Bridging EU and Domestic Implementation: A Cross-National Comparison

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by

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Introduction

This paper tackles a topic of interdisciplinary interest and current policy importance in countries around the world: the regulation of safe, efficacious and quality medical devices for use in patient care. Regulation in this field is thirty years behind the regulation of medicines in the European Union, and thirty years behind medical device regulation in the US. Specifically, the paper looks at the implementation of three medical device directives in France, Germany and the United Kingdom, through the lens of domestic implementation literature, evolving over a period of thirty years. The central concerns of this literature arguably coincide with many of the concerns and distinctive features of the historical and sociological version of the new institutionalism rather than rational choice (Peters 1999).

Questions are raised about the significance of *domestic constraints and opportunities* in adapting to EU directives on medical devices. What kinds of domestic policy and contextual constraints and opportunities exist? How do they affect the domestic implementation process? What are the domestic outcomes? And, finally, how do we explain variations in outcomes of implementing the same EU directives on medical devices across the three countries? [1]

Arguments

Drawing on ongoing field research, three arguments will be presented. The first argument is that domestic governance structures are as powerful in producing adaptations of regulatory practices as are EU directives in all three cases. Second, the domestic context and the distribution of veto points in each country are sources of *constraints and opportunities* which matter in a number of crucial ways addressed below; but these ways largely depend on specific regulatory issues and vary significantly across the three countries The third argument is methodological. A more meso-level analysis moves from the national level down the diverse pathways of implementation as the inquiry reveals traces of divergence in administrative/regulatory practices across the three cases. This is true despite the convergence of European rules, norms and procedures and regulatory approaches observed at the aggregate level in each country. "Domestic context" in this cross-national research project is explicated and delineated below in a

[1] Variations in policy outcomes have been documented as part of the current research project, but cannot be dealt with in this paper.

discussion of the "critical" components, which are assumed to influence domestic implementation from national to ground levels.

The unique and arbitrary use of the concept of "implementation" in the construction of the European Union—the concept (legal and political) was limited to the relations between EU institutions and member states—was first dealt with in *Bridging European and Member State Implementation: The Case of Medical Goods, In Vitro Diagnostics and Equipment* (Altenstetter, forthcoming)[2]. The current paper starts where the earlier work left off. European regulatory policy typically tends to be discussed in (a) "the comitology" system of EU governance with strong participation of national bureaucratic experts (Wessel 1998, 1997) and (b) the bureaucratic arena in the member states.

The regulatory regime on medical devices has been described elsewhere and needs no repetition (Altenstetter 1998a and 1998b, 2002, 2003). Still, this paper will provide a brief summary of the key points in EU medical device regulation at the European level and the essential nature of medical devices as a backdrop to the discussion on implementation. Next, the external and internal parameters of implementing EU directives on medical devices will be established. Then the paper will identify key instances of domestic constraints and opportunities in the medical device sector in the three countries, discuss how these matter for implementation, and selectively use evidence for each instance chosen. It should be noted that removing specific instances from the overall context of a case itself is a *tour de force* if context is seen as the interaction of clusters of country-specific variables assumed to produce final outcomes. Finally, a conclusion will round up the paper.

What are medical devices?

Medical devices are commercial goods and, as such, benefit from the priorities of the Single European Market (an *exclusive* EU prerogative). They also benefit from the principle of subsidiary institutionalized in the Treaties' Article 3, which tends to turn most competencies over medical products into *shared* competencies between the member states and the European Union.

[2] Drawing a distinction between pre-decisional and post-decisional processes of bargaining over compliance with EU rules, Tallberg and Jonsson (2001:2) identified three bodies of literature: public policy research on implementation; legal and political research on the European Commission's execution of its functions as "guardian of the treaties;" and legal and political research on the interaction between the ECJ and national courts in the decentralized enforcement of EC law. Each research school uses the concepts of compliance, enforcement and

In healthcare policies the member states have not offered any leeway or incentives to the EU to control medical products. On the contrary, each time the Treaty of Rome was amended (1985, 1993, 1997), they insisted on the insertion of explicit language in order to reinforce their preferences for keeping control over national health protection schemes (NHS or NHI) for themselves. The Treaty of Amsterdam added Article 152 on public health, which includes a requirement that the Commission must base all internal market proposals on scientific evidence (Article 100a(3)). Responsibilities over public health policy is largely shared between the EU and the member states. In sum, medical device regulatory policy-making is located at the intersection of these three policy domains and is shaped by the preferences of the stakeholders involved in each domain.

Yet medical devices are not normal industrial products. The term medical device is widely used for a host of broadly different products (Table 1). A typical hospital may have a few dozen of one type of medical device (such as imaging and operating room equipment) and huge volumes of others (such as syringes or sutures). Clearly, medical devices in all their various forms, shapes, and sizes are not only tools for addressing major health problems, but they are the stuff of which healthcare delivery is made.

Patients can be recipients of prescription drugs, medical devices or transplanted tissues. Devices may incorporate drugs, and drugs may need a medical device to deliver it to a patient (e.g., an asthma inhaler). Medical devices also may be transplants and incorporate human cells, biologically or pharmacologically active substances, or synthetic device-like structures. This differentiation matters a great deal for the development of a legally clear and fair regulatory regime, appropriate regulatory strategies, and feasible mechanisms for compliance, enforcement and implementation.

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implementation slightly differently; but the analytical focus rarely extends past the relations between EU institutions and member states.

Table 1: Examples of Medical Devices	
Anesthetic and respiratory equipment: CEN/TC 215 • tracheal and breathing tubes • anesthetic machines • medical breathing systems • medical gas supply systems • lung ventilators • pressure regulators • flow metering devices • connectors	**Implants for surgery: CEN/TC 285** • cardiac implants • vascular implants • osteosynthesis implants • reconstructive implants • joint replacement tools • mechanical contraceptives
Non-active medical devices: CEN/TC 205 • urinary and drainage catheters • hypodermic syringes and needles • plasma filters • condoms • extracorporeal circuits • blood gas exchangers • transfusion and infusion sets • parenteral devices • medical gloves • clinical thermometers • anti-embolism hosiery • pen injectors • enteral feeding tubes • surgical tapes and gowns	**Electrical equipment** • X-ray equipment • medical electron systems and accelerators • cardiac defibrillators and monitors • ultrasonic therapy equipment • nerve and muscle stimulators • lung ventilators • electroconvulsive therapy equipment • endoscopic equipment • baby incubators and radiant warmers • electrocardiography • blood pressure monitoring equipment • external cardiac pacemakers • magnetic resonance equipment • heated pads, blankets and mattresses • electrically operated hospital beds

Source: Cutler IR. The Role of Technical Standards. In: Adcock J, Sorrel S Watts J, eds. Medical devices manual (Rev.). Haslemere: Euromed Communications Ltd.; 1998:6.1-6.14.

The external parameters of *constraints and opportunities*

Given that the European Union has competence over trade, competition and international competitiveness; that a good many powers over public health—for example, product safety, efficacy and quality—are shared between EU institutions and member states; and that healthcare policy is an exclusive power of the member states, the single most important source of constraints and opportunities in the domestic context is the allocation of jurisdictional powers to the EU institutions and the member states. A key issue for France, Germany and the United Kingdom is how domestic policy makers can, and will, create the conditions for balancing between public health, healthcare policy and industrial trade while maintaining the safety and quality levels they had prior to the EU regulatory regime. Also key is how they will organize and adapt requirements for pre-market approval and, more importantly, organize and implement

post-market surveillance. A final issue is how they will balance between vigilance of medical devices on the market on one hand, and professional rights to practice medicine and property rights to run health facilities on the other. All member states, including the three countries chosen for this comparison, have the same mandate and operate under the same EU framework. They are called upon to transpose the EU directives into national law, and to issue or amend existing implementing decrees, ordinances and specifying other details for sub-national and front-line implementation.

The opportunities offered by European integration for institutionalizing one's own preferences in a new regulatory regime were not ignored. Instead, they were seized by that segment of an otherwise fragmented industry that operates globally and which simultaneously put pressure not only on the European Commission but also on the national governments in France, Germany and the United Kingdom to promote a European-wide regulatory regime on medical devices. They were the only countries that significantly regulated medical devices prior to the EU regime, but they perceived different aspects as requiring regulation. Unsurprisingly, the same three countries took the tactical and strategic leadership along with the European Commission and the industry in developing a European-wide regulatory regime, which is embedded in the general policy on the single market (Art. 100 and 100a). It comprises three medical device-specific directives and one draft directive.

- The Council directive on active implantable medical devices (AIMD, 90/385/EEC) of June 20, 1990, in force in the member states since January 1, 1993.
- The Council directive on medical devices (MDD, 93/42/42/EEC), effective since January 1, 1995.
- The *In vitro* Diagnostic Devices directive (IVDD, 98/79/EC) of the European Parliament and of the Council of October 27, 1998, which was adopted on December 8, 1998, a delay of some eight years after a first draft became available.
- Draft directive on quality and safety standards for human tissue and cells.

Why would France, Germany and the United Kingdom be motivated to provide leadership in promoting a medical device regulatory regime? As will be seen in a later section, the presence of the industry is strong in these three countries. Heritier offers a plausible argument that a country with a high level of regulation—environmental in her case (1996, p. 282), and health and product safety in this comparative case—will do the following:

(i) seeks to impose its own regulatory style and regulatory philosophy on the other Member States in order to reduce the costs of legal adaptation to European legislation.....

(ii) seeks to present the national industry with a certain regulatory stability because the absolute costs of environmental investments are less important than the stability and predictability of those costs.

(iii) High-regulating Member States seek to establish the same level of regulatory strictness on the European level in order not to jeopardize the competitive situation of their own industries.

(iv) Governmental actors in Member States with high regulatory standards are interested in raising standards on the European level to their own because lower European standards reduce the bargaining power in dealing with industry in the national network.[3]

Safety, quality, performance, efficacy and evaluation of medical devices are the key goals of regulation of these products for use in medical treatment. These policy variables come into play in different mixes and institutional arrangements in each country. The CE-mark[4] serves as a kind of market authorization, but should not be confused with the stringent market authorization process for pharmaceuticals or voluntary standards (for details, see Altenstetter 2003). Adherence to voluntary standards is another requirement. Medical devices are regulated by level of risks; with each level regulatory requirements are raised.

For France the CE-mark has been, and remains, an insufficient test of safety and quality. France insisted on getting the directives *right* from the beginning. Her representatives in Brussels argued that conformity procedures leading up to the CE-mark may be a good test of performance of equipment and machines before these products reach the market; but they argued that the CE-mark is entirely inappropriate for allowing high-risk, highest-risk (about 1,000 product types worldwide) and extremely high-risk medical devices (about 100 types worldwide) and in particular *in vitro* diagnostic products on the market. The remaining medical devices have a moderate risk potential (about 10,000 types), and lowest risk potential includes about 100,000 different samples available worldwide.

By contrast, the United Kingdom and Germany initially were willing to compromise on rigor, biological safety and efficacy of medical devices in medical and surgical procedures in the interest of creating a single market and facilitating unhampered trade. They, along with those EU member states which had no regulation on the books, were more interested in adopting directives as early and fast as possible, fully aware that the wording of a directive would need to be revised

[3] We have not investigated the extent to which the organization of national interests in Brussels has had a bearing on the relative success of each country in getting its preferences written into the directives (France: 75 staff members; Germany 81; the United Kingdom 54, according to Kassim *et al.*, 2001).

[4] Contrary to widespread misunderstanding, CE does not stand for *Communeaute Europeenne.* Rather, it stands for conforming with European directives, or *conformite Europeenne.*

upwards as soon as it was adopted. But it took years before this could happen when the IVDD was adopted in December 1998 and amended the AIMD and MDD in significant ways. In sum, Britain and Germany pushed for trade and competition while France pushed for high safety and efficacy measures during the years preceding the adoption of the IVDD. After two years of the isolation of France on the European level, most member states have come around the French position. Today, there is agreement that the EU regulatory regime is appropriate for 90% of medical devices while the remaining 10% (about 100 products in class III and class IIb worldwide) have a an extremely high risk potential and require stringent regulatory measures.

The increasing complexity of shared powers concerning the regulation of medical devices between the member states and the European Union is shown in Table 2. It reflects a "fundamental contradiction" of health policy at the European level (Mossialos and McKee, 2002:27) because member states have constructed a social model of healthcare politically and socially over decades and continue to be committed to it while the European Union tends to be dedicated to market rules and dynamics. By relying on market mechanisms and competition law, the "social" of healthcare may be jeopardized.

This "fundamental contradiction" translates into the existence of competing, if not contradictory, policy objectives between industrial policy, healthcare policy and public health policy and associated regulatory legacies pertinent to each area.[5] With economic and professional vested interests in support of, or in opposition to, a specific policy issue, each country is faced with a strong need to balance among these competing interests at member state and European Union levels. The driving force for striking a balance are domestic politics and pressures to adapt to the regional and global environment.

In domestic implementation in each country the same stakeholders are the targets of EU directives: regulatory agencies, companies and notified bodies (or third party certification organizations). They participate in the political and the administrative (regulatory) game in each country; but their interaction in the political process tends to produce final results in France that differ from those in Germany and the United Kingdom. In micro-level implementation of a

[5] Govin Permanand, in a superb doctoral dissertation entitled *Regulating Under Constraint: The Case of EU Pharmaceutical Policy* at the London School of Economics and Political Science, October 2002, has dissected these three policy sectors, identified the major thrust and driving forces. He convincingly shows that because of these diverse goals the pharmaceutical industry is not like any other industry. European and domestic policy-making concerning the medical device industry(ies) operates under the same triple constraints.

medical vigilance system, the players are even more diverse. The essence of the implementation process in each country is their variability.

Table 2: Power sharing arrangements in the European Union and the member states

Policy issues within EU jurisdiction	Policy issues that are shared between EU and M-S*	Policy issues within sole member state jurisdiction
Trade Commerce International competitiveness		Health care Health and safety Pricing and reimbursement Clinical investigations/ evaluation//clinical trials
AIMD (1990) MDD (1993) IVDD (1998) Draft directive on Quality and Safety Standards for Human Tissues and Cells		Laws on labeling Advertising/promotional laws Medical institutions and health facilities
EU Advertising Directive (Directive 84/450/EEC on Misleading Advertising and Comparative Advertising Directive (Directive 97/55/EEC Concerning Misleading Advertising (weak)		Post-market controls & surveillance Distribution Installation Vigilance Notification/registration for placing on the market
Data Protection Directive (95/46/EEC) On the Protection of Individuals with Regard to the Processing of Personal Data And on the Free Movement of such Data		Unregulated medical devices Professional and lay users Coverage decisions (NHS and NHI Reimbursement (NHS and NHI) Price-setting (NHS and NHI) Evaluation (NHS and NHI)

The entries in the table are incomplete; they are arranged in no order of priority and spacing has no specific meaning. It can be argued that practically every entry in the right column is affected by Single Market Directives, the medical device-specific directives and other EU directives on medicines, blood products, cosmetics etc. in one way or another.

Sources: Mossialos, E. and M. McKee. EU Law and the Social Character of Health Care Vol. 1; and McKee, M. E. Mossialos and R. Baeten (eds.). The Impact of EU Law on Health Care Systems. Vol. 2. Brussels: P.I.E. Peter Lang, 2002 Jil. B.Deal, Principal, Fish & Richardson, P.C. Washington DC. "Role of the regulatory affairs professional. A focus upon European Union legal affairs. London, April 1998 conference.

The internal parameters of *constraints and opportunities*

Building on table 2, it is clear that the internal parameters of *opportunities and constraints* are as much a product of the allocation policies between the European Union and the member states as they are the product of the distribution of "veto points" in each political-administrative system and strong legacies of regulatory policies and contextual variables, which differ from country to country. What factors in the domestic context are considered "critical" for shaping, though not determining, the process of implementation and eventually final outcomes? For this study, the "critical" components (following Najam 1995) are:

- The *content* of regulatory policy before and after EU directives
- The *context* (dominance of organizational actors)
- *Commitment* in support of, or in opposition to, EU medical device directives
- *Capacities* (manpower, skills, funds, information and communication)
- *Clients and coalitions* (target groups affected by EU regulatory policy which include regulators, notified bodies, manufacturers, and in the healthcare delivery system clinicians, nurses, patients, home caregivers).

Political Institutions

Constraints and opportunities are a function of both established institutional arrangements for implementation in each country and specific policies and policy variables. The internal parameters of constraints and/or opportunities will be established by looking at three sources: (1) state structures, (2) state-industry relations, and (3) connections between the state and healthcare systems.

A second instance of constraints and/or opportunities arises from the continued influence of strong legal and administrative traditions in each country. These tend to influence the way(s) in which the policy discourse is conducted and medical device-related issues are framed—whether as industrial issues, healthcare issues or public health issues—and they tend to influence the perceptions of policy actors and policy processes (in both formulation and implementation).

A third source of constraints and/or opportunities derives from the literature which groups the three countries as falling in the category of having a state-centered governance system. The variants of state centrism in, for example, Britain and France are well known. State offices tend to dominate. By contrast, Katzenstein's "semi-sovereign" state in Germany (1987) involves a strong separation of the state from self-regulating or self-governing societal groups

and a strong interdependency between the two structures. Their interaction in Germany is clearly corporatist. In Germany, corporatist self-governance by association in health care entails substantial state regulation and even emergency decree power by the state (Streeck and Schmitter 1985). State offices are dominant, if not always highly visible; a command-and-control logic tends to prevail in both offices of the state and corporatist self-governance.

A fourth source of likely constraints and/or opportunities are state-business relations. In the political science literature, France and the United Kingdom are usually described as having a *pluralist* pattern of state-business interaction where power is dispersed throughout society, while, as previously mentioned, Germany experiences a strong *corporatist* pattern where power is concentrated in fewer but stronger interest groups and where the state has delegated policy (regulatory) responsibilities to corporatist groups.

Finally, the implementation of EU directives and professional traditions may look unrelated (e.g., in health clinicians, nurses, technicians, and in regulating medical devices from materials experts and laboratory specialists). In the domestic context, they are closely linked in each of the three cases. The medical profession has long suffered from the stringency of recent cost containment policies and healthcare reform. As a result their economic and political power has greatly declined, even though medical associations retain control over medical issues and peer review, and physicians remain respected knowledge bearers and respected craftsmen. Their positions have been undermined further by technology assessment in health care (HTA), evidence-based medicine (EBM) and practice guidelines. If institutional arrangements have been transformed, they are the result of domestic healthcare reform and institutional engineering driven by domestic political forces and pressures (Knill and Lenschow 1998; Knill 2002) rather than by European developments.

State-centered governance

State centrism in France and the United Kingdom, the "semi-sovereign" state in Germany, and the concomitant political institutions—interest groups, political parties and party systems, electoral systems, party government and party politics and coalition governments in the case of France and Germany, and majority rule in the case of the United Kingdom—all play an important role in national policy-making, as does the bureaucracy and the judiciary.

Two different legal approaches to regulatory policy-making on medical devices also come into play in this comparison. Case law on medical devices is slowly emerging, and both the ECJ and national courts have ruled on medical devices and surgical and medical procedures, thus creating *new* or reinforcing *old* constraints and opportunities. The two legal systems are common law (Great Britain) and Roman law (France and Germany). Rose (1990:81) caricatures these by referring to Max Weber, who viewed continental courts as operating like a "legal vending machine" (*Paragraphenautomat*): "legal submissions are put in at the top along with the fees and costs and a judgement comes out at the bottom along with a standard printed justification." This characterization may be slightly exaggerated; yet there is a kernel of truth, as it has come into play in judicial policy-making about medical devices (Hodges et al. 1999a, 1999b, 1996c). Unlike judicial decisions which ultimately settle policy controversies in France and Germany, political decisions must resolve policy controversies based on the century-old embedded principle of parliamentary sovereignty.

Since all three countries are parliamentary democracies, any democratic government, majority or coalition, controls executive-legislative relations with executive dominance over legislative inputs. Draft bills, decrees and ordinances are initiated in the executive branch and drafted by civil servants, whose influence comes to bear three times: first, in drafting new legislation (or adapting existing rules to EU directives), in planning new executive rules; and third in monitoring compliance, enforcement and implementation.

The dominance of the executive branch in regulatory policy making

The macrostructural characteristics described above do matter for the political process and policy-making process in general, but their influence in this case is arguably reduced for two reasons. First, "protective regulatory policy" is generally assumed to differ from distributive, redistributive and "competitive regulatory policy" (Ripley and Franklin 1991) in terms of the primary policy actors (i.e., appointed regulators rather than elected officials), stability of relationships (bureaucrats and industry representatives) and lack of transparency of decisions, except for legally enforceable rules and procedures. In all three cases, regulatory policy-making is typically and primarily a prerogative of the executive branch. It decides on the final mixture of EU regulatory and domestic government instrument(s) and regulatory requirements, which apply to implementation. Instruments can a) strictly speaking, affect the EU alone; b) be made up of

domestic rules and procedures; or, more likely c) a mixture of the two. Administrative law specialists tend to argue that once EU directives are transposed into national law, implementing officials simply enforce the law and enforce compliance with established procedures, regardless of their European or domestic origin.

Second, enforcement of compliance with rules, norms and procedures typically runs through a maze of public and private bureaucracies (Page and Wright 2000). Given these characterizations of both regulatory policy-making and implementation, the domestic institutional arrangements for implementation and rule-writing move the domestic context more sharply into focus as potential determinants shaping, rather than determining, the final outcomes of EU directives.

Problem-oriented implementation

A *problem*-oriented implementation perspective takes cues from the substantive issues at hand, and asks how these are being approached, decided on, and implemented by stakeholders. A problem-oriented implementation perspective is not concerned whether implementation is guided by a top-down or a bottom up perspective, and accepts a two-way process as a given; but it is concerned that rules for product safety and health safety are in place. While elements of hierarchical channels and top-down influences certainly do come into play—European law itself establishes a certain hierarchy over national law (Hodges *et al.* 1996—some issues that are central to the scholarly debate on implementation do not apply.

For example, a top-down approach assigns policy design factors a central role in producing the desired results. However, this view overlooks the fact that the implementation of a particular policy design is mediated through domestic institutional arrangements which may shape and distort original intentions, and final outcomes. By contrast, a bottom-up perspective emphasizes the importance of regional and local factors and rule-enforcing civil servants and other professionals. They have and use discretion in enforcing compliance with the law and in responding to bottlenecks in the implementation process not anticipated by central policy designers.

Implementing EU directives across the EU-member state nexus and within a member state across the national and subnational levels illustrates that the type of thinking which may be good for policy design, that is, thinking in horizontal terms, is not only insufficient, but is in fact,

divorced from reality, and captures only part of what is implementation in the real world. EU directives spell out the major policy instruments, which will be binding on national regulators, companies and others. Accordingly, policy design issues diminish in importance in the domestic setting while institutional arrangements, which mediate implementation, gain in importance as explanatory variables. EU instruments are complemented, and often expanded, by additional policy instrument choices and regulatory requirements, which are formulated by the national regulator and which have to be implemented by front-line implementers. The coexistence of European and domestic rules often is the source of different and opposite dynamics coming from the European level or from the field.

Methods

The analytical framework mentioned above provides the clues for research design, methodology and data collection. A two-track research design was adopted, although both tracks are intertwined. The first track involves analysis of primary and secondary sources, including a huge amount of "gray" materials. Track two consists of observational, interview and process-generated data. A descriptive mapping phase—not yet complete—consists of three sets of activities:

- first, an analysis of published primary EU and member state documents;
- second, the development of comprehensive scenarios of implementation; and
- third, data analysis around a three-dimensional matrix characterizing implementation activities, including functions/responsibilities/tasks, the organizational level (structure, design, control model, authority), and the actors of implementation.

Through process tracing, we intended to reconstruct the implementation process by addressing formal and informal procedures and the relationship between the stakeholders. We also sought to find out how each country frames, defines, and treats the five core elements of the EU regulatory regime on medical devices: safety, quality, performance, evaluation, and efficacy of medical devices. The first case study on France nears completion and draws on 80 interviews. 40 interviews were conducted in the UK but only sections are drafted. For Germany, the information on formal and informal factors is incomplete. Field work in Germany has not yet begun to complement an analysis of the formal framework (Altenstetter 1998c).

Because of the different stage of fieldwork, the next section on comparative analysis and empirical findings is uneven. Empirical findings on the regulatory process in France are rich and extensive but information with the same details and attention are missing for Germany and the

UK. However, the available information is sufficient to establish commonalities across the three cases.

Comparative Analysis and Empirical Findings

State-centric governance

As evidence of state centrism, consider the organization of regulatory functions in all three countries and the policy networks centered around the regulation of medical devices issues. In the initial period of the early 1990s, the ministry of health served as national regulator or *device competent authority*, a Euro-shorthand for a *lead* agency. Within a few years, the ministry of health was replaced by a separate national regulatory body, and regulatory functions were separated from day-to-day management functions of the ministry of health. In-house staff and experts under contract to the agencies jointly engage in reviewing and evaluating manufacturers' submissions for product approval, including documentation on clinical trials, performance, efficacy, etc.

Each country seized the opportunity of having to transpose EU directives into national law by restructuring governmental responsibilities, amending established laws and decrees, and adding new regulatory requirements over and above the EU directives. Moreover, in each country policy-makers had hoped to transpose the EU directives as a "package" law. This was not possible in any of the cases because of delays in Brussels due to differences between the Council, the Commission and the European Parliament, as well as the complexity of legal and procedural hurdles in each country, which made "package" laws impossible.

The devil of regulatory intentions is in the details. These are formulated in existing administrative decrees and ordinances (e.g., in Germany, a total of 14 pre-existing ordinances had to be amended or consolidated); many new implementing decrees were necessary (e.g., in France, 11 decrees) before a transposed directive could begin to be implemented. In all three countries, these were published with considerable delays due in part to the number of "veto points" in the system where stakeholders can agree, disagree, modify, delay or even veto drafts of regulations and decrees, and in part as the result of a cumbersome and non-transparent bureaucratic process. Despite streamlining regulatory functions in agencies, this process has not necessarily become more effective.

United Kingdom. The UK was the first to introduce a separate executive agency, the Medical Device Agency (MDA), which resulted from internal governmental reorganization initiated by the Thatcher government in the UK. MDA was created with statutory authority distinct from that of the pharmaceutical regulator. In 2002, MDA was merged with the Medicines Control Agency (PCA) after having sustained its autonomous status for close to a decade and survived a parliamentary inquiry into a possible merger in 2000, which at that time was rejected.

France. In France, following the HIV-contaminated blood scandal, institutional engineering was the hallmark of the 1980s and 1990s. Of all the agencies created since 1994, the medicinal drug agency *(Agence du Medicament-AdM)* stands out for one important reason: Enormous state powers were delegated to the agency and were substantially expanded in 1999 when the Health Care Product Safety Agency (AFSSAPS) replaced AdM. The agency is said to hand down close to 40,000 decisions on behalf of the state per year. The director of the agency has dual powers: he is director of the agency and a decision-maker in his own right without being subject to *la tutelle.*. AFSSAPS has acquired an ever increasing set of regulatory powers over *all* healthcare products, regardless of how different these may be. Responsibilities of the agency were significantly amplified, ranging from authority to engage in evaluation and clinical investigations, to the power of inspecting manufacturing sites and laboratories. AFSSAPS is assisted in its mission by pooling expertise in eleven scientific commissions who are recruited from academia, research institutes and hospitals.

The evolution of a regulatory agency from a drug agency to a healthcare product safety agency was driven by strong domestic institutionalization forces: beginning with the so-called Huriet-Serusclat law on bioethics and clinical research in 1988, picking up speed with a 1994 law transposing the AIMD and the MDD and a 1996 French law setting in motion a medical vigilance system, and culminating in the law on the reinforcement of health monitoring and health safety controls of July 1, 1998.

As can be seen from Table 3, the regulatory process in France is anchored in the bureaucratic domain of several ministries: the ministry of health, AFSSAPS (since 1999), the ministry of industry, the ministry of finance (post-market surveillance and customs), and the secretariat general of inter-ministerial coordination (SGCI), and involves various public and private vested interests.

Table 3: Stakeholders and evolving networks among organizations and administrative services

The ministry of health (DH) in 1997 and AFSSAPS since 1999

- steers the implementation process
- drafts the *texts* for transposition into national law
- assures the monitoring of the market
- sets up the *materiovigilance*
- participates in formal and informal committees set up by the Commission
- dialogues with the Commission in close collaboration with the secretariat general *du comite interministeriel* (SGCI) for all questions of European economic cooperation (SGCI) responsible for internal coordination and communication across the ministries

The ministry of industry (in 1999 the ministry of the economy, finance and industry)

- secures coherence of the application of all new approach legislation in France
- assigns the notified body—one for all of France (striking contrast to the UK and Germany)-- in consultation with the ministry of health

The ministry of finance (DGCCRF and customs)

- is in charge of monitoring all CE-marked products on the French market and when high risk devices are involved with the ministry of health and now AFSSAPS

The secretariat general of SGCI

- secures the coordination and institutional exchanges to the Commission
- the French notified body is G-MED, a *groupement pour l'evaluation des dispositifs medicaux,* responsible for the CE mark

AFNOR initiates standardization work jointly with CEN

Professional (trade) associations of manufacturers serve as liaison and contact points for public authorities

Health facilities buy and utilize medical devices

- buyer
- physician
- pharmacist
- bio-medical engineer
- nurse

They have a role as "verifier" that the DM carries a CE mark; under French law they are liable if they do not report incidents (a striking contrast to Germany and the UK)

Incidents are reported by

- local safety officers (*correspondant de materiovigilance*)
- they coordinate activities inside health sites
- inform the ministry of health about reported incidents
- professionals as users of medical devices assume responsibility in their domain.

Source: Grisoni and Toussaint, 1997.

Germany. In Germany, responsibility for the conduct of regulatory business now lies with the Federal Institute for Drugs and Medical Devices (BfArM) which has regulatory authority over drugs and medical devices. Regulatory activities carried out by the federal ministry of health were consolidated in BfArM in 1995, and a new organizational unit was

created for medical devices. A distinction is drawn between federal ministries and federal authorities (*Bundesbehoerden*). The federal ministries typically deal with matters of policy and strategy, and prepare legislation and regulations which often require coordination among several ministries, as in France and the UK. BfArM has operational responsibilities and serves as competent authority.

Operational responsibilities are fragmented between BfArM and regional public administrations (accreditation, certification and verification – legal metrology). Following administrative practices in other policy domains, the 16 *Lander* agreed to create two separate regional offices: one for product safety issues attached to the Bavarian government, and the other for all other health safety issues attached to the regional health authority of Northrhine Westfalia (with another regional office in Thuringia serving the five regions in the former German Democratic Republic). These two offices are to coordinate regulatory activities for all regional administrations, as *all* oversight functions are their responsibility in Germany. In large measure, regional implementation follows the old regulatory framework, which existed prior to the AIMD, MDD and IVDD. It involves inter-organizational networks of public and private accreditors, certifiers, licensers and verifiers. Local implementation is an even more complex mix of street-level implementers in companies, health facilities, laboratories, testing houses, hospital laboratories etc. and state-based actors.

State-industry relations

As evidence of state-industry relations, consider the pattern of interest representation and the interaction of business with state officials. Leaving the participation of European trade associations at the European level aside, in all three cases national trade associations have played a dual role in the emerging EU regulatory regime in the last decade: as two-way communication and information channels up and down the European level and as contact points and liaison between national regulators and firms. In state-business relations, trade associations are called upon to balance the competing and diverse interests of large firms (operating globally and regionally) and small firms (mostly operating on a national market). They serve as mediator, facilitator and problem-solver, advisor and consultant to member firms, and are in constant contact with the regulators; they participate in many of the working groups, committees and subcommittees convened by the regulatory agency at the national level.

State-business relations differ across the three cases and producer branches, as does the input of trade associations in the regulatory process (Lane 1995; Schmidt 1996). In the United Kingdom, ABHI includes member firms, legal counsels, consultants and other professionals. ABHI fits a particular style of management and organization and is embedded in a "soft" state-industry tradition that significantly differs from what is described as a "hard" state-industry tradition in France and Germany (Rose 1990), where membership in SNITEM in France and BvMed in Germany is limited to firm members and distributors.

Capture?

Given that medical devices are not normal industrial products, that expertise about highly sophisticated products largely comes from the industry and academic experts, and that breakthrough medical innovations depend on the relations between firms and clinical researchers, one is inclined to see evidence of capture in state-business relations in all three countries. But there is more to it. Govin Permanand, in his study on pharmaceutical regulation (2002), speaks to the mutual dependence of the industry and the government, more specifically the ministry of health. Because the ministry of health lacks expertise and/or resources, it has no choice but to "trust" the industry to produce new and safe products and medicines in what then becomes relationship of mutual dependence. As he argues, this ensures industry—often represented by its trade association—a considerable say in policy. This case is described as a case of "clientele pluralism" (Permanand relying on Lexchin 2001, but he found no single pattern of government-industry relationship in the pharmaceutical sector in the four cases included in his study (UK, Germany, Spain and Italy).

On the surface, it is tempting to treat the situation Permanand describes for the pharmaceutical industry as the same for the medical device industry. However, before settling on this interpretation and suggesting there is capture, we would need to deal with a number of significant differences between the two industries. First, medical devices involve a highly innovative, specialized and differentiated industry; there are a few global and research-intensive companies, but 90% are small and medium-sized companies (many US subsidiaries). Second, decision-making processes on coverage, reimbursement and pricing conditions for medical devices differ from those for prescription drugs; accordingly, the political dynamics are bound to differ from those in the pharmaceutical sector. Third, because of the heterogeneous nature of

medical devices and the concomitant need for different expertise, the circle of participants in state-industry relations differ substantially. Finally, we have no evidence as yet that shows that the influence of political culture, bargaining style, and the nature of the industry—all are expected to shape preferences of the actors and final outcomes—necessarily come into play in the same way as they do in pharmaceuticals, and as established by literature that has strong macro-structural orientation.

As evidence of the interaction of the state and healthcare systems, consider the role of state as regulator and operator of the healthcare system. There is a direct link between the type of healthcare system and the role of the state. If the state is payer and regulator (as is the case in the UK which operates the NHS) and the governmental system is highly centralized (as in the UK and France), it can impose control measures that can be hard to duplicate. For example, Germany has social insurance-based healthcare system with a wide distribution of "veto points" because of a fragmented federal system combined with a corporatist governance structure of sickness funds and physicians. Veto players include organized physicians and sickness funds but also may be regional governments and public administrations. They can block regulatory measures and season the political soupe more easily than the same players can do in the two unitary systems.

Let us take another example from the regulatory cycle, evaluation—that is, the evaluation of the clinical efficacy and added value of a device in new medical and surgical procedures over existing ones. The evaluation of medical devices clearly establishes close links between regulatory functions carried out by the national regulatory agency and the delivery system and patient care. As to the evaluation of medical devices for efficacy in medical treatment, France and Germany (with insurance-based healthcare systems) are using a two-pronged evaluation process, closely following the evaluation process for pharmaceuticals. For example, in France manufacturers must submit documentation and clinical evidence to AFSSAPS for market approval. Evidence must be submitted to the *Commission de l'Evaluation des Dispositifs Medicaux (CEDM)*, which will evaluate the benefit of a new product. A second pricing committee attached to the ministry of health, the *Comite Economique des Produits de Sante (CEPS)*, will fix the final prices for medical devices and pharmaceuticals, with considerable input from the ministry of finance.

In Germany, manufacturers deal with BfArM for market authorizations and traditionally, manufacturers have enjoyed privileges. For example, contrary to French and British rules which

require healthcare providers and others in the delivery system to report, Germany's strong legalistic tradition leads to manufacturers as the only source of information on accidents and adverse incidents. Whether this helps to explain sharp differences in the reporting rate of accidents and adverse incidents involving the use of medical devices in patient care in the UK and France when compared to Germany is an empirical question that requires further study. Linking the state and economic interests to the diversity of the industry, product types and end users and complex technology and competing policy objectives—industrial policy, healthcare policy and public health policy—requires a closer look at the profile of the industry.

The Industry

The European Medical Technology and Medical Devices (MTD) Industry is not as significant in terms of production, turnover, sales and employment potential in Europe compared to the pharmaceutical industry or telecommunications. To the extent that it offers employment opportunities, it is for highly skilled and specialized professionals. Germany employs about 100,000 (31.3% of total European employment in this industry) followed by the UK with about 50,000 (or 14.2%) and France with a total of 35,000 jobs (or 10%) in this industrial sector.

If European public policy outcomes, like domestic policy outcomes, are shaped by the attributes of the policy domain(s) and industrial sector(s) of which they are a part, and by the substantive issues at stake—which much of policy literature assumes—we need to provide a profile of the most important industrial sub-sectors and highlight key features of the industry through empirical data from the leading European and American trade associations, EUCOMED, and AdvaMed, previously HIMA. The US industry is present on the European market (EU and EFTA) as much as it is present in European research facilities and health sites.

During much of the 1990s, the industry—intentionally or unintentionally—kept a low profile when compared to the pharmaceuticals industry until about the late 1990s and early 2000s. Under pressure from national governments and recipient of domestic healthcare reform, the industry through the American (HIMA, now AdvaMed) and European trade associations (EUCOMED having absorbed IAPM) launched a global and European campaign to present a more favorable vision about the industry.[6] The industry started from a weak position in that it

[6] HIMA and EUCOMED Understanding on HTA 1999 (internal document).

was not organized and mobilized either transnationally nor nationally. However, in a short period of time the industry overcame its fragmentation and sectorization, defended several product sectors vis-a-vis a powerful pharmaceutical industry at the EU level, and convinced domestic decision-makers that medical devices make life-saving and life-maintaining contributions. The campaign was carried into each member state, and sectoral trade associations—ABHI, SNITEM and BvMed--were key players who presented their case to the state, payers and parliaments..

According to the latest available figures in 2001, the total value of sales of medical technology in Europe is estimated at 45 billion Euro. Five EU countries—Germany, France, Italy, the UK and Spain—account for 75% of the market, with almost 50% coming from Germany and France. The data on R&D spending below are just as rough aggregate figures, as they are for the remainder. Obviously, R&D spending is affordable only by global companies who dominate the electro-medical global market (such as Hewlett Packart, Toshiba, Siemens, Philips and GE-Thompson). In the implantable sector Boston Scientific and Medronic and several smaller firms stand out. In the in-vitro sector, seven or eight global companies dominate between 70 to 75 percent of the market.

Table 4	**Medical Technologies in billions of Euro**		**Estimated sales of of medical technology**		**R & D Spending in % of Sales**
Country	**Exports**	**Imports**	**% of EU**	**Sales in Euro**	
UK	2	1.6	9%	3.9 bn	N.A.
France	1.8	2.5	17%	7.6 bn	7%
Germany	5.7	3	31%	3.9 bn	9%

Source: Extracted from Eucomed Member Associations, AdvaMed, 2001. Brochure, p.5

European healthcare systems are good laboratories for innovation and medical progress where practically everybody is covered by NHS, NHI or private insurance. Advances in medical technologies and the safe use of technologies require close cooperation between clinical researchers and the industry. Medical devices are primarily used in clinical research, tested in clinical trials and experiments through the clinician as intermediary. This is in some striking contrast to pharmaceutical drugs which are tested in laboratories. Accordingly, the industry claims that it invests heavily in regular user training about which next to nothing is known. Nor is anything known about the interface between investors, clinical investigators and vendors, test sites in hospital sites or other sites funded by medical supplier firms, the conditions under which they operate, or the training opportunities offered and donations. More recently, some

information has become available such as the figures above. Micro-level information is available only on an ad hoc basis.

Payers and the Industry

Excessive regulation of patient care (institutional and personal) under NHI and NHS in each country set parameters for the industry in the post-war period. Cost containment has hung like a sword of Damocles over the industry for the last ten years, and continues to do so. Payers view medical technology as culprit of rising healthcare costs. Advocates of medical technology and high-tech medicine are pitted against payers (public and private and regardless of NHS or NHI) who are difficult to convince that medical devices are not only driving costs up but are also life-saving and contributing to the quality of life of incapacitated individuals on a daily basis. NHS and NHI are the flip side of a regulated health market. The two tables below are used for one purpose only: to illustrate variations in outcomes across the three cases without attempting to explain why these variations exist and what they might mean. They deserve in-depth analysis and explanation.

Table 5 Hospital Spending, Utilization, And Staffing in France, Germany and the United Kingdom, 1999.

	Hospital spending					
	Spending per capita (SPPP)	Percent of total health spending	Acute care hospital bed days per capita (SPPP)	Acute care hospital costs per day (SPPP)	Average length of acute care hospital stay (days)	Acute care hospital staff
France	695	44.0	1.1	632	5.5	1.1
Ger-many	632a	34.0	1.9	333a	10.4	1.5
United Kingdom	-	-	1.0b	-	5.0b	3.7a

a 1998; b 1997.
Source: Extracted and adjusted from Julio Frenck and Octavio Gómez-Dantés. "Globalization and The Challenges to Health Systems." Health Affairs, pp.160-181, here p.176.

Table 6 Medical Technology and Use of High-Technology Medical Procedures in France, Germany and the United Kingdom

	MRIs per million people	CT scanners per million people	Coronary bypass procedures per 100,000 people	Coronary angioplasty procedures per 100,000 people	Patients undergoing dialysis per 100,000 people	Bone marrow transplants per 100,000 people
France	2.5b	9.7c	35b	73b	37.0c	-
Germany	6.2c	17.1c	38f	86b	58.5a	-
United Kingdom	4.5	6.1	41e	35e	27.0	-

a) 1998; b) 1993; c) 1997; d) 1994; e) 1996; f) 1992.

Source: Data extracted and adjusted from Julio Frenck and Octavio Gómez-Dantés. "Globalization and The Challenges to Health Systems." Health Affairs, Volume 21, Number 3, May-June 2002, pp.160-181, here p.178.

Two observation stand out in both tables. The data on Germany mirror the absence of any controls on the distribution of medical technologies until fairly recently (Banta et al. 1994). And Germany is resources-rich.

The *In-Vitro* Diagnostic Industry

The presence of the IVD-industry is strong in France and Germany and much weaker in the UK. Why France and Germany took the leadership in the negotiations in Brussels concerning this industrial subsector is easily glanced from table 8 below. The industry has a profile that is similar to the other industrial sectors. It is concentrated in a few leading global companies (see table 7) with the remaining being small and medium-sized firms. Knowledge from four fields of expertise (biochemistry, microbiology, immunochemistry and hematology) is used in this industrial subsector rather than knowledge in engineering and materials engineering.

Strict regulations are not at issue. What has been at issue are the organization of regulation, its scope and depth, and how much should be left to self-regulation by the industry (Germany and UK), and how much regulation requires the intervention of a strong state which delegates regulatory authority to an agency (France). The high-risk nature of in-vitro diagnostics explains why the final version of the IVD-directive was stringent, and why the CE-mark was seen as a major problem not only by France, Germany and the USA but also by the industry; the CE-mark does not address the issue of safe use, the efficacy of medical devices, or patient safety.

Fearing that member states would develop their own regulations (work was going on in France, Germany and Portugal at the time), the industry asked the European Commission to develop a directive. Some circles hoped that the Commission would draft regulation which would come close to the 510(k) procedure used by the FDA. If the Commission had taken that route, this would have meant stricter regulations. Others were mesmerized by the Commission proposal that treated in-vitro products like other consumer goods.

Without taking into account the then on-going merger at the time of Bio-Rad-Pasteur and Sanofi Diagnostics, the distribution of diagnostic companies on the world market by market shares in 1999 is indicated in Table 7.

Table 7 Global companies by market share

Roche Diagnostics	17 %
Abbott	16 %
Johnson & Johnson	12 %
Bayer Diagnostic	10 %
Date Behring	8 %
Beckman Coulter	8 %
Becton Dickinson	5 %
BioMérieux	3 %
Instrumentation Laboratory	2 %
Other	19 %

Source: *Biologie et Sante. La Lettre de l'Industrie du Diagnostic in Vitro,* October 1999, No.7.

Data on public spending on diagnostic products used in the NHS and NHI are difficult to come by. Data are available for France, where spending on IVD-products as a percentage of total spending by NHI was estimated roughly at 2.7% of total health expenditure in 1997, which constituted 2.2% of the expenditures by CNAMS, the French public health insurance. The highly specialized and high-risk nature of IVD-products is shown in table 8.

Table 8 European market of in-vitro diagnostic products by product groups, and market shares, 1998

	European market	Market shares by country	
Biochemistry	31.90 %	Germany	26%
Microbiology*	23.50 %	France	17%
Immunochemistry	30.70 %	United Kingdom	9%
Hematology/Histology/ Cystology	13.90%		
* of which			
culture	6.9%		
Infectious immunology	16.6%		

Source: EDMA figures distributed by SFRL, the Syndicat de l=Industrie du Diagnostic in Vitro, Paris, August 26, 1999. EDMA Press Release.

As for innovative capabilities, France is reported to rank at the bottom in comparative perspective. The UK is reported ahead with the highest number of publications (8.5% of world-wide publications) followed by Germany (6.3%). The UK occupies a remarkable position in medical research (12% globally) ahead of France and Germany taken together. In physics and chemistry, Germany is clearly leading (8.1%, respectively 8.3%). In engineering sciences the UK passes ahead of Germany and France (5.4%, respectively 3.8%) (Guillaume, ANVAR).

Conclusion

Medical device regulation is a *shared* competence between the Commission and the member states, which retain substantial control not only over product safety issues but also over the delivery of healthcare, including over professional licensing and compensation. Domestic governance structures mediate not only *shared* policy-making between the EU institutions and the member states but they also mediate the entire implementation process from national to local in each country. In each country, the tripartite regulatory structure—regulatory agency, industry and the notified bodies—is fairly similar within a state centric context specific to each country. Except for France, which has one notified body for the whole country subject to the supervision of the regulator, the UK has between 6 and 9 and Germany has over 40 entities, all competing for business and profits.

The co-existence of two sources of dynamics—EU and domestic—in each country makes the decision-making process extremely complex in each case, regardless of the unitary or federal nature of the political-administrative system. Unsurprisingly, decision-making in the federal

system of Germany is considerably fragmented and decentralized. Decision-making involves an array of different organizational actors (public and private) at the macro-, meso- and micro level.

Processes of implementation differ across the three cases. This is not surprising given that each country has specific institutional arrangements within a state-centric setting, and has a different health protection scheme in place which is driven by distinct forces and are not necessarily identical with those forces promoting industrial policy. The three cases also vary in the extent to which they pursue only a few of the five policy elements—safety, quality, performance, efficacy and evaluation.

The participation of several ministries—health, economics, and agriculture, just to mention a few—makes reconciliation among the competing interests of industrial policy, healthcare policy and public health policy exceedingly complex. It also makes it hard to put equitable access to new medical innovations and concern for public health in a hierarchy of priorities ahead of economic interests and public payers (NHS and NHI).

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