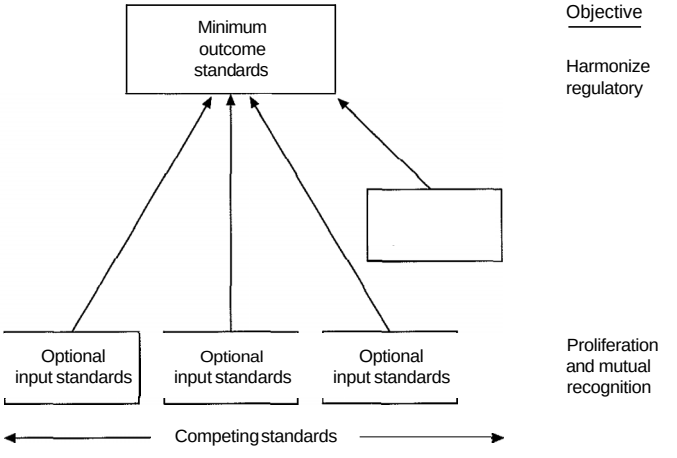
A 10-step strategy is advanced for delivering these six seemingly incompatible objectives. The strategy distinguishes between minimum outcomes (like the crashworthiness of a motor vehicle at *50* kph) and specified regulatory inputs intended to achieve those outcomes (like bumper bars of a specified type). Outcomes are often called **performance or outcome standards** and inputs for achieving them **specification or input standards** (these and the following terms are defined in the Glossary).

The basic idea of the strategy is that minimum performance standards should be harmonized and so should ***one*** acceptable set of input standards. The latter are called the **default input standards** because these are the input standards that will be expected internationally if the govcrnmcnt concerned does not come up with another set of inputs that will secure the required outcomes. Meeting the defaults is a "safe harbour" if you want to be accepted as satisfying the minimum outcomes. **A** proliferation of **optional input standards,** developed mostly by private organisations and subject to mutual recognition by governments, is the other foundation of the strategy, as summarised in Figure 1.

In summary, the strategy rests on three elements: harmonized outcomes, harmonized default inputs, and a proliferation of competing optional inputs. Intergovernmental consensus is easier to build on outcomes than on input standards: outcomes do not require such constant adjustment in the face of changing technology as do input standards, and outcome standards are harder to use as non-tariff barriers than input standards. We will consider how this package can deliver our six objectives after a quick summary of the ten steps that comprise the strategy.

1. Strengthen international bargaining forums where governments can agree on minimum acceptable regulatory outcomes (performance standards) and on

Figure **1. Harmonized regulatory outcomes and competing inputs**



schedules for improving these minima over time, or at least for reviewing their levels periodically.

2. Either: *a)* Use these international bargaining forums to have governments harmonize on default input standards; or *b)* Strengthen the capacity and legitimacy of voluntary international standard setting bodies like the International Standards Organisation to promulgate default input standards.
3. Where deadlocks arise with bargaining on 1 and 2, widen the agenda. If some nations want tougher defaults on intellectual property regulation (*e.g.* **X** year patents for pharmaceuticals) while other nations (who are against this) want tougher outcomes on deregulation of agricultural protection, put both agendas on the table. This means strengthening international institutions like the GATT and the OECD that have the capacity to widen agendas, to some extent at the expense of specialised international institutions like the World Intellectual Property Organisation or the Codex Alimentarius Commission.
4. Strengthen governmental capacities to formulate optional input standards.
5. Nurture private capacities to formulate optional input standards.
6. Use international bargaining forums to secure mutual recognition of the optional input standards developed under steps 4 and 5, so long as those options can be shown to deliver the minimum performance outcomes under step **1** (or perform at least as well as the minimum default inputs in step 2).
7. Use international bargaining forums to secure the agreement of nations to arbitration by committees of experts from third countries when disputes arise

over mutual recognition. These committees can also arbitrate on complaints about nations free-riding on the international agreement by failing to achieve the minimum outcomes in step 1.

8. Strengthen the capacity of international organisations to undertake comparative research to inform the deliberations under steps 6 and 7 and to inform competition among regulatory innovations. This means research on the performance of different packages of input standards in delivering regulatory outcomes and minimising secondary effects such as posing barriers to trade.
9. Strengthen practical capacities for national parliamentary sovereignty by establishing international committees of parliamentarians to produce oversight reports on the work of selected international organisations. These international parliamentary committees can be linked to national parliamentary systems of oversight committees.
10. Strengthen practical capacities for popular sovereignty by requiring selected international organisations to fund international NGOs and to empower them with open access to technical discussions about standard setting. The empowerment of an international NGO with resources, information and a voice at the bargaining table should depend on its having a constitution that ensures democratic accountability to relevant national citizen groups.

Now the chapter will move on to a more discursive treatment of what this strategy involves and how it can shift the international system toward win-win-win-win-win-win outcomes on the six objectives set out in this paper.

A) Tackling free-riding

The keys to reducing free-riding on efforts to tackle international problems (objective C) in this strategy are: *a)* international agreement on minimum outcomes (step 1); *b)* agenda-broadening to secure this agreement when the going gets tough (step 3); and c) arbitration by experts from third countries when other nations or NGOs lodge complaints about free-riding on agreed minimum standards (step 7). The strategic importance of agenda broadening in getting nations to agree to arbitration by a committee of third country experts cannot be underestimated.] If the EC, Japan and the US want Southern nations to respect Northern patents and copyright or to honour tough management plans for tropical rainforests, one of the best ways they can move toward such objectives is to put on the table a willingness to bargain about freer access of rice or sugar to these Northern markets, or transfer of technology agreements from North to South. Agenda broadening is the ally of regulatory rapprochement because it enables the creative search for ways where both sides can yield major concessions while leaving both better off overall. This is what the GATT should be, and sometimes is, all about.

B) Tackling non-tariff barriers

The arbitration procedure in step 7 is also obviously the key to reducing regulatory non-tariff barriers to trade (objective B). That is, when one country erects a non-tariff

barrier by refusing recognition of a second's input standards, the second country can seek independent arbitration of the dispute. The arbitrators would find if the second nation's input standards do or do not assure internationally agreed minimum outcome standards. There is nothing radical in this aspect of the strategy because such an arbitration process already exists under the GATT and in the EC. However, such arbitration processes will not effect broad change until they can work from the foundation of many different agreements on minimum performance outcomes (step 1) and comparative research on the performance of different packages of input standards in delivering regulatory outcomes (step 8).

C) *Shifting to outcomes: motor vehicles*

Agreement on minimum acceptable regulatory outcomes is no simple matter. Consider, for example, how tough an agenda this is with motor vehicle safety standards. The stakes are enormous here because consumers pay so dearly for duplicative inefficiencies in automobile manufacture, because competition is constantly being thwarted by nations using standards as non-tariff barriers and because many lives can be needlessly lost when nations settle for suboptimal vehicle design standards. But the change that would bc required to deliver **step** 1 of the strategy is revolutionary. The United States has a regulatory system based on performance standards. What counts in the US system is, for example, the damage done to dummies when cars randomly selected off the production line are crash tested. Europe, in contrast, has a type approval system. EC type approval directives in tlie past have tended to be minimum specifications that car bodies must meet. Once a design gets a type approval as meeting these input standards, all vehicles manufactured to this design are approved. There is no outcome testing of the performance of cars randomly selected from the production line. In a moment we will see, however, that this distinction is becoming increasingly blurred, as EC standards become progressively more extreme-oriented.

What is implied by the strategy of this paper is that Europe should make all the concessions – ***transforming*** **its** entire vehicle regulatory system from type approval toward the more outcome oriented approach of the National Highway Traffic Safety Administration in the United States. Here is where agenda widening is needed. There are other areas of regulation where it is the United States that is more input-oriented (perhaps financial and pharmaceuticals regulation) and therefore where it is the United **States** that would be required to make bigger concessions than Europe. Finally, it should be said that while the transformation from the status quo to the ideal world of this 10-step plan is radical, there are innumerable more conservative transitional positions between the two. Indeed, under tlie auspices of Working Party 29 of thc Economic Commission for Europe, rapprochement between the US and European paradigms of automobile regulation has made slow and painful progress over a number of years. This has been achieved by agreement on common test procedures so that approved types are designated on the basis of common performance criteria. The world is disappearing where car5 with sound lighting performance but which do not have a bright yellow colour could be kept out of France.

D) The challenges of harmonized inputs and mutual recognition: pharmaceuticals

If the tough transition were achieved and acceptable international minimum outcomes could be agreed (step 1), achieving step 2 of the strategy need not be so difficult. This is so, at least, if option *b)* of step 2 were chosen: strengthen the capacity and legitimacy of voluntary international standard setting bodies like the ISO to promulgate international default input standards. This means that the ISO would design a set of agreed technical inputs that would guarantee at least the minimum international performance standard Voluntary standard setting bodies have a good track record of being able to do just this (Cheit, 1990). Option *b)* is essentially the model that is working increasingly smoothly with rapprochement in many domains of regulation in the European Community. The Council of Ministers promulgates agreed regulatory minima. There is then mutual recognition of national regulations to deliver these minima with provision for arbitration of disputes. Then it is left to voluntary standards setting bodies like the European Committee for Standardisation (CEN) and the European Committee for Electro-technical Standardisation (CENELEC) to recommend input standards.

Recommended input standards are important. It is quite naive to believe that performance standards are all you ever need. Input standards are needed to ensure that one technology can plug into another. They are needed to give practical guidance to small or unsophisticated producers who lack the R&D resources to invent their own inputs for meeting outcomes. Finally, they are needed in domains where the costs of getting inputs wrong are so high that investment will not occur unless firms can be given some assurances on what inputs will be accepted as satisfactory for delivering mandated outcomes

When assurances of the international acceptability of inputs are critical to investment, we will want to consider the most demanding task of using international bargaining forums to harmonize on minimum national default input standards (step 2 *a)).* A case in point is pharmaceuticals. International agreement on outcome standards for the safety and efficacy of drugs is desirable and attainable, but it is not enough. On average, in 1990 it cost US$ 231 million to develop and test a new drug (D'Arcy and Harron, 1991). Firms will not make that investment without assurances of what they must do to get their product approved by national health authorities. They need standards that specify just what sorts of tests they must do on how many different kinds of patients. The costs of duplicative inefficiencies of such specification standards in the pharmaceutical industry are enormous. These are not just dollar costs to firms which must do essentially the same tests with somewhat different specifications in different countries to satisfy the requirements of different national health authorities.[2] They also can be costs in lives as duplicative tests are awaited and as patients are unnecessarily exposed to placebos rather than active treatment for the sake of duplicative trials, or as new drugs remain undeveloped because of approval costs.

What is needed is international agreement on default inputs for pharmaceutical testing. By default we mean a safe harbour: *a)* firms can assure that all nations will accept their results if their trials comply with these inputs, **and** *b)* firms can ignore the defaults and come up with innovative research methodologies that exceed performance standards for data quality. The ideal here is international agreement on one set of acceptable input

standards (the default option) combined with nurturing innovation to discover better ways of achieving outcomes. Mutual recognition of optional input standards that achieve satisfactory outcomes is the way to encourage both states and firms to discover innovative approaches to the delivery of outcomes.

The pharmaceutical industries and regulators of the United States, Japan and particularly of the EC have shown leadership in this general direction with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH process involves experts from these nations, with observers from other nations, meeting regularly to arrive at consensus requirements for drug testing and registration that the three regulators and the three industry associations agree to be the state of the art. The process is a fragile accomplishment that could break down at any time. But at this point, progress seems to be being made, not dramatic but steady progress. To accomplish this, leadership from the centres of economic power in the industry has been needed, a leadership that the World Health Organisation had been unable to provide. In the face of this failure of WHO leadership, the European Commission took the initiative, establishing its own bargaining forum with the United States and Japan. WHO leadership has failed because at the WHO there has tended always to be a "veto coalition" to block progress on most fronts. The lesson of the ICH is that there is nothing to stop harmonizers from ignoring veto coalitions by creating new bargaining forums where only those with a genuine interest in harmonization have a seat.

The view of the EC in establishing the bargaining forum was that consensus on harmonized default standards could not be achieved with too many players at the table. But of course as soon as the rest of the world could see that ICH was where the action was, everyone wanted a seat at the table. The three economic powers say they are not writing rules for the world. They are just reaching a consensus among themselves on what they think the regulatory state of the art is or should be. Every nation can then make their own decisions on whether they wish to adopt them or to offer a regulatory alternative that they think is less costly or more effective. Yet if the United States, the EC and Japan all decide on the same regulatory requirement, not many nations will take a different path. This is particularly so when almost all nations have pharmaceutical industries dominated by US, EC and Japanese firms.

Within Europe, the regulatory rapprochement is going much further. With the exception of biotechnology products, pharmaceutical companies can choose to seek registration of the new chemical entity in any EC member. Under a mutual recognition principle, other EC members will then be encouraged to accept the assessment done in the chosen nation, but will be free to reject it and insist on their own assessment. In effect, there will increasingly be competition between European registration authorities for the business of approving new drugs for the European market. The cynics' view is that this will lead to a race to the bottom. They assume that companies will choose the most lax national authorities to consider their application. I do not accept that this will necessarily be so. There might be competition for credibility rather than competition for laxity. That is, firms will want to secure mutual recognition; they will be wary of registration with an authority that other authorities do not trust.

Potentially, the interface of ICH default harmonization and competition within Europe for registration that is subject to non-binding mutual recognition is a promising one. Duplicative inefficiencies might be reduced (objective **A)** by the default harmonization. But the capacity to opt out of mutual recognition leaves space for regulatory innovation (objective E). The competition among national regulators increases the capacity of firms to shop for lowest-cost regulation (objective F), while also giving firms a way of hitting back at regulators who use registration delay or other tactics as non-tariff barriers to trade (objective B). The potential deficit with this initiative, however, is the democratic deficit (objective D) and fear of lost national sovereignty is the big obstacle in the path of widespread practical implementation of the strategy (Koberstein, 1993).

The ICH holds out considerable promise of win-win rapprochement. If the fragile diplomatic process does not break down, duplicative inefficiencies should be reduced saving scarce R&D dollars for drugs and, more importantly, saving scarce research talent for innovative rather than duplicative research, reducing drug lags, increasing incentives for innovation, and preventing suffering among people and animals currently subjected to duplicative experimentation. The very transparency of this whole process and the documentation being produced pursuant to it is proving a resource for less sophisticated governments to build their drug regulatory capacities. Thereby it should lift the worldwide minimum standards of drug regulation (objective C). **As** an official of the International Federation of Pharmaceutical Manufacturers' Associations explained to me, the ICH process is not about "minimum standards" but about "state of the art standards". In short, both industry and consumers in both developed and developing worlds should be better off for the European Community's leadership in pursuing harmonization of default inputs while allowing competition between national authorities in the provision of regulatory services.

E) The challenge of regulatory innovation

The key idea of steps 2 to *6* of the 10-step strategy is that less innovative firms can obtain guidance on how to meet the minimum outcomes in step 1 either from voluntary international standards or through harmonized default inputs. But more innovative firms and more innovative governments can opt out of the harmonized defaults and the international voluntary standards. These innovators then develop regulatory and self-regulatory strategies and technologies that compete for allegiance throughout the world. Some of these regulatory innovations may command such support that in time they become new harmonized default inputs.

In this process of regulatory innovation, both private and public innovators are important. Public innovators seek to push their firms to be world leaders with regard to a regulatory outcome by urging their firms to consider a tougher optional set of input standards. They might even offer tax breaks to firms that make an extra investment in control technology over and above that required by the default standard. Private innovators, such as environmental or health and safety consultancy firms, may design packages of standards for firms who want to be at the cutting edge of innovation in control technology. Other private innovators may compete with packages of standards that secure

the same level of protection as the harmonized defaults, but at lower cost. Unleashing the rulemaking and regulatory design genius of private as well as public managers is the key to constant improvement in regulatory design. Perfect harmonization on a single default, without mutual recognition of creative new optional standards, would see the death of regulatory progress. International organisations that undertake comparative research on the cost-effectiveness of competing packages of input standards (step 8) can increase the rewards for regulatory innovation by publicising the accomplishments of innovative regulatory paradigms. The research increases the capacity of firms to shop for lowest-cost or highest-effectiveness regulation.

F) From democratic deficit to democratic surplus

We must start our analysis of the democratic deficit by shedding a few delusions. Democratic accountability over business regulatory standard setting is minimal. Elected parliamentarians have little understanding of or influence over the myriad national business regulations that pass under their noses year in and year out. If they do express an interest in intervening, increasingly they find that the standard is a reflection of "international market realities" that national parliaments, especially in less economically powerful nations, are in no position to change. Australian parliamentarians have no capacity to change standards for telecommunications equipment that are written by a group of technocrats who meet in Geneva, even if they understood them. In turn, Australian citizens are in no position to demand from their elected representatives different standards to make their telecommunications equipment better, safer or cheaper. In so much regulatory decision-making there is no democratic sovereignty to lose.

Yet there is some possibility of sovereignty regained. Democratic influence over business regulation that is so often massive in its detail and technically sophisticated requires organisation. At a national level, the organisation required for a reassertion of some parliamentary sovereignty involves selected parliamentarians dedicating themselves to acquiring the competence and diligence through oversight committees to watch over areas of regulation in which they have a special interest. The organisation required for a reassertion of some popular sovereignty at the national level involves citizens organising themselves into NGOs with special interest in consumer protection regulation, environmental protection, equal opportunities and so on. At the levels of both parliamentary and popular sovereignty, however, this organisation mostly fails because there is simply too much regulation happening, too much technical complexity to come to grips with. There is just not enough energy to go around.

Just as organisation and the acquisition of focused competence is what is required to assert sovcrcignty at the national level, this is also what is required at the international level. At the international level, it is a second-order organisation based on national organisation. Hence, the oversight of telecommunications standards setting can involve consumers of telecommunications services organising themselves through international NGOs such as the International Telecommunications Users Group (representing business consumers) and the International Organisation of Consumers' Unions (representing domestic consumers).

Ironically, the possibility for organised popular oversight of technocratic standard-setting is somewhat greater at this international level than it is at the national level, though it is still rather weak. National consumer groups outside the United States (and perhaps a few other OECD countries) have virtually no capacity to monitor the highly technical deliberations of their national authorities as they go about the day to day business of pharmaceuticals regulation and approval, for example. Health Action International (HAI – a prominent consumer health NGO) still has only a very limited capacity to monitor the deliberations of the ICH. But national consumer groups actually may have more influence by pooling their resources and their best and most expert people through HAI to focus their monitoring on the ICH than they can have through national regulators. In a world of increasingly internationalised regulation, focusing the weak glimmers of scrutiny from 100 national consumer groups onto one international forum of decision making may increase popular sovereignty from nothing to something. An irony for consumer groups of the ICH negotiation process among the EC, the United States and Japan is that it occurs much more in the open than national regulatory negotiations. Why? Not to allow citizen sovereignty over the regulatory process, not as a concession to consunier groups demanding accountability. It has been so open arid well documented as a concession to ***governments*** who have been complaining because of their exclusion from the process.

Even more ironically, similar considerations to direct citizen sovereignty apply with parliamentary sovereignty. There are too many business regulatory agencies (considerably over 100 in Australia) and not enough parliamentarians to go around for oversight at the national level. All the parliamentarians of all the world's governments is a much larger group, however. What I am suggesting is that the Inter-Parliamentary Union appoint committees to produce oversight reports on the work of selected international organisations concerned with business regulation. Some sovereignty, you might say, to select a handful of parliamentarians to represent one hundred and seventy governments in overseeing an international organisation. Yet this is a standard problem in international diplomacy, with some standard solutions. Nations group themselves into coalitions with rather similar interests on particular issues. On many issues there is a large group with little or no interest. Slovakians are not very interested in the regulation of whaling. If the issue is the regulation of intellectual property, there are nations like the United States and Germany with very similar interests as major intellectual property exporters, each of which may be prepared to trust the other to take turns in representing their collective interests on a key committee. Then there are nations like South Korea, Taiwan, Mexico, India and Brazil that are major technology importers and exploiters, who share common interests. There are underdeveloped countries that import massively but that never export or exploit intellectual property rights. Then there are many countries like Australia that are net importers of intellectual property but that also have significant exporting interests. A committee can be constituted with representatives of each of these different groups of nations.

Such international committees would give parliamentarians a more potent opportunity to exercise oversight than they could ever enjoy at the national level. Committee reports would be tabled in many parliaments around the world, mostly, to be sure, only to gather dust in the parliamentary library. But where the national interests touched by the

international standard-setting were profound, a communication channel would have been dug so that the information might flow and alarms might nng to waken the sleepy guardians of our sovereignty.

No claim is made here that parliamentary and NGO networking to wire international forums back to the people can establish a Jeffersonian sovereignty for the modern world. The claim is that it can create a little more sovereignty than the delusion of popular and parliamentary sovereignty that is the status quo of the technically and quantitatively demanding domain of business regulation. The claim is based on the view: *a)* that increasingly it is at the international level where the action is, and *b)* that there are economies from focusing scarce national oversight energies on international forums so long as the selected watchdogs are accountable to a set of national constituents and are required to report back to that set of constituents. It is often said that representative democracy is inferior to direct democracy, but at least is feasible and superior to no democracy. So second-order sovereignty in the international regulatory system may be inferior to direct sovereignty but better than no sovereignty. In taking the possibility of such second-order sovereignty seriously, we may actually be able to move from a world where internationalisation is causing a democratic deficit to one where it causes a democratic surplus – still deeply imperfect democracy, but enhanced democracy.

G) Taking many small steps: APEC

It is evolutionary rather than revolutionary change that can move us towards a world that better accomplishes all six objectives set out in this paper. Grand blueprints are neither possible nor desirable. International bargaining forums of many sorts, private and intergovernmental, can be strengthened to these ends. Opportunities can be seized at many levels to harmonize outcomes intergovernmentally, to harmonize default standards privately, to nurture a proliferation of competing optional inputs, to increase levels of mutual recognition of these optional inputs and to strengthen parliamentary oversight and NGO participation in all of these international activities.

Most importantly, creative opportunities to widen agendas so that progress can be made on all these fronts are available throughout the world system. For example, Australia is advocating the use of APEC as a forum for regional trade liberalization and harmonization of standards.[3] The challenge is how one descends from the commanding heights of APEC meetings to the nitty gritty of a particular food standard. What is needed is leadership from above that nurtures leadership from below. Entrepreneurship for specific harmonizations must come from the technically competent. Leaders with the passion to show the way to harmonizing electrical standards can only come from people whose daily work lives are all about electrical standards.

All APEC governments could agree to urge their own industry associations, their own NGOs, their own regulators, to put forward ideas for bilateral and multilateral harmonizations that will serve their national interests. One way would be to award prestigious national prizes for the best ideas. Then, rather on the GATT model, a politically sage APEC mediator would have the job of packaging sets of widened agendas. A wants this harmonization out of B; B wants that harmonization out of C;

C wants another out of A. So A, B, and C are put together to hammer out a mutually satisfactory harmonization of all three standards, being mindful of the need to sell this package to the other governments in the region.

The model is of fomenting a chaos of harmonization agendas led from below, followed by co-ordination of bargaining forums and bundling of issues from above. It cannot be over-emphasised that harmonization ideas that are bold and innovative enough to set new agendas must come from below. Top-down harmonization agendas will have less sustainability. Those who think that we need a world government to bring about regulatory harmonization not only have a naive idea: they have a bad idea. Note that the imperative for rejecting top-down in favour of bottom-up framing of harmonization agendas improves prospects of moving from a democratic deficit to a democratic surplus.

A successful Soviet bureaucrat once said: "Regulation is good; control is better." To be beneficial, regulatory rapprochement should not be about control; it should be about entrepreneurship and parleying mutual advantage.

H) Win-Win Rapprochement

The purpose of this paper was to ask if international regulatory rapprochement is possible that simultaneously achieves six objectives:

A. Reduce duplicative inefficiencies;
B. Reduce non-tariff barriers to trade;
C. Reduce free riding on efforts to tackle international problems;
D. Increase popular sovereignty over the regulatory process;
E. Increase regulatory innovation; and
F. Increase the capacity of firms to shop for lowest-cost regulation.

Surprisingly, the conclusion is that win-win-win-win-win-win is possible, where win means not perfection but improvement on the status quo. Equally, a result with five wins and one loss is possible, or four and two, or any other combination. There is no necessary reason why these outcomes must either hang together or fall apart. The purpose of the paper is simply to show that there is every reason to struggle optimistically for outcomes that deliver improvements on all six fronts, spurning cynics who contend that it is incoherent to do so.

The ICH is an interesting case study of the possibilities for win-win rapprochement; to be sure, possibilities still to be realised. Here, I think the practical advice of Fernand Sauer, the head of pharmaceuticals regulation at the EC and the driving force behind ICH, should be heeded. First, he advises, don't be deterred by long histories of previous failures to secure rapprochement in other forums. You can always create new bargaining forums in the international system. Second, he advises that it is better to start slowly rather than fail quickly with overly ambitious plans.

The third bit of political advice which I privilege in this conclusion is when negotiations are deadlocked, widen the agenda. Don't start with a wide agenda; narrow agendas are simpler and can get quicker agreement when consensus is possible. But when consensus is not possible on a narrow agenda, the deadlock can often be broken by

broadening the agenda. This I think is a key reason for the remarkable accomplishment of 104 nations now being ready to sign the **TRIPS** agreement of the Uruguay Round of the GATT. It is especially remarkable because more than 90 of these nations are net importers of intellectual property rights and hence have a structural interest in weaker intellectual property regulation rather than the stronger regulation the TRIPS agreement provides. **As** someone from a nation that is a net importer, and as a cynic about the economic benefits of patent monopolies, I have some deep reservations as to whether this agreement is a good thing. But my point here is not to debate the respects in which it is a good or a bad agreement; it is to marvel at how agreement is possible among so many countries that have so many reasons for rejecting it. For present purposes, one reason should be noted – the power of agenda broadening.[4] While the US negotiating position for the Uruguay round was no TRIPS, no round, the negotiating position of my own country, and the Cairns group generally, was no agriculture, no round. It has been from the champions of TRIPS – the agriculturally protectionist nations of the EC, the United States and Japan – from which the Cairns group has been most desperate to seek agricultural concessions. So both the Cairns group and the EC–US–Japan will probably sign both for TRIPS and for some freeing of agricultural markets.

It was suggested at the beginning of this paper that international institutions do not generally solve international regulatory problems by directing effective enforcement against rent-seeking nations or firms. Powerful states can do that to some extent and thereby bring free-riding nations to the international bargaining table – witness the US targeting of nations such as Taiwan, India and Korea for intellectual property infractions using Section 301 of its Omnibus Trade and Competitiveness Act of 1988.

The Harvard research team on international environmental institutions found that the ways international institutions make progress are through: 1) increasing governmental concern (*e.g.* disseminating scientific knowledge that magnifies domestic public pressure); 2) enhancing the contractual environment (*e.g.* providing bargaining forums, monitoring national performance indicators of environmental outcomes); and 3) building national capacity (*e.g.* transfer of regulatory technology, boosting the bureaucratic power of domestic allies by requiring them to generate accountability data for international treaty purposes).

We tend to lose sight of the fact that the nations with the lowest regulatory standards in the world system are often in that position because they lack the national capacity to make their regulation work. This may have the effect of attracting some investment that seeks out the locales with the lowest standards. The free rider effect may induce a certain inertia about raising regulatory standards to international minima. These benefits of free riding may be a reason for the persistence of the problem, but it is often incompetence, lack of national capacity, that is the original reason for the problem. It is in these circumstances, which I contend are rather common, that OECD nations with national capacities to regulate effectively have an interest in transfemng regulatory technology to nations which lack national regulatory capacity and would like to have it.

International institutions such as the OECD are not well placed to do most of the things that need to be done to secure win-win regulatory rapprochement. I have sought to show that only national governments are well placed to play certain roles (*e.g.* enforce-

ment against free riding), international industry associations and other NGOs are in the best position to make other contributions, international private standard-setting bodies like the ISO in the best position to do certain other things. But there are arenas where the OECD can make major contributions to international regulatory rapprochement by 1) increasing governmental concern; 2) enhancing the contractual environment and 3) building national capacity. The internationalisation of hazardous chemicals regulation is one area where the OECD has done an important job in all three respects (OECD, 1988).

VII. What OECD Members can do towards win-win rapprochement

I have explained that there are major contributions to be made toward rapprochement by international organisations, voluntary standards setting bodies and NGOs. But what are the key things national governments can do? Rapprochement requires leadership by OECD countries at many different levels:

1. *Intranationally,* where different standards apply in different parts of the same country (for example, the 1992 Australian Intergovernmental Agreement on the Environment which advanced the principles of nationally agreed outcomes and mutual recognition of regulatory inputs) (Wilkins, 1993).
2. *Bilaterally* (for example, substantial convergence of antitrust law between New Zealand and Australia under the auspices of the Closer Economic Relations Agreement) (Ministry of Commerce *et al.,* 1992).
3. *Trilaterally* (for example, the ICH for pharmaceuticals between Japan, the United States and the EC; environmental and occupational health and safety convergence among the United States, Canada and Mexico under the North American Free Trade Agreement).[5]
4. *Multilaterally* (for example, the leadership of the Bank of England and the United States Federal Reserve Board in moving the G-10 toward increased minimum prudential standards for banks in 1987) (Kapstein, 1989).
5. *Regionally* (pre-eminently, the mutual recognition of standards on a wide variety of products and services achieved by the European Community (Commission of the European Communities, 1991), with these then spreading to the European Free Trade Association nations and then to the post-communist natinns; also, the aspirations President Clinton articulated for APEC in Tokyo this year).
6. *Globally* (for example, the leadership of the United States in setting up the global regulation of satellite telecommunications through INTELSTAT in the 1960s and its leadership towards some international deregulation in this domain in the 1980s) (Colino, 1985).

The substantive tasks required at these different levels are many:

1. Funding research that helps other nations to recognise their own interests. Most nations will not realise the costs associated with a regulatory problem that might be addressed by rapprochement. The Australian government has adopted this

research-based approach in seeking to persuade the EC of the costs to its consumers of protection and non-tariff bamers in agricultural trade (Bureau of Agricultural Economics, 1985).

2. Creating deliberative forums that give other nations an opportunity to discover the interests they have in rapprochement. This is what the EC did with establishing the International Conference on Harmonisation for pharmaceuticals.
3. Giving technical assistance to nations who would like to put in place the regulatory infrastructure to achieve internationally accepted minimum outcome standards, but who are unable to do so or unwilling to give this problem priority in their budget. Germany and some other OECD members are doing this in their technical assistance to post-communist societies to secure improved environmental outcomes.
4. Nurturing private standard setting and private innovation in regulatory technologies by resisting the temptation to insist on a state monopoly of standard setting. The nurturing of CEN and CENELEC by the EC is exemplary here.
5. Be accommodating to mutual recognition of radically different input standards applied by other governments when those inputs deliver internationally acceptable minimum outcomes. Agree to be bound by independent arbitration of disputes over mutual recognition.
6. Foster interest by national parliamentary committees in oversight of the activities of international standard setting bodies.
7. Share information on international standard setting with national NGOs. For example, with regard to environmental standards, comply with the OECD's "Transparency and Consultation'' guidelines on ''Trade and Environment".[6]
8. Urge national industry associations, NGOs and regulators to put forward rapprochement proposals that will advance the national interest.

Why should OECD members bother with any of this? The simple practical answer is self-interest. If every nation aggressively pushed through these means only those regulatory rapprochements where there is a significant national interest at stake, then a huge amount of rapprochement would occur. International regulatory rapprochement is a domain where the challenge is vast. but where prospects for the public use of private interest and the international use of national interest are substantial.

Notes

1. I am indebted to David Vines for this insight, which he in turn credits to Sidney Pollard.
2. "In Japan, Baycr, for cxnmplc, **runs** a stability laboratory with a staff of ***25*** people. whose only task is to repeat stability tests that were carried out before at company headquarters in Germany in order to get marketing authorization in Japan." (D'Arcy and Harron, p. 52).
3. This initiative was discussed in Andrew Elek (1992), "Pacific Economic Co-operation: Policy Choices foı the 1990s'', *Asian-Pacific Economic Literature*, Vol. *6*, No. 1, pp. 1-15.
4. Peter Drahos and I will seek to fully articulate the range of reasons in future research.
5. See, for example, the NAFTA preparatory work in Occupational Safety and Health Administration (1992), A *Comparison of Occupational Safety and Health Programs in the United States and Mexico: An Overview*, US Government Printing Office, Washington D.C.
6. See Annex Two to Chapter One.

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