

US Perspectives on the EU Medical Device Approval System, and Lessons Learned from the United States

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The literature on the regulation of drugs at the FDA and the European Union is substantial, yet little research has provided comparative analyses and robust empirical data on the regulation of medical devices in the United States and the European Union. As medical and health markets become increasingly globalized, and the U.S. and the EU compete for leadership and recognition, salient domestic regulatory issues are becoming increasingly international and transnational policy issues. Building on Carpenter's (2010) work on drug regulation at the FDA, but taking a slightly narrower yet at the same time a broader approach by drawing on interdisciplinary studies instead of limiting ourselves to only the Political Science literature, this comparison focuses on key aspects of risk regulation and governance of medical devices in the U.S. and the EU, and shows how and why individual and organizational learning is imperative in each case.

Introduction

In a global context, the FDA-based and the EU regulatory frameworks for medical devices are granted legitimacy and validity by the relevant communities – regulatory authorities, industry and academic scientific communities and interest groups – for the evaluation and market approval of medical technologies worldwide. Cross-national research reveals a number of puzzles which serve as important context for the arguments we wish to develop in this discussion. A first puzzle derives from documented evidence that the FDA, rather than leading foreign regulatory authorities, tends to follow the initiatives of other countries such as the United

Kingdom, Sweden and Australia. For example, aided by the information from a patient registry in orthopaedics, the respective regulatory authorities of the aforementioned countries recalled metal-on-metal hip implants, wires and heart stents much earlier than the FDA, before faulty implants were placed in a large number of patients. Even more pronounced, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) prohibited the use of metal-on-metal implants altogether. Utilizing all tools of regulatory science, the regulators paid attention to pre-market requirements and above all post-market surveillance of clinical data in assessing potential harm and risks. Clearly, they made evidence-based decisions before the FDA did. Congressional politics and lobbying pressures as well as existing medical device law may explain the delay.

A second puzzle surrounds why the same countries around the globe, which eagerly and comprehensively copied the FDA's model in drug regulation, as per Daniel Carpenter,¹ did not reproduce the FDA's approach in medical device regulation and, instead, adopted the fundamentals of the EU approach. Japan, Australia, China, and South Korea, as well as countries in South America and Central and Eastern Europe, have borrowed many aspects from the EU legal approach to medical device regulation, including

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1 Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton, NJ: Princeton University Press 2010).

consumer safety and liability law.² In sum, the FDA's approach to medical device regulation, notably through the 510(k) clearance process, seems to be unique. In 2011, the Institute of Medicine (IOM) found that "[O]ther countries that tightly regulate medical devices do not rely solely on substantial equivalence to a predicate for premarket review of medium-risk devices. The Global Harmonization Task Force also does not offer as part of its guidance a predicate-based system for premarket review of medical devices."³ More tellingly, from a cross-national perspective the U.S. med-tech industry has enjoyed a comparative advantage.⁴ Politics and lobbying play out differently in a business-friendly environment than in a more protectionist climate. European businesses have benefited from an integrated European market and a business-friendly climate since the passage of the Single European Act (SEA) of 1987.

Third, why do American manufacturers increasingly turn to the European Union to submit their products for market approval before they submit them to the FDA? According to recent reporting by the news media and statements by AdvaMed (the medical technology industry association in the United States), venture capitalists, who generously invested in American companies in the past, seem to be moving their money away from companies based in the United States and shifting their business to the European Union and lately to Asia. It is said to cost jobs, R&D and clinical trials. Among the reasons for this move identified in congressional hearings are the "uncertainty" and "unpredictability" of regulatory decisions by the FDA, its "arbitrary style of decision-making," the delays, and its uneven practices, including a "lack of predictability, consistency and transparency" of the rules that will be applied in medical device cases. Others doubt the FDA's ability to handle complex technologies in the future. The FDA's decisions and practices not only impact upon manufacturers and scientists but also delay accessibility to innovative devices, thereby restricting patients' and doctors' choices in treatment.⁵

The U.S. FDA and the European Union share a fourth puzzle. Why have both regulators created a double standard in risk assessment and approval processes between drugs and devices? The FDA, the EU and individual Member States apply strict rules, norms, and principles of public health and safety around the authorization and enforcement of controls over drugs, while the pathways to the market for medical devices tend to be elastic and, in the case

of high-risk devices, misguided. This observation holds for the U.S. Medical Devices Amendments Act adopted in 1976 and for the first medical device-specific directives in the EU and subsequent amendments from 1990 to the present. Yet, according to the record, high-risk medical devices pose as many risks to human health and patients as drugs. "Recalls of medical implants – from heart valves and defibrillators to artificial hips – are as common as drug recalls."⁶ And according to a 2011 study, the overall statistics on recalls are fairly similar between the FDA and the EU.⁷ It is intriguing why this double standard has been tolerated for so long, and why it receives serious attention only now.

Finally, despite substantial differences in regulatory policy, law, and regulatory science, institutional developments as well as politics, and independent of the respective approach to regulation in each case, both frameworks have come under critical scrutiny for inadequacy, ineffectiveness, and a serious imbalance in regulatory objectives. Specifically, they have both been charged with facilitating innovation and fast access to the market and profits over securing patient and user safety. It seems that the nature of technology and medical-clinical practice tends to override the traditional salience of political, legal, institutional and motivational factors. While regulatory practices may have been appropriate for the technologies available in earlier periods, obviously they are no longer adequate for the revolutionary advances of today's com-

- 2 Christopher Hodges, *European Regulation of Consumer Product Safety* (Oxford: Oxford University Press 2005); Luke Nottage, "Comparing Product Safety and Liability Law in Minamata to Mad Cows – and Mitsubishi", in Duncan Fairgrieve (ed.), *Product Liability Law in Comparative Perspective* (Cambridge: Cambridge University Press 2005), pp. 334 et seq.
- 3 Institute of Medicine, *Medical Devices and the Public's Health. The FDA 510(k) Clearance Process at 35 Years* (Washington, DC: The National Academies Press 2011a), at pp. 183–184.
- 4 Graham K. Wilson, *Business and Politics. A Comparative Introduction*, 3rd ed. (Chatham, NJ: Chatham House Publishers, Inc. 2002).
- 5 BCG Boston Consulting Group, "EU Medical Device Approval Safety Assessment. A Comparative Analysis of Medical Devices Recalls 2005–2009", January 2011, available on the Internet at: <www.medtecheurope.org.newsletternews/203/89> (last accessed on 29 April 2013); BCG Boston Consulting Group, "Regulation and Access to Innovative Medical Technologies. A comparison of the FDA and EU Approval Processes and their Impact on Patients and Industry", June 2012, available on the Internet at: <www.medtecheurope.org.newsletternews/203/89> (last accessed on 29 April 2013).
- 6 Richard Deyo, "Don't Be Eager to Try the Latest Medical Gadgets", *The Seattle Times*, 5 June 2008, available on the Internet at: <http://seattletimes.newsource.com> (last accessed on 6 August 2008).
- 7 Boston Consulting Group, *supra* note 5.

plex technologies. A comprehensive review of many different sources of evidence form the basis of this account. These are summarized in the following section.

I. Source materials

Methods and data

This contribution builds on four types of source material: congressional hearings⁸ and European parliamentary documents,⁹ secondary literature in various disciplines, including macro and micro-level studies focusing on specific devices, predominantly those used in cardiology and orthopaedics. We draw on articles written by regulatory affairs experts in e-newsletters (Script Regulatory Affairs, the Emergo Group, *AdvaMed* and *MedtechEurope*) and on articles in *The New York Times*, *The New England Journal of Medicine* and the *Journal of the American Medical Association* and other academic journals. Medical experts in diverse fields pertinent to medical devices have written much of the critical documentation on the 510(k) clearance process and pre-market authorization (PMA) in the U.S., and the empirical data on which this discussion draws derive from internal reports, data sets, and statistics collected by the FDA and the IOM.

Legal scholars and political scientists focus on regulatory studies that assess the varieties of preventive governance in world risk society,¹⁰ and typically dif-

ferentiate between a “scientific technocratic” perspective and a “socio-political” (or “social constructivist”/“social-psychological”)¹¹ stance. A substantial empirical literature on the varieties of risk and uncertainty exists that examines regulation and governance across a number of sectors. This literature includes case studies on the drug but not the medical device sectors, and cuts across national, transnational (regional) and international levels.¹² While some scholars differentiate between “democratic” and “normative legitimacy,”¹³ most use a path-dependent approach to analysis, as this contribution does.¹⁴ While democratic legitimacy is well understood in a nation-state context, the constitutive features of normative legitimacy based on consensus and trust among the parties involved rather than solely based on a hierarchy of legal rules are essential for understanding multi-level regulation in the EU. At the EU level the definition for the EU28 and the five non-EU member states that participate in EU market rules (EFTA countries and Turkey) is clear, but at the national level medical devices can be regulated in any one of three ways: under the medicinal, the medical device, or the cosmetic framework. While these variations in law have their origin and development in the historical trajectory of each country,¹⁵ they do not necessarily make for common interpretations across all entities. If the U.S. FDA and the EU Commission intend to further harmonize national regulation and jointly develop global rules, which they have stated that they do, then they must better account for the

- 8 The main congressional research materials used are as follows: The US Senate Health, Education, Labor and Pension Committee, The US Senate Finance Committee, The Senate Special Committee on Aging, The House Energy and Commerce Committee – Subcommittee on Health, and the House Ways and Means Committee in the period of 1994 to 2012.
- 9 European Parliament documents available on the internet at: <www.europarl.europa.eu/portal/en.>
- 10 Edgar Grande and Bernhard Zangl, *Varieties of Preventive Governance in World Risk Society* (Ludwig-Maximilians-Universität München: Geschwister Scholl-Institut für Politikwissenschaft, 2011).
- 11 Ian Bartle, “Risk-based Regulation and Better Regulation in the UK”, presentation held at the 2nd Biennial Conference of the ECPR Standing Group on Regulatory Governance, Utrecht University, 5–7 June 2008.
- 12 David Moss, *When All Else Fails. Government as the Ultimate Risk Manager* (Cambridge, Mass.: Harvard University Press 2002); Daniel Levi-Faur, “Regulation & Regulatory Governance”, 2 *Jerusalem Papers in Regulation & Governance* (February 2010), pp. 1–47; Tim Büthe and Walter Mattli, *The New Global Rulers. The Privatization of Regulation in the World Economy* (Princeton, NJ: Princeton University Press 2011); Daniel Drezner, *All Politics is Global. Explaining International Regulatory Regimes* (Princeton, NJ: Princeton University Press 2007); Mark A. Pollack and Gregory C. Shaffer, *When Government Fails. The International Law and*

Politics of Genetically Modified Foods (Oxford: Oxford University Press 2009), pp. 235 *et seq.*

- 13 Ramses A. Wessel and Jan Wouters, “The Phenomenon of Multi-level Regulation: Interaction between Global, EU and National Regulatory Spheres. Towards A Research Agenda”, in Andreas Follesdal, Ramses A. Wessel and Jan Wouters (eds), *Multilevel Regulation and the EU. The Interplay between Global, European and National Normative Processes* (Leiden and Boston: Martinus Nijhoff Publishers 2008), pp. 9 *et seq.*; Nupur Chowdhury and Ramses A. Wessel, “Conceptualising Multilevel Regulation in the EU: A Legal Translation of Multilevel Governance?” 18(3) *European Law Journal* (2012), pp. 335 *et seq.*
- 14 Sven Steinmo, Katherine Thelen and Frank Longstreth, *Structuring Politics. Historical Institutionalism in Comparative Perspective* (Cambridge: Cambridge University Press 1992); Walter W. Powell and Paul J. DiMaggio, *The New Institutionalism in Organizational Analysis* (Chicago: University of Chicago Press 1991).
- 15 The so-called MEDDEV Guidance Documents are a case in point, they are Commission documents and are agreed upon by the national medical device chiefs meeting as Medical Device Expert Groups (MDEG), a Commission body. Although not legally binding, they express the consensus among the national device chiefs, Commission staff, Eucomed and the Notified Body Expert Group (NBEG) about the interpretation of particular issues, but national courts may interpret MEDDEVs differently.

salience of the dual meaning of legitimacy in EU multi-level regulation and governance.

Carpenter's work on the FDA is the richest source of information on the role and powers of the FDA in drug regulation, and is a useful reference for this research on medical devices.¹⁶ Carpenter, a political scientist, and Angell (2010), a physician and former editor of the *New England Journal of Medicine*, disagree on key points of what matters for preventive governance and risk regulation.¹⁷ Carpenter's objective is to offer a workable theory and narrative about the FDA as regulator of drugs. By contrast, this current effort is interested in what the FDA does or does not do, why it does what it does, and the manner in which it does it. Two key issues are important: first, the FDA-CDRH was assigned the responsibility to protect public health and patients against risks and harm; and second, does the FDA live up to meet these responsibilities? Reputation and power explain the *status quo* and why the FDA has gotten away with its practices favouring a fast track and lax approval process of devices (even high-risk devices such as orthopaedic implants) for so long, but power alone does not explain the FDA's record over a 35-year span.

This article will provide an account of the perspectives it brings to the analysis, namely, interdisciplinary and interpretive, multi-level regulatory governance, and regulatory science. We then put regulation into the broader context of the relevant historical and institutional legacies and identify the respective conditions in which the revisions of medical device regulation are debated, negotiated, bargained as well as adopted. Reforms never start from scratch, they always build on precedence. The aim of the following two sections is to show how the respective historical paths and the institutional and policy legacies shape and impact the perceptions and motivations of the full range of stakeholders. From an ontological and cognitive perspective, paradigmatic assumptions about one's own system are often erroneously projected onto other systems. This can ultimately distort insights and compromise conclusions. After introducing the definitions of medical devices under U.S. and EU law, we address the FDA's various roles and explore the growing criticism of its political and administrative processes. We will also address the rationales underlying the two pathways to market – pre-market authorization (PMA) for high-risk devices in class III and the 510(k) clearance notification procedure. While U.S. perspectives on the EU system are

dispersed throughout the contribution, the main focus of the final section is exclusively on the U.S., and on lessons that can be learned from its experience.

II. The reform of medical device regulation in comparative perspective

1. The FDA and the EU Commission under fire

Facing increasing criticism, the U.S. FDA and the EU Commission have responded with efforts to improve their respective regulatory frameworks for medical devices. The on-going revisions in the United States come 35 years after the U.S. Congress adopted the first legislation on medical devices in 1976.¹⁸ In the European Union, the revisions come 20 years after the *new approach* to product regulation in the integrated market was launched in 1987, which provides the legal and administrative umbrella for the three relevant directives adopted: the Active Implantable Medical Devices Directive (AIMDD) of 1990, the Medical Device Directive (MDD) of 1993, and a draft of the *In Vitro* Diagnostic Directive (IVDD) adopted in 1998. These directives, last amended in 2007, are binding on Member State administrations and private stakeholders after transposition into national law, and on countries that have chosen to follow EU market rules, such as the EFTA countries and Turkey. The *new approach* was replaced by a *new legislative framework* for marketing of products in the EU on 13 August 2008.¹⁹

16 Daniel Carpenter, *supra* note 1; Marcia Angell, "The FDA. This Agency Can Be Dangerous", *New York Review of Books*, 30 September 2011, at pp. 66–68.

17 David DeMortain in his review of Carpenter's 900-page opus magnum applauds him for his "untiring exploitation of archives and publications, great narrative skills, and capacity for elegant theorizing" while also raising critical issues about Carpenter's failure to deal with the FDA's decline of reputation in recent years, the one-sided understanding of conceptual power, and his failure to acknowledge "the variety of ways in which concepts are put in practice across the world and indeed transformed as they diffuse", David DeMortain, "Review of David Carpenter's Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA", *25(2) Governance*(2012), pp. 347 et seq.

18 Jonathan S. Kahan, *Medical Device Development: Regulation and Law* (Needham, MA: Barnett Educational Services 2009); John B. Reiss (ed.), *Bringing Your Medical Device to Market*, 3rd ed. (Washington D.C.: The Food and Drug Law Institute 2013).

19 References to legal texts of the Commission are available on the Internet at: <<http://ec.europa.eu/enterprise/policies/single-market>> (last accessed on 11 May 2013).

Regulation means different things to different stakeholders.²⁰ In its crudest meaning, and following Carpenter's use, regulation consists of "rules that are backed by the power of the FDA, intended to modify behaviour." Beyond a political science perspective that speaks to policymaking and politics, law is a constant companion to regulation, which runs the gamut of "a comprehensive policy cycle in which regulations are designed, assessed and evaluated *ex-ante* and *ex-post*, revised and enforced at all levels of government, and supported by appropriate institutions."²¹ For each phase in the life cycle of medical devices, specific responsibilities and tasks are assigned to distinct stakeholders who, in theory, are accountable for their actions, with the FDA serving as ultimate decision-maker and monitor in the U.S. case, and a variety of transnational governmental and non-governmental actors in the EU. Reality may differ, and so will the interpretations by lawyers or political scientists on either side of the Atlantic.

Risks are product specific or specific to families of devices: In the U.S., these include Class I (low risk), Class II (medium), and Class III (highest risks), or individual high-risk devices (notably implants). This risk classification goes back to the original 1976 leg-

islation and has remained largely unchanged. The European approach has been to classify medical devices in four categories: class I, class IIa and IIb and class III. As technology is becoming ever more complex and diversified, risks are less easily predictable, hence the lines between the risk classes are increasingly blurring, notably with an increasing number of so-called combination products on the market.²² The EU upclassified some implants (knee, shoulder, hip, heart, skin, breast) to class III high risk devices in 2003 and 2005.²³

Increasingly, failures of medical devices are public knowledge.²⁴ In the U.S., patient advocates and some scientific circles insist on a better balance between early market release and profits. They demand that health and patient safety concerns inform this decision, even at the risk of delaying the release of a new medical device that may promise superior therapeutic treatment.²⁵ Any solution in the U.S. and the EU will have to be worked out within embedded legal, administrative and complex institutional legacies. What these legacies and practices are is the subject of the following section.

2. Medical device regulation seen from a perspective of law and political science

Debates about the two systems are routinely framed in fairly narrow terms of law, yet risk regulation and governance require a broader perspective. Risks – actual and perceived – are contingent on context. In his most recent study, David Vogel, a prolific writer on corporate responsibility and transatlantic comparisons, establishes this context for the regulation and governance of food, environmental, and health policy in the U.S. and the EU.²⁶ He highlights the deep cultural, political, and legal differences in how regulators, manufacturers, and scientists on both sides of the Atlantic approach risks and uncertainty. These differences are important and are reflected in risk-based policy-making decisions in the U.S. and Europe. Vogel writes:

"The extent to which scientific knowledge or risk assessments provide sufficient information to enable policy makers to rely on them in making decisions that adequately protect public health, safety, and environmental quality represents a critical

20 Robert Baldwin, Martin Cave and Martin Lodge, *Understanding Regulatory Theory, Strategy and Practice*, 2nd ed. (Oxford: Oxford University Press 2012).

21 Organization for Economic Cooperation and Development, *Recommendation of the Council on Regulatory Policy and Governance* (Paris: OECD 2012), available on the Internet at: <www.oecd.org/documentprint> (last accessed on 5 April 2012).

22 Over 500,000 different medical devices are on the market. Many are combination products which experts divide into three groups: (i) a device that combines devices and drugs (e.g. drug eluting stent where the medical device is key or a prefilled syringe where the drug is key); (ii) medical devices and in-vitro diagnostics (e.g. a specimen testing device where the medical device is primary agent; or a pregnancy test where the IVD plays that role); (iii) different medical devices in which several devices are combined in one implant (e.g. implantation pump).

23 Commission Directive 2005/50/EC on the Reclassification of Hip, Knee and Shoulder Joint Replacements in the Framework of Council Directive 93/42/EEC Concerning Medical Devices, OJ L 210/41; Directive 2003/12/EC on the Reclassification of Breast Implants in the Framework of Directive 93/42/EEC Concerning Medical Devices, OJ L 28/43.

24 Barry Meier regularly informs about the FDA and medical devices in *The New York Times*.

25 Institute of Medicine, *supra* note 3.

26 David Vogel, *The Politics of Precaution. Regulating Health, Safety, and Environment* (Princeton, NJ: Princeton University Press 2012); David Vogel and Johan F. M. Swinnen, *Transatlantic Regulatory Cooperation. The Shifting Roles of the EU, the US and California* (Cheltenham, Mass.: Edward Elgar Publishing 2011); Jonathan Wiener and Michael D. Rogers, "Comparing Precaution in the United States and Europe", 5(4) *European Journal of Risk Research* (2002), pp. 317 et sqq.

difference between recent European and American approaches to risk management”²⁷

Evidence of this cultural divide and underlying value differences between the U.S. and the EU are found in transatlantic comparative analysis. A key issue is the extent to which the origin and the development of institutional contexts give specific meaning to risk perceptions and motivations of actors today and shape policy responses and scientific knowledge. A relative dearth of applied research and empirical data makes a complex task of cross-national comparison even more difficult.²⁸ The two cases are both fine illustrations of how and why regulatory science²⁹ is contested, and why it should not be mistaken for academic science. To recap, the U.S. and the EU cases are both embedded in their own distinct cultural, social and political-institutional contexts and developments.

Regulatory science is not the only venue to apply scientific knowledge and risk assessment to policy-making. Comparative effectiveness research is a complementary practice of risk assessment. For historical and institutional reasons, it is typically conducted by distinct public and/or private organizations outside the narrow confines of regulation but is closely related to national health programs and, more importantly, to clinical treatment and diagnosis. The benefit of new devices to patients is assessed for reasons of safety, cost containment and reimbursement.³⁰ According to Franklin and Budenholzer, in several European countries patient registries are mandated as

a component of the health care system, and registration is required for all implantations of high-risk devices. Other countries use laws on data privacy and professional autonomy to explain the absence of patient registries. In the United States, the Agency for Healthcare Research and Quality (AHRQ),³¹ as well as many U.S. states and non-governmental organizations are conducting effectiveness research. In 2009, the FDA tracked only 14 types of devices, including pacemakers, heart valves and breast implants,³² but not other high-risk implants, such as orthopedic implants. While the U.S. has no nation-wide system of securing registries for high-risk devices,³³ efforts are now under way to promote registry development. A former critical observer, now an FDA-insider, William H. Maisel, testified that the FDA is now involved in 20 registry efforts.³⁴ Experts consider patient registries the only valid databanks for obtaining reliable and comparable clinical data that count as evidence³⁵ and meet the standards of *safety and effectiveness* of high and medium-risk devices in the U.S. and the EU standards of *safety and performance*. Even the FDA now concedes that the absence of registries is a significant weakness of the FDA-based system.

Understanding the historical roots and institutional development in the U.S. and the EU over time is indispensable for any informed discussion of ‘best practice’ and effective operations. We find the frequent claims that argue that the FDA-based system is inherently superior to the EU system striking; there is little robust empirical data to go on, except for as-

27 Vogel, *supra* note 26 at p. 276.

28 Corinna Sorenson and Michael Drummond, “Socioeconomic Value of Orthopedic Devices: Evidence and Methodological Challenges”, 4 *Orthopedic Research and Reviews* (2012), pp. 87 *et seq.*

29 The National Institutes of Health defines regulatory science as: “the development and use of the scientific knowledge, tools, standards, and approaches necessary for the assessment of medical product safety, efficacy, quality, potency and performance, and the role of what is a specialized and interdisciplinary area of biomedical research than can generate new knowledge and tools for assessing experimental therapies, preventive therapies and diagnostics”. Ashley Yeo, “The Regulator’s Chance to Catch Up with Science”, available on the Internet at: <<http://raj.com/productsector/medicaldevices>> (received on 28 May 2012); Food and Drug Administration (FDA), “Regulatory Science in FDA’s Center for Devices and Radiological Health. A Vital Framework for Protecting and Promoting Public Health” (UCM 274162, created on 26 September 2011, modified on 5 October 2011).

30 Gary M. Franklin and Brian R. Budenholzer, “Implementing Evidence-Based Health Policy in Washington State”, 362(18) *N Engl J Med* (2009), pp. 1722 *et seq.*

31 Agency for Healthcare Research and Quality, *Advances in Patient Safety: From Research to Implementation*, available on the Internet at: <www.arhq.gov/legacy/qual/advances/index.html> (last accessed on 5 June 2013).

32 David B. Caruso, “US Has No Good System to Track Medical Implants”, Associated Press, 5 October 2009, available on the Internet at: <<http://phys.org/news173974663.html>> (last accessed on 8 June 2013).

33 Frederic S. Resnic, and Sharon-Lise T. Normand, “Postmarketing Surveillance of Medical Devices – Filling in the Gaps”, 366 (10) *N Engl J Med* (2012), pp. 875 *et seq.*, at p. 876.

34 William Maisel, M.D., M.P.H. Deputy Director for Science, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services, Before the Senate Special Committee on Aging, United States Senate, “A Delicate Balance: FDA and the Reform of the Medical Device Approval Process”, April 13, 2011, pp. 120 *et seq.*, at pp. 134–135.

35 Arjun Sharma, Anthony Blank, Parashar Patel, and Kenneth Stein, “Health Care Policy and Regulatory Implications on Medical Device Innovations: A Cardiac Rhythm Medical Device Industry Perspective”, 36 *J Interv Card Electrophysiol* (2013), pp. 107 *et seq.*, DOI/10.1007/s10840-013-9781-y.

sertions and loud voices. Individuals – regulators, scientists, business and lobbyists as well as healthcare professionals and patients – bring their own perceptions, experiences, and expectations, including a tolerance of risks, to their tasks in each unique historical-institutional context. In regulating medical devices as well as markets and companies, individuals depend on a given legal framework and within this context build on existing rules, norms, and procedures time tested through the respective historical trajectory. One works with what *is* and *has been*, not what *should* be or one *wishes*, as illustrated in the next section.

3. Historical background

The medical device regulatory framework in the U.S. spans more than forty years, ranging from pre-market notification to post-market surveillance and adverse event reporting across an expanding set of complex scientific and regulatory issues – commonly referred to as a “life cycle concept” of medical device regulation. The historical narrative begins with the first authorized legislation in 1938, to the Medical Device Amendments of 1976, which established a medical device structure separate from drugs, to the recent amendments in 1990 and 1997, and again in 2000 and 2007. The amendments in 1990 and 1997 were primarily concerned with clarifying the conditions for pre-market clearance, the submission of clinical studies and data to support applications for market approvals *ex-ante*, and the requirements for adverse event reporting by health facilities *ex-post*. The Medical Device User Fee and Modernization Act of 2002 was a response to the chronic underfunding of the Center for Devices and Radiological Health (CDRH) medical device unit within the FDA. The Act introduced user fees to hire additional staff and speed up review times. User fees were extended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and again extended by the Food and Drug

Administration Safety and Innovation Act of 2012 (FDASIA).³⁶

Unlike the U.S. approach, EU medical device regulation is transnational, overseeing since 1 July 2013, 28 national and highly diverse regulatory systems. It began as an EU-wide stand-alone legal framework separate from the drug framework, but entirely depends on decentralized implementation by Member State authorities and/or public or private organizations and actors. The EU system evolved in three distinct waves from 1987 to the present within the dynamics of several enlargements (in 1995, 2004 and 2007 and 2013), internal institutional restructurings, and evolving relationships between EU institutions and the Member States within a multi-level governance system. Various networks of stakeholders operate across several policy domains and national boundaries. The adoption of the Single European Act (1987) to integrate a regional market within the global economy prompted an overhaul of legislation and regulatory practices and the drafting of close to 300 directives to be adopted by 1993, among them the three directives relevant to medical devices.

The second period, from 1997 to 2002, saw a first review of the ten-year old legal framework by the Medical Device Expert Group (MDEG), composed of national medical device expert officials. The MDEG did not find fault with the legal framework, it pointed to major weaknesses in implementation, uneven interpretation and variations in organizational, oversight and monitoring capabilities of the Competent Authorities (CAs) of the Member States over the so-called Notified Bodies (NBs) or certification bodies. Little was done. Ten years later, the same and new complaints are at the core of the current debates.

A third phase began just one year after the Directive 2007/43/EC amended the original MDD and AIMDD for the first time in 2008. The EU Commission launched a two-year consultation process among all stakeholders which ended with the publication of the current Commission proposals for a “Proposal for a Regulation of the European Parliament and of the Council on medical devices”³⁷ (MDR) and a “Proposal for a Regulation of the European Parliament and of the Council on *in vitro diagnostic* medical devices (IVDR) in September 26, 2012³⁸ the third wave drew to its end. Over 1,300 amendments were on the table, 907 on medical devices and some 400 amendments

36 Kahan, *supra* note 18.

37 Commission Proposal for a Regulation of the European Parliament and of the Council on Medical Devices and Amending Directive 2001/82/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, (COM(2012) 542).

38 Commission Proposal for a Regulation of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, (COM(2012) 541 final).

on *in vitro diagnostic* products.³⁹ The completion of the lawmaking process is expected in June 2014.⁴⁰ Three alternatives for the reform are debated: (i) adopting a pharma-style (centralized and decentralized) procedure as requested by the European Parliament and its influential Committee on the Environment, Public Health and Food Safety (ENVI); (ii) retaining the *status quo* while closing loopholes and considerably strengthening implementation and oversight in the Member States (Commission position and the industry); or, finally, (iii) using common technical specifications (CTs) and specifying new guidelines for some high-risk devices (favored by the European Economic and Social Committee (EESC) and the Parliamentary Committee on the Internal Market and Consumer Protection (IMCO)).⁴¹ While the respective European trade associations support the Commission proposal to a large extent, they do not support the first option.⁴² Instead, they argue, “We strongly believe that it is in Europe’s best interest to have a clear, predictable and effective regulatory system that

- Guarantees the highest level of safety for patients;
- Ensures timely access to the latest innovative technologies;
- Enjoys the trust of its stakeholders;
- Contributes to the sustainability of national healthcare systems;
- Maintains an environment that encourages and keeps innovation and research in Europe.”

The draft MDR and the IVDR introduce a legal novelty to encourage convergence in interpreting EU

rules, hence legal certainty and coordinated regulatory practices and control by the Competent Authorities of the EU Member States, including better oversight and monitoring of the 72 Notified Bodies, and 27 Notified Bodies for *in vitro* diagnostic medical devices, which certify conformity with the essential requirements, i.e. European law. Unlike directives which need transposition by national parliaments, regulations are directly enforceable and stakeholders are accountable under EU law. The European Parliament and the Council share lawmaking powers and will have to agree on the final drafts in 2014. After some transition period, legal convergence is to be achieved by 2017 plus 20 days for medical devices, and 2019 plus 20 days for diagnostic products.⁴³

Summing up the historical developments in the EU until 2012, a centralized pre-market authorization similar to the FDA’s pre-market authorization was not part of the repertoire in the past, nor was the FDA’s so-called 510(k) approval/clearance⁴⁴ ever seriously considered. Creating a centralized European medical device agency never made it beyond the discussion stage due to strong opposition from Member State authorities.⁴⁵ Finally, a single approach to implementation in the Member States was considered not necessary, desirable, or even feasible given the variations in public administration, regulatory practices, and public health traditions across the 28 EU Member States and the five countries which follow EU market rules. This is no longer true in 2013 since ENVI handed down its vote on the MDR and the IVDR.

39 Amanda Maxwell, “Third Way Surfaces in EU Medtech Regulatory Reform Debate”, 17 May 2013, available on the Internet at: <www.rajpharma.com/productsector/medicaldevices/> (downloaded on 21 May 2013).

40 European Parliament Committee on the Environment, Public Health and Food Safety, Rapporteur: Dagmar Roth-Behrendt, MEP (S&D, Germany), *Draft Report on the Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, and Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. COM(2012)0542 – C7-0318/2012 – 2012 /0266(COD)*; Rapporteur: Peter Liese (MEP, EEP, Germany), *Draft Report on the Proposal for a Regulation of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices*, 3 April 2013, available at the Internet at: <www.europarl.europa.eu/sides/getDoc.do?pubRef=2f%2fEP%2f%2fINONSGML%2bCOM-PAAARL%2bPE-506.196%2b01%2bDOC%2bPDF%2bV0%2f%2fEN> (last accessed on 30 April 2013).

41 Under the Lisbon Treaty (2009) new legislation has to be adopted respecting “non-legislative acts”, which can be “delegated acts” or “implementing acts.” These acts need to be defined before EU-level committees of national device chiefs, scientific-academic experts and Commission staff can take up their work.

42 Eucomed Medical Technology, “Position Paper. Towards a Regulation That Guarantees Patient Safety, Ensures Patient Access and Keeps Innovation in Europe. Eucomed’s Response to the Commission’s Proposal for the Revision of the EU Medical Device Directive”, 30 January 2013, available on the Internet at: <<http://eucomed.org/key-themes/medical-devices-directives>> (downloaded on 29 April 2013). On the IVDR, see Jesus Rueda Rodriguez, “Industry’s View on the Future of In Vitro Diagnostic (IVD) Legislation in Europe”, 10 May 2013, available on the Internet at: <<http://medtecheurope.org/newsletternews/218/86>>.

43 Art. 97(1) of the proposed Medical Device Regulation; and Art. 90(2) of the proposed In Vitro Diagnostic Medical Device Regulation, *supra* note 37.

44 510(k) refers to the article in the 1976 legislation.

45 Christopher Hodges, “Do We Need a Medical Devices Agency?”, 12(3) *Medical Law Review* (2004), pp. 268 *et seq*; Emily Jackson, “The Regulation of Medicinal Products and Medical Devices”, in Andrew Grubb, Judith Laing and Jean McHale (eds), *The Principles of Medical Law* (Oxford: Oxford University Press 2011); Giandomenico Majone, “Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform”, 1 *EJRR* (2010), pp. 5 *et seq*. Majone is an advocate of EU agencies American style.

ENVI votes on the draft MDR and IVDR

On September 25, 2013, after several postponements, ENVI voted on a controversial proposal. While it did reject the more radical version proposed by Dagmar Roth-Behrendt (S&D and lawyer), the rapporteur on the MDR who had endorsed a pharma-style centralized pre-market approval system FDA-style, the ENVI voted in favor of greater regulatory oversight. This outcome raises salient points that should be commented upon before the dust has settled, and prior to the final vote in 2014.

European lawmakers love to experiment, and the European Parliament as co-legislator with the Council is keen on challenging the Commission and the Council. ENVI wanted to do both. The vote went beyond the original Commission proposal of September 26, 2012, and includes novel governance elements not even on the table in prior meetings. The end result is a hotly-contested compromise put together in great haste that combines various political, organizational, and procedural rationales. This text was voted on by the plenary of the European Parliament on 22 October, and it still needs to pass a final vote in the Council, if all goes according to schedule. However, until June 2014 when the two Regulations are expected to become law, and before the European Parliament is dissolved and members have to stand for new elections to the EP, lobbyists will have ample opportunities to pressure the Commission, the Member State governments, and other relevant decision-makers to substantially modify the current text to more closely resemble the original more modest Commission proposal, which was supported by the industry in many aspects. One exception to this initial support was the so-called scrutiny procedure (Art. 44), a kind of centralized pre-market authorization system. The industry vehemently rejected this idea and is determined to fight it in the future. In the interim, other stakeholders, for example, insurers (public and private), health care systems, health ac-

tivists and patient advocates, may advocate for more patient safety, safer products as well as clinical evaluations, and trials along the lines of the proposals of the European Society of Cardiology⁴⁶. In addition, other groups not yet heard from may also bring allies in support of stricter controls on high-risk medical devices.⁴⁷

Is this a step in the right direction? Is the voted proposal so unreasonable that it justifies the massive *cris de guerre* that the industry has staged in both the EU and U.S. media? An assessment will be split. As an idea and theory behind risk regulation, it is a move in the right direction given that the regulation of high-risk medical devices in the past has been half-backed in both the EU and the U.S.. Both frameworks relied on equivalence methodology and few clinical trials, and limited or in some cases no evidence drawn from patient outcomes in post-market clinical trials conducted by independent clinicians rather than by the industry. Imagine a recipient of an orthopedic implant (shoulder, knee or hip) or a stent (aorta) who hopes that the device will support her for a lifetime and then discovers that the device has failed and was not tested for clinical effectiveness (medical errors are excluded here) and longevity.

Why the assessment is split has to do with a second element: an unrealistic claim and assessment of the operations necessary to make the reform work from the EU level to the level of clinical care (details discussed below). At the risk of being misread, the compromise mixes different rationales together. The tension between concept and reality becomes apparent when the draft proposal is disaggregated into various dimensions and the normative elements separated from the empirical elements. Normative elements behind a law or procedures typically assume "idealized situations" that exist for enforcement, implementation and performance. The empirical elements point to the mechanisms that are needed to translate the intended goals into tangible results, first, more patient safety and, second, more legitimacy, transparency, and accountability on the part of all parties involved travelling the life cycle of the regulatory process. We must not underestimate how much complexity and ambivalence is at the crossroads of law and procedures with practices in the real world in the 28 Member States.

There is wide agreement that the existing regulatory framework needs improvement. The twenty-

46 Alan G. Fraser, Jean-Claude Daubert, Frans de Werf, Mark Estes 3rd, Sidney C. Smith Jr, Mitchell W. Krucoff, Panos E. Vardas, and Michel Komajda, on behalf of the participants/ "Clinical Evaluation of Cardiovascular Devices: Principles, Problems, and Proposals for European Regulatory Reform. Report of a Policy Conference of the European Society of Cardiology" *European Heart Journal* (2011) 32, 1673 *et seq.*, Doi:10.1093/eurheartj/ehrl71.

47 Deborah Cohen and Matthew Billingsley, "Europeans Are Left to Their Own Devices", 342 *BMJ* (2011);342:d2748doi:10.1136/bmj.d2748), pp. 1 *et seq.*

year old system has relied on manufacturers' claims of the performance (EU law) or the effectiveness (U.S. law) of high-risk medical devices (implants), but with little input from clinical practitioners and academic scientists. Hence it makes a great deal of sense to give more considerations to clinical data, clinical assessments, and make use of clinicians' experience with patient outcomes. It also makes sense to be confident that this experiment eventually might work in the long run – five or ten years down the road achieving the first goal put forward by Eucomed, the European trade association. The decision-making format, advice giving, and governance borrows from the time tested network governance in the EU. Multi-level regulatory network governance has worked reasonably well in the drug sector and the IVD sector where manufacturers have asked for strict rules in the past, so what is so special about medical devices that warrants granting high-risk medical device makers dispensation from stricter controls and requirements for clinical data and evidence? Hardly anything.

The unreasonable part is an idealized vision for governance and operations. First, law and procedures are not self-executing, and the normative goals behind them do not translate automatically into the workable and efficient mechanisms that produced desired outcomes EU-wide and in the health care systems in the 28 Member States. Second, the tremendous demands for policy coordination among numerous players is a deceptively simple regulatory tool and easy for politicians to agree on because it comes at no costs to them. To put the requirement for policy coordination into law is easy, but extremely complex to put into practice in any meaningful way further down the implementation path because hardly any player wants to be coordinated.

The jury is out regarding who will win and who will lose. It is naïve to think that the surprise compromise came from nowhere and was not the subject of behind-the-door discreet and not-so-discreet lobbying and negotiating different alternatives among various stakeholder groups: MEPs and national parliamentarians, social and professional groups across the Member States, and various circles of health bureaucracies and civil society organizations. Communication by social media should not be underestimated either. Changes and fine-tuning are predictable. In the meantime, let's ask: has anybody assessed and thought through the implications of this

compromise for operations and performance in all 28 EU Member States beyond law and procedures on paper?

At the core of concerns are managerial and organizational innovations. This text, if voted into law, would create two new committees – an Assessment Committee for Medical Devices (ADMD) responsible for a case-by-case evaluation of high-risk medical devices, and a Medical Device Advisory Committee (MDAC). MDAC would be composed of experts and representatives of stakeholders, and would streamline all advisory functions on technical, scientific and economics aspects of regulation for the Commission. Members of these committees will need to be recruited and appointed from the scientific-medical communities –academic or otherwise – in Europe and provide the necessary scientific and expert knowledge to the regulatory process. Recruitment, appointment, and certification of special Notified Bodies (SBNs) for high-risk medical devices in large part will involve the European Medicines Agency. The Medical Device Coordination Group (MDCG), originally in the Commission proposal, will be upgraded and its responsibilities expanded. It will have major oversight over Notified Bodies and the new Specialized Notified Bodies (SNBs) which are to assess certain high-risk devices, audit manufacturers of high-risk devices and possibly check on the clinical tests conducted by the device maker. Members of the SNBs with the necessary qualifications would be appointed by EMA. As a competent authority operating EU-wide, MDCG would offer expertise over several areas: vigilance, market surveillance, guidance, harmonized practices and other implementation issues. The less controversial draft report of Peter Liese (EPP and physician), parliamentary rapporteur on the IVDR, intends to strengthen patient safety, institutionalize an ethics committee, and require informed consent prior to any tests for HIV and of DNA. It also requires genetic counseling. These requirements are not unreasonable.

A call for policy coordination is a preferred tool used by politicians to get support for their proposal at no political cost to them, as previously mentioned. To express concern about patient safety and construct mechanisms *de novo* that would enhance patient safety is a must for elected parliamentarians and to congratulate themselves for having called for stricter controls on high-risk medical devices in the MDR and asking for informed consent in the IV-

DR.⁴⁸ It is considerably harder to vote on a solution that balances not only between an agenda for innovation and early patient access to innovative medical devices – the status quo – but that also ensures that clinical assessments of patient outcomes are conducted, and complexity and obstacles reduced instead of added. Does the draft really increase the “socio-political” and “scientific-technocratic” legitimacy, transparency, and accountability of the new social mechanisms without at the same time risking to forego the widely documented advantages of the EU approval system – earlier patient access to innovative devices than in the U.S. by three to five years and considerable innovative capabilities of small and medium-sized firms in Europe?

In any new legislation, a legally inclined reader might look for procedural fairness and whether the new law provides legal certainty.⁴⁹ A social science minded reader has other concerns. Where are the necessary capabilities and resources, and the diverse knowledge and expertise necessary for a highly diverse universe of even high-risk devices to all of a sudden come from? Assessing high-risk devices needs expertise in cardiology, orthopedics and other fields of medicine. Who will finance the functioning of advisory committees? How will the members of the two committees be recruited? How will apparent

conflicts of interest be resolved? Until now, conflicts of interest have been largely overlooked in the EU in both matters of clinical practice as well as in advice giving to the Commission and/or national regulatory authorities. Does the reform improve on the *status quo* and offer added value for patients? Is anybody concerned about feasibility and implementability in all 28 Member States? What do we know about multi-party networks working and EMA-style committees in terms of transparency, accountability, and conflicts of interest issues? Simply filling out forms is insufficient, and it seems naïve to assume that most European physicians meet higher professional standards than their American counterparts in contact with business interests.

Other issues are of interest: Does EMA have a roster of scientific experts in the entire range of medical expertise necessary to address high-risks implantables? As long as politicians and lay persons are confused about drugs and medical devices – and they are – one is less than confident that the outcome of the legislative process will add value for patients. For example, the debate on combination products continues to be conducted mostly as “drug/medical device combinations”, which requires expertise in pharmacology. A significant number of device/drug combinations exist that require diverse expertise in medical devices. Do scientific advisors in pharmaceuticals become experts of high-risk devices overnight? How can the new approach provide better patient safety unless mandatory reporting of adverse events by clinicians and health facilities in the Member States is required? Should vigilance, clinical data collection, and trial data collection in all 28 Member States not also be addressed and improved? Simply reformulating the law on an umbrella framework and leaving the rest to the Member States is inadequate. They do not fall into place themselves.⁵⁰

Finally, that the vote would provoke strong reactions by the European medical technology industry was to be expected.⁵¹ Their arguments, repeated and noted in all forums around the globe that matter for medical device regulation, include reduced innovation, job losses, slow down of business, including delays in bringing innovative devices to patients and going off shore. Are these arguments – seldom backed up with evidence – convincing? Not necessarily.⁵² Depending on context conditions, the structure of the industry, and the ideological position of

48 European Parliament Press release, “Health MEPs Call For Stricter Controls on Medical Devices”, 25 September 2013, available on the Internet at: <http://www.europarl.europa.eu/news/en/news-room/content/20130923IPR20607/html/Health-MEPs-call-for-stricter-controls-on-medical-devices>; European Parliament Committee on the Environment, Public Health and Food Safety, ENVI(2013)0925_1. Draft Agenda, OJ/PE519526v02-00en.rtf PE519.526v02-00.

49 Francois-Regis Babinet and Peter Bogart, “Innovation vs. Safety: The New Proposed Rules for Medical Devices in the European Union”, Update, The Food and Drug Law Institute, January/February 2013, available on the Internet at: www.fdpi.org; Nupur Chowdhury, “Pursuing Legal Certainty in Multilevel Regulation. A Socio-legal Study of Medical Device & Pharmaceutical Regulation in Europe” (doctoral thesis on file at the University of Twente, 2013).

50 House of Commons Science & Technology Committee (STC), “Regulation of Medical Implants in the EU and UK”, 1 November 2012, available on the Internet at: www.publications.parliament.uk/pa/cm/201213/cmselect/cmsctech/163/16393.htm (downloaded on 5 November 2012).

51 Eucomed, “Rushed Deal Leaves Patients and Jobs in Second Place”, Press Release of 25 September 2013, available from: thenewsroom@eucomed.org (received on 25 September 2013).

52 Paul Van de Water, “Excise Tax on Medical Devices Should Not Be Repealed. Industry Lobbyists Distort Tax’s Impact”, Updated 2 October 2013, Center on Budget and Policy Priorities, Washington, DC, available on the Internet at: www.cbpp.org/cms/?fa=view&id=3684 (downloaded on 3 October 2013).

the analyst, stricter rules on device makers in the EU – or a tax on medical devices in the US⁵³ – may show an impact on individual companies, not the industry as a whole.⁵⁴ A stricter rule or a tax is only one factor among many others that impinge upon companies' productivity. Van de Water (p. 5) cites from a study by Pricewaterhouse Coopers (PwC) which identifies the five pillars of medical technology innovation: financial incentives, human and physical resources, a favorable regulatory climate, demanding and price sensitive patients, and a supportive investment community.⁵⁵ The demands for more medical devices by current and future aging populations in developed and developing countries, and the likely endorsement of new technologies by payers of health care when they discover innovative devices as a cost containment tool secure a bright future for the industry.

In conclusion, political expediency to stay within the originally set time frame, the choice of easy regulatory tools for lawmakers, and considerations of what is acceptable to the Member State regulatory authorities for a vote in the Council seem to have guided the voting members of ENVI. How the ideas behind the proposal are to be realized is of secondary interest. This vote shows once again that politicians play by different rules than lay people, scientists, or analysts.

The respective U.S. and EU legacies and institutional developments over time, including the latest debates form the foundations of the respective medical device frameworks.

4. Regulatory policy: culture, law, and institutions

The dominance of law in regulatory policy is a key characteristic of regulatory policy. In the U.S. case, legitimacy and authority are embedded in statutory law, congressional decision-making and reinterpretation by bureaucratic and technocratic decision-makers. A third feature is the presence of an executive-legislative balance of power within a legal system of checks and balances. However, at the end of the day, the drivers of policymaking and law-making are old fashioned politics, horse-trading, and interest group pressures, including aggressive lobbying, which may undermine any previous balance and compromise.

What is a medical device? There is no universally accepted definition, and the U.S. and the EU legal frameworks define medical devices very differently. The impact of this variation in scope of regulation should not be underestimated.⁵⁶ According to the Federal Food, Drug and Cosmetic Act (FFDCA),

“a medical device can be an instrument, apparatus, implant, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, provided it meets one of three conditions of being: Recognized in the official National Formulary, or the US Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purpose”.

The EU defines a medical device as follows:

“medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process, or

53 Barry Meier, “Medical Device Industry Fears Law’s Tax on Sales,” *The New York Times*, 1 October 2013, at p. A14.

54 The formal position of the Medical Device Manufacturers Association (MDMA) is available on the Internet at: <www.medicaldevices.org/issues/Health-Care-Reform,-Device-Tax>; Elizabeth Warren, the consumer advocate, rejects the tax, available on the Internet at: <<http://abcnews.go.com/blogs/politics/2012/09/why-elizabeth-warren-wants-to-repeal-part-of-obamacare/>> and <<http://www.massdevice.com/blogs/massdevice/mass-sen-hopeful-elizabeth-warren-device-tax-fda-and-climate-innovation>>.

55 Pricewaterhouse Coopers (PwC), “Medical Technology Innovation Scorecard: The Race for Global Leadership”, January 2011.

56 Institute of Medicine, *supra* note 3, at pp. 16–17.

- Control of conception.⁵⁷

According to the IVDD, “in vitro diagnostic medical device” means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimen, including blood and tissue donations, derive from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state, or
- Concerning a congenital abnormality, or
- To determine the safety and compatibility with potential recipient, or
- To monitor therapeutic measures.⁵⁸

In addition, significant structural and organizational differences include the approval processes, the role of government or third party certifying organizations (or Notified Bodies) in these processes, and the respective scientific advisory systems, including acceptable scientific tests for safety and effectiveness and adverse event reporting.⁵⁹ The U.S. approach is highly centralized and relies on two procedures: a pre-market authorization for Class III devices and the

so-called 510(k) clearance process, which hinges on a comparison of new medical devices with current satisfactory devices on the market as a basis for safety and effectiveness (the so-called “predicates” and “substantial equivalence”). About 80 % of all devices, and even up to 95 % depending on the source, were approved under the 510(k) procedure and the remaining few through the stricter pre-market authorization process (PMA).

By contrast, the EU framework is exceedingly decentralized and works through multiple levels of decision-making and committees made up of Commission staff and national officials. They work through two-way multilayered mechanisms reaching from the EU to the national and local levels and the reverse. Legitimacy, authority and legislative powers derive from a highly decentralized system and are rooted in two major sources – treaty-based obligations and national sovereignty over health, clinical and R&D issues. A good number of responsibilities are shared between the two governmental levels transcending national boundaries. Conflicts and disagreements are resolved through inter-institutional arrangements and multidimensional layers of EU and national rules, norms and procedures, including diagnosis and treatment under national health programs. The Commission organizes its expertise around scientists/academics, consultants, and the relevant trade associations in Europe. The system rests on compliance standards for medical devices (scientific/medical) and technical specifications (TCs) for *in vitro-diagnostic* medical devices⁶⁰ as the basis for *safety and performance*, and uses third-party certification by Notified Bodies for market approval. In other words, scientific standards are integrated into the regulatory framework.⁶¹ There is a presumption of conformity with EU law, but, as is known,⁶² they are unevenly applied in the Member States, and are no longer consistent with scientific and engineering advances in high-risk devices.

In congressional testimony in February 2011, Dr. Jeffrey Shuren, the current medical device chief of the Center for Devices and Radiological Health (CDRH) within the FDA, underscored other safety differences salient from the U.S. perspective. In a prepared text, he stated: “The European system

- does not require government review before a company may market a device;
- does not require demonstration of device effectiveness – the U.S. standard in law is safety and ef-

57 Grant Castle and Robin Blaney, “European Union Regulation of In Vitro Diagnostic Medical Devices”, in Scott D. Danzis and Ellen Flannery (eds), *In Vitro Diagnostics: The Complete Regulatory Guide* (Washington, D.C.: The Food and Drug Law Institute, 2010), at pp. 231–232.

58 *Ibid.*, at p. 231.

59 Institute of Medicine, *Public Health Effectiveness of the FDA 510(k) Clearance Process. Balancing Patient Safety and Innovation* (Washington, D.C.: The National Academies Press, 2011); Elisabeth Ann Wright and Steven B. Datlof, “Adverse Event Reporting in the EU and the US. Similarities and differences”, 7(3) *Journal of Medical Device Regulation* (2010), pp. 14 *et seq.*

60 Commission Decision on Common Technical Specifications for In Vitro-Diagnostic Medical Devices, OJ L 131/17; Commission Decision Amending Decision 2002/364/EC Common Technical Specifications for In Vitro-Diagnostic Medical Devices, OJ L 318/25; Compendium to Commission Decision 2009/886/EC, OJ L 348/94.

61 This co-regulation instrument was used historically in some EU Member States prior to its incorporation into the legal system of the single market.

62 Nupur Chowdury, “Common Market But Divergent Regulatory Practices: Exploring European Regulation and The Effect on Regulatory Uncertainty in The Marketing Authorization of Medical Products”, *Journal of European Integration* (2012), DOI:10.1080/07036337.2012.711825, available on the Internet at: <www.tandonline.com7loi/geui20> (last accessed on 8 June 2013).

- fectiveness; The EU standard is safety and performance, meaning the device must perform as indicated in the device description by manufacturers;
- allows the manufacturers to “forum-shop” their applications among third party reviewers who are subject to minimal oversight;
 - provides minimal information to the public about the evidence supporting company claims; for example, summaries describing the basis for third-party reviewer decisions to grant a CE mark are not provided to the public;
 - has no centralized authority for tracking safety information related to medical devices and no EU-wide post-market surveillance system; as a result the EU is less likely to detect new safety problems as compared to the United States; and
 - has no centralized database of information about the performance of the various regulatory systems (such as time spent on pre-market review), making it difficult to compare the performance of the EU and the U.S. systems.⁶³

These observations are interesting not for what they say about the EU approach – most is known – but for what they imply: namely the U.S. counterparts to the missing pieces in the EU framework and the relevant capabilities allegedly are in place, work well, and produce FDA-favourable outcomes. However, the record of the FDA, as it has come to light (discussed below) hardly supports this claim. Much of what is implied as FDA best practice is still in a planning stage.⁶⁴ To elevate government supervision – highly contested and certainly not a core political value in the U.S. – to a measure of effectiveness and performance is hardly persuasive. A myriad of intermediary structures (public and private) at the interface of three streams – regulatory, professional-scientific and clinical practice – are apparently stepping in to do what government agencies and the White House cannot, for example, order and run registries and databanks, keep checks on companies and health facilities, report adverse events, and trace medical devices to patients. Control over the medical profession, medical specialities and clinicians, as well as clinical research organizations (CROs) which do the bulk of clinical trials are beyond the reach of government. If private regulation is to fill in for missing or inadequate public regulation, this is a losing proposition. In sum, equating the significant differences between the U.S. and the EU entities with a conclusion of superior per-

formance by the FDA's model does not make for a sound argument. European bashing is no stranger to congressional politics; it conveniently distracts from the FDA's own deficiencies.

There is no doubt that the FDA-based regulatory processes are more transparent regarding procedure, compliance and enforcement data, and availability of information on clinical trial results. This comes with the territory: transparency and openness are *sine qua non* in American society. Comparable processes in EU institutions, including various advisory and consulting committees, and Member States authorities fade by comparison in terms of transparency. However, since risks are product-specific, yet results of clinical studies are sometimes not available for reasons of intellectual property rights and trade secrets, often such information is revealed not as a matter of willing transparency but as a result of court procedures and rulings. Analyzing the “FDA Transparency Initiative” launched by FDA commissioner Dr. Margaret Hamburg in June 2012, Liz Fuller, lawyer and consultant, writes: “There is no indication in any available FDA documentation that any research has been conducted to show how patients, physicians or industry will benefit from this increased transparency. In fact, the report itself states that the task force did not consider the feasibility of implementing the proposals.”⁶⁵

In the future, institutional and organizational differences in conjunction with cultural, political and legal dissimilarities between the FDA and the EU perspectives will endure, but the trend in the last ten

63 Statement of Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services Before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, 17 February 2011, available on the Internet at: <www.fda.gov/NewsEvents/Testimony/ucm243716.htm> (downloaded on 5 April 2013); for more details of U.S. perspectives on the EU system, see “FDA User Fees 2012: How Innovation Helps Patients and Jobs (JS).” Statement by Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health. Food and Drug Administration, Department of Health and Human Services Before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, 18 April 2012, available on the Internet at: <www.fda.gov/NewsEvents/Testimony> (downloaded on 5 April 2013).

64 Center for Devices and Radiological Health. U.S. Food and Drug Administration, “Strengthening Our National System for Medical Device Postmarket Surveillance. Update and Next Steps”, April 2013, available on the Internet at: <www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf> (downloaded on 29 April 2013).

65 Liz Fuller, “Transparency Policies at the US FDA”, 26 October 2012, available on the Internet at: <www.rajpharma.com> (received on 29 October 2012).

years has been for both to agree on converging or harmonizing their respective regulatory systems and policies. Demonstrations of this shared commitment include the UDI process (unique device identifier) designed to improve the traceability of medical devices to patients, international standards and product-specific issues, GMP (good manufacturing practices), audits, aligning the labelling requirements with those of the EU through stand alone symbols on devices, and aligning standards for medium and high-risk devices. The European Parliament, co-legislator with the Council,⁶⁶ is leaving regulatory issues no longer exclusively to the experts, as was the case in earlier periods and as late as 2006 when it deliberated on the Directive 2007/43/EC.⁶⁷ The period of discussing, negotiating and bargaining behind closed doors may be ending. Now that the comparative historical paths of the EU and the US regulatory systems have been explored, the institutional differences laid out, and the variation underlying the two regulatory designs identified, we turn to a review of the record of the FDA and point to empirical gaps in the triangle from political rhetoric to legislative intentions and outcomes.

III. The Federal Drug and Food Administration

1. Protecting Public Health

The FDA is the protector of public health and patient safety in the United States and an active participant

in global harmonization efforts in world markets. Yet domestically, running through the congressional hearings over a twenty-year period are themes and commentaries that are hardly laudatory.⁶⁸ The FDA is criticized for allegedly using imperfect regulatory tools and clearing medical devices for the market without ensuring the safety and effectiveness of products on the market.⁶⁹ Members of the Senate and the House, scientific/professional communities, and businesses are raising their voice and express their discontent, as patient advocates testify in Congress. Criticism ranges from the contention that the FDA imposes too many stringent and arbitrary approval standards, thus creating entry barriers, to long review times, to depriving physicians and patients of life-improving and life-sustaining medical devices and not shielding them from harm and injury.⁷⁰ The FDA is also charged with harming the medical technology innovations of U.S. companies.⁷¹

Several questions arise: first, why has the FDA not used its power and reputation to bring safe and efficacious medical implants and other devices on the market? Second, why has it not allegedly asked “the right questions” about the safety and efficacy of, for example, stents and implants?⁷² And, finally, why has it not carried out the mandate of the Safe Medical Devices Act of 1990, which clarified that the FDA should use its premarket approval authority for high-risk Class III devices, or reclassify them to a lower risk category? For over 35 years the FDA has used “substantial equivalence” as the “gold standard” for

66 On 14 June 2012, the European Parliament voted on a pharmacy-style regulation for medical devices. The report by ENVI submitted on 12 April 2013, by Dagmar Roth-Behrend, rapporteur of ENVI, upheld this recommendation.

67 Steven Bridges, “Medical Devices in the EU Spotlight”, 18 December 2012, available on the Internet at: <<http://www.rajcom.com>> (downloaded on 19 December 2012), pp. 1–2.

68 Congressional hearings, *supra* note 8.

69 William H. Maisel, “Medical-Device Safety and the FDA (correspondence)”, 358 *N Engl J Med* (3 July 2008), pp. 88 *et seq* (downloaded on 24 March 2012); William H. Maisel, “Semper Fidelis – Consumer Protection for Patients with Implanted Medical Devices”, 358(10) *N Engl J Med* (6 March 2008), pp. 985 *et seq* (downloaded on 24 March 2012); Maisel, W.H. and T. Kohno, “Improving the Security and Privacy of Implantable Medical Devices”, 362(13) *N Engl J Med* (2010), pp. 1164 *et seq*; Lawrence S. Makow, “Medical Device Review at the Food and Drug Administration: Lessons from Magnetic Resonance Spectroscopy and Biliary Lithotripsy”, 46 *Stanford Law Review*, pp. 709 *et seq*; David R. Challoner and William W. Vodra, “Medical Devices and Health – Creating a New Regulatory Framework for Moderate Risk-Devices”, 365(11) *N Engl J Med* (2011), pp. 977 *et seq*; Gregory D. Curfman and Rita Redberg, “Medical Devices –

Balancing Regulation and Innovation”, 365(11) *N Engl J Med* (2011), pp. 975 *et seq*.

70 General Accounting Office, *Shortcomings in FDA's Premarket Review, Postmarket Surveillance and Inspections of Device Manufacturing Establishments* (Washington, D.C. GAO-09370T, 2009).

71 Josh Makower, M.D. with support from Medical Device Manufacturers Association (MDMA), National Capital Association (NCA) and multiple State medical industry organizations, “FDA Impact on U.S. Medical Technology Innovation. A Survey of Over 200 Medical Technology Companies”, November 2010, pp. 20 *et seq*, available on the Internet at: <www.medtechEurope.org/newsletters/news/203/86> (downloaded on 29 April 2013).

72 Susan Okie, “Reviving the FDA”, 363(16) *N Engl J Med* (2010), pp. 1492 *et seq* (downloaded on 9 October, 2011); Rebecca Voelker, “FDA Ponders Regulation and Innovation”, 35(15) *JAMA* (2011), pp. 1523 *et seq* (downloaded on 25 March 2012); Diana Zuckerman, “Do Conflicts of Interest Undermine FDA Approval Decisions?”, 16(5) *Regulatory Affairs Journal Devices* (2008), pp. 309 *et seq*; Diana Zuckerman, Paul Brown and Steven E. Nissen, “Medical Device Recalls and the FDA Approval Process”. Reprinted, *Arch Intern Med published online*, 14 February 2011, available on the Internet at: <www.archinternmed.com> (downloaded on 21 April 2011).

assessing effectiveness. It has accepted the industry's claim that device modifications are not changing the safety and effectiveness of devices as long as they are "substantially equivalent" to an old device in use. Congress and the FDA did not consider any changes. In its report in 2011, the Institute of Medicine noted: "After 35 years, the FDA has not completed the task of calling for PMAs (premarket notification) for or reclassifying pre-amendment Class III device types. Until the FDA completes that task, those devices are allowed to enter the market through the 510(k) clearance process"⁷³ – and a solid 80% (even up to 95% depending on the source) of all medical devices went through this process. When the FDA asked the Institute of Medicine to review the 510(k) pre-market approval procedure for class II devices, the issue whether new medical devices bring better benefits to patients than already approved and clinically used medical devices was not part of its brief.

In retrospect, some authors consider the distinction between drugs and medical devices "an artificial distinction" and a "historical and legislative artifact."⁷⁴ All devices after 1976 were classified as Class III (high-risk) devices; but specific exceptions were allowed (FFDCA § 513(f), 21 USC § 360c(f)(1) (2006)), which favoured early commercialization and access to the market. Any medical devices that were considered "substantially equivalent" to a "type of device" defined as a device was classified as class II or class I device. For medical devices submitted to the FDA after 1976 a manufacturer could petition the FDA to classify the device as a Class I and II device provided it could show that the new device was "substantially equivalent" to a pre-amendment device in Class I or class II. The FDA was to be guided by considerations of risk when ruling on a petition only. In reality, according to IOM's report, the FDA faced an enormous task to process "increasing numbers of PMAs or have to go through a reclassification process that was procedurally cumbersome, labour-intensive, and time-consuming."⁷⁵ Instead, the FDA permitted the manufacturer of a post-amendment device to demonstrate "substantial equivalence" to a pre-amendment device in Class I or II as part of the 510(k) submission."

The idea of "substantial equivalence" came from the FDA. Taking a pragmatic and "liberal" interpretation, it cleared most post-amendment devices in one of two ways: (i) as substantially equivalent to a

pre-amendment device or (ii) even to a post-amendment device previously cleared through the 510(k) process ("a process known as piggybacking one device onto a series of precedents"). Fearing a legal challenge of its authority through a court ruling, the FDA sought congressional ratification of its interpretation which it received in 1990. The new congressional text reads as follows:

"A. For purposes of determinations of substantial equivalence... the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same use as the predicate device and that [the FDA] by order has found that the device –

- (i) has the same technological characteristics as the predicate device, or
- (ii) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by [the FDA], that demonstrates that the device is as safe and effective as a legally marketed device and (II) does not raise different questions of safety and efficacy than the predicate device.

B. For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device."⁷⁶

... "Once a device is cleared through the 510(k) process and becomes eligible as a predicate, it cannot be removed from the pool of available predicates unless it has been banned or declared substantially adulterated or misbranded and pulled from the market."⁷⁷

In brief, in this period Congress and the FDA were uninterested in risk-related issues.

⁷³ Institute of Medicine, *supra* note 3, at p. 204.

⁷⁴ Mitchell D. Feldman, Amy J. Petersen, Leah S. Karliner and Jeffrey A. Tice, "Who is Responsible for Evaluating the Safety and Effectiveness of Medical Devices? The Role of Independent Technology Assessment", 23 *Suppl. 1 J Gen Intern Med* 23 (2007) (DOI: 10.1007/s11606-007-0275-4), pp. 57 *et seq.*, at p. 57.

⁷⁵ Institute of Medicine, *supra* note 3, at p. 87.

⁷⁶ *Ibid.*, at p. 3 and p. 87.

⁷⁷ *Ibid.*, at p. 89.

2. Regulatory Environment: Highly Politicized

The FDA is a global trendsetter in drug regulation, and the U.S. is a leader in medical innovation, yet the empirical data reviewed for this essay do not suggest that the FDA is a leader and trendsetter in medical device regulation and enforcement. The FDA is not an autonomous entity, and its leadership depends on who the occupant of the White House is, which majority controls the Congress, and what the Supreme Court and state courts allow the FDA to do.⁷⁸ There are strong supporters of medical device companies on both sides of the aisle in Congress. Moreover, a certain correlation exists between the location of the industry and the electoral districts of senators and members of the House and their voting pattern for industry-friendly amendments. In March 2011, a bipartisan Senate Medical Technology Caucus formed to promote the interests of the medical-device industry. In the 2008 November elections as well as in later elections, U.S. device companies have showered members of Congress with generous cash for electoral campaigns. With few exceptions, Congress and lobbyists from different segments of the med-tech industry alike continue to push for fewer regulation, faster approvals, and the continuation of the FDA's two-pronged approach to the market – through pre-market notification (PMA) and the so-called 510(K) notification procedure. They quietly concede that a few areas need improvement and/or tailor-made regulation depending on device-specific risks. The ongoing debates after the Obama Administration took office in 2008 and within the FDA indicate that the

current leadership under Dr. Margaret Hamburg intends to turn the FDA around.⁷⁹ Broadly drawing on Carpenter's clarification of the various roles of the FDA in the drug sector, this section concentrates on the central powers and gate-keeping functions of the U.S. FDA's CDHR.

3. "Gatekeeper" and Judge

The FDA-CDHR is the principal agent of device regulation, at times an accomplice, and at times an opponent of the industry. The FDA occasionally is also a prisoner of congressional politics and policies that impede its ability to act; but it is also the case that the FDA has power in the medical device field, notably in post-marketing surveillance, which it chose not to use, according to the IOM.⁸⁰ While internationally the FDA throws its weight around among the international community of regulatory authorities, the FDA's domestic activities are solely guided by U.S. statutory and regulatory rules on the book, court rulings, and its own assessment of what science-based evidence means or should mean for U.S. scientists.⁸¹

The authority of the FDA-CDHR over medical devices is formidable.⁸² Medical devices, like drugs, can only be marketed and sold in the United States when the FDA has declared them to be "safe and efficacious" for their primary "intended purposes." This is achieved through one of two established regulatory routes: (i) a pre-market approval (PMA) for high-risk devices in Class III, and (ii) the laxer 510(k) program. The FDA lays down the rules for advertising and labeling and is indirectly instrumental in securing important global market shares and profits for the industry. Like for drugs, the FDA's decisions to reject applications for a PMA and/or 510(k) may mean a death sentence for a business, particularly smaller ones.

The medical-device sector has a few distinct, sector-specific properties that are often overlooked, but which limit the applicability of lessons from studies on the drug sector – for example, risk classification and the 510(k) approval procedure for low and moderate risk devices, including some high and highest risk devices. One might argue that the political dynamics of both sectors are the same in the U.S., yet it does not make sense to treat the FDA as a unitary actor. It has a classic bureaucratic structure with a

78 Russell Korobkin, "Who Should Protect the Public? The Supreme Court and Medical Device Regulation", 357(17) *N Engl J Med* (2007), pp. 1680 *et seq*; Alan M. Garber, "Modernizing Device Regulation", 362(13) *N Engl J Med*. (2010), pp. 1161 *et seq*.

79 Okie, *supra* note 72; Zuckerman, Brown and Nissen, *supra* note 72.

80 David R. Challoner, Chair, Committee on the Public Health Effectiveness of the FDA (510(k) Clearance Process, Letter to Dr. Shuren, Director, CDHR, 20 July 2011; Institute of Medicine, *supra* note 4.

81 This irrespective of what global harmonization might mean in the global context and a definition of "good clinical practice," "clinical evidence" and good "regulatory science" they and FDA have worked and agreed on in the Global Harmonization Task Force (GHTF 2007) between 1992 and 2012.

82 United States International Trade Commission (USITC), *Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets* (Washington, D.C.: USITC Publication 3909, 2007).

strong hierarchy of command and control. Even with the same macro-institutional constellations – public and private law, the historical trajectory as well as the political economy – the political dynamics play out differently – internally for the FDA and CDHR leadership, staff and management as well as the organization, and externally in relation to Congress and lobbyists. What is true for the domestic sector also applies to the international side where the FDA-CDHR is expected to play a different role in the GHTF-IMDRF for medical devices⁸³ than its counterpart responsible for drugs in the ICH.⁸⁴ Personalities and sector-specific networks, or what Carpenter calls “audiences”, crowd the political space; specific rules, norms and procedures apply for each product sector, and responsibilities are assigned to different organizational units within the FDA. Finally, the scientific advisory systems for drugs and devices do not work the same way neither in the U.S.⁸⁵ or in the EU.⁸⁶

4. Legislative-Executive Politics, 1976–2013

Unquestionably, Congress and the FDA have tolerated the *status quo* for over 35 years; both in tandem have erred on the side of the principle of “least burdensome regulation” and faster access to the market to the detriment of public health and patient safety, particularly for high-risk categories. Three constant themes and two variables emerge in the over 35 years’ history.⁸⁷ The two variables are first the changing relations between the FDA and Congress in two distinct time periods: from 1976 to 1990, and from 1990 to the present. The second variable is the changing content of regulatory policy from the original 1976 legislation to more flexibility and the adoption of the principle of “least burdensome regulation” introduced by Congress in 1997 through the Food and Drug Administration and Modernization Act (FDAMA), renewed in 2002, 2007 and 2012.

The first theme is the perennial complaint regarding funding limitations which prevent the FDA from hiring scientific staff and engaging in all tasks necessary to ensure that only safe devices reach the market. The consequences are, in the words of the device chief Dr. Shuren, “high reviewer and manager turnover at CDHR, which is almost double that of the Center for Drugs and our Center for Biologics,

insufficient reviewer training, extremely high ratios of front line supervisors to reviewers, insufficient oversight by managers, rapidly growing work load caused by increase in complexity of the devices and the rapidly increasing overall number of submissions we receive; sometimes unnecessary or inconsistent data requirements imposed on device companies, insufficient guidance for industry and FDA staff and poor quality submission from industry.”⁸⁸ The second theme is the repeated but empty promises by the FDA leadership and device chiefs to Congress that the FDA would restore balance between pre-market considerations and post-market controls, including safety surveillance and vigilance.⁸⁹

A third theme is the periodic attacks against the EU approach to device regulation starting in the early to mid-1990s under the device chief Mr. Bruce Burlington and David Kessler, the Commissioner of the FDA, and again as recently as February 2011 when Dr. Jeffrey Shuren, the current U.S. device chief at the FDA, testified before the House Energy and Commerce Committee’s Subcommittee on Health and pointed to the stronger regulatory standards in the U.S. Are the allegedly stricter U.S. standards resulting in safer devices? In response, Representative Joe Pitts said: “But, according to recent studies, medical devices [...] are statistically as safe as FDA-cleared or approved devices and have comparable outcomes.” Confirming the delays and practices of the FDA, AdvaMed argues “with no discernible benefit in patient safety or out-

83 The GHTF was a joint regulator-industry forum from 1992 to March 2012 when it was replaced by a regulatory-only forum, the International Medical Device Regulators Forum (IMDRF).

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

85 FDA Advisory Committees, available on the Internet at: <[www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Medical Devices](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Medical%20Devices/)> (last accessed on 14 April 2013).

86 In Europe, scientific input to drug regulation is channelled to the European Medicinal Agency, while numerous EU-level expert committees and three scientific committees on emerging and newly identified health risks (SCENIHR), on consumer safety (SCCs) and health and environmental risks (SCHER) are directly reporting to the Commission. Commission Decision Setting Up an Advisory Structure of Scientific Committees and Experts in the Field of Consumer Safety, Public Health and the Environment and Repealing Decision 2004/210/EC, OJ 2008 L 241/21.

87 Congressional hearings, *supra* note 8.

88 Dr. Shuren’s spoken words, 2011.

89 Daniel Schultz, Director, CDHR, “PMS Transformation. Connecting the Dots”, presentation held at the GHTF 2006 Conference, Lübeck, 28–30 June 2006.

come.”⁹⁰ Maureen Kenny, the chief editor of *Script Regulatory Affairs*, the leading journal in this sector worldwide, wrote on 28 May 2012: “U.S. regulators have again chosen to defend their system of medical device regulation by denigrating the system in the EU.”

This extensive review of recent literature on the FDA hardly suggests that the FDA's record is superior to that of EU regulation. The authors of the most systematic attempt to compare the EU and U.S. approaches to date deplore the lack of reliable, credible, and comparable data.⁹¹ According to them, review times and recalls – widely used measures in both systems – are inappropriate indicators for assessing performance. They write: “Yet it still remains unclear whether the U.S. or the EU approach achieves better outcomes for patients receiving devices. This assessment is further complicated by the multiple stakeholders – including patients, payers, physicians, and manufactures – whose perspectives on system performance vary by virtue of how they weigh the importance of outcomes such as cost, speed, safety and effectiveness.” On the other hand, Eudamed, the EU databank for medical device information, is a pitiable source of relevant information, but it is the only EU-wide one. Summing up, the FDA has made substantial efforts to rebalance its priorities, closely monitoring compliance and enforcement, including devoting more staff time and resources to post-market surveillance and rewriting guidance documents.⁹² The cur-

rent level of criticism is forcing both the FDA-CDHR leadership to face up to the charges, and Congress to act.

5. The Institute of Medicine

In 2009, the FDA asked IOM to review the adequacy of the 510(k) clearance process without asking, however, a key question of the benefits of new medical devices compared to those in clinical use. Following two workshops, wide consultations, and internal debates,⁹³ the IOM scientists and experts concluded that it would be preferable to design a medical device regulatory framework more in line with the requirements of modern science, medicine and technology rather than keep an outdated 510(k) procedure. As a result, “the recommendations are focused not on making improvements in the 510(k) process but rather on steps needed to develop a more rational medical device regulatory framework.”⁹⁴ Experts argued that “it would be short-sighted to forgo a thorough vetting on the strengths and weaknesses of IOM recommendations because the primary conclusion – that the 510(k) clearance process should be scrapped – seems too extreme to be realistically considered.”⁹⁵ “Instead, the report should be carefully considered in the greater context of the ongoing reform process and dialogue between the FDA, industry, and the public to continue bringing improvements to the 510(k) programme.”⁹⁶ Some recommendations were considered “bold, yet vague,” and had “merits and pitfalls.”

Tellingly, in a highly unusual, but orchestrated and tactical move in advance of the publication of the final report, AdvaMed, the trade group that speaks for the U.S. med-tech industry and majority of device companies, released a press release (dated 29 July 2011) which attacked the IOM's recommendations.

“The report's conclusions do not deserve serious consideration from the Congress or the Administration. It proposes abandoning efforts to address the serious problems with the administration of the current program by replacing it at some unknown date with an untried, unproven and unspecified new legal structure. This would be a disservice to patients and the public health. ...Numerous academic studies have shown that the 510(k) process is overwhelmingly safe.”⁹⁷

90 Vibha Sharma, “US Medical Device User Fee Programme Edges Closer to Implementation”, 19 March 2012, available on the Internet at: <www.rajpharma.com> (received on 21 March 2012).

91 Daniel B. Kramer, Shuai Xu and Aaron S. Kesselheim, “Regulation of Medical Devices in the United States and European Union”, 366 *N Engl J Med* (2012), pp. 848 *et seq.*, at p. 8.

92 Jennifer D. Newberger, “New Guidance from the US FDA May Mean Just One Thing for Medical Device Manufacturers – More 510(k)”, 1 August 2011, available on the Internet at: <www.rajpharma.com> (received on 1 August 2011).

93 Institute of Medicine, *supra* note 4 and note 50; Institute of Medicine, *Public Health Effectiveness of the FDA 510(k) Clearance Process. Balancing Patient Safety and Innovation. Workshop Report*, Theresa Wizemann (ed.), (Washington, D.C.: The National Academies Press, 2010).

94 Challoner, *supra* note 80, at p. 2.

95 Meaghan Bailey and Jack Kent, “The IOM Report on the 510(k) Clearance Process in the US: A Starting Point for Debate”, available on the Internet at: <www.rajpharma.com/productsector/medicaldevices/> (received on 13 September 2011), at p. 1.

96 Bailey and Kent, *supra* note 95, at p. 1.

97 AdvaMed, “Statement on IOM Report 510(k)”, Press Release, 29 July 2011, available on the Internet at: <www.advamed.org.com>.

Most studies referred to above were commissioned by the industry. In response to the IOM report, the CDRH proposed several recommendations for improving the 510(k) process and extending post-market surveillance capabilities. The IOM committee argued that the CDHR had sufficient authority concerning post-market surveillance, but simply chose not to use it. "The FDA has not adequately explained the limitations of the tools and why it has not used them more widely. ... The IOM committee supports the concept of allowing conditional clearance based on post-market surveillance in appropriate cases and has suggested this option as a potential component of a modified *de novo* process."⁹⁸ This controversy between the IOM, the FDA, scientists,⁹⁹ and lobbyists,¹⁰⁰ and subsequent controversial debates, brought to light the dominant concerns, namely power politics. A lack of resources seemed to overshadow the FDA's interaction and negotiations with Congress and the industry while it sought to simultaneously ensure the safety of medical devices.

Prior to the report's publication, and in response to growing domestic criticism of the declining performance over the previous decade, the FDA reviewed what changes might be necessary, feasible, and not too controversial.¹⁰¹ In August 2010, it came out with 50 recommendations addressing medical devices in all three risk classes (I, II, and III). Twenty-five were chosen for immediate action, while the remaining more controversial elements required awaiting the final report by the IOM.¹⁰² In early January 2011, the FDA announced that it planned to tackle three reform elements immediately

- (i) Streamlining the Class III *de novo* classification process (in other words, addressing new high-risk devices submissions for market authorization),
- (ii) Clarifying the conditions under which 510(k) applicants must submit clinical data in order to make their review processes more efficient; and
- (iii) Forming a Center Science Council made up of senior FDA experts to develop business processes and standard operating procedures.¹⁰³

One year later, developments are moving on.¹⁰⁴ The FDA appeared willing to pay equal attention to pre-market and post-market activities in exchange for a deal with Congress: trading faster reviews for increased funding by Congress through the user fee program paid by the industry. The negotiations be-

tween the FDA and the industry were tough and controversial, yet the FDA's political strategy and tactics paid off.

6. User fees

The user fee program, which was up for renewal on 30 September 2012, for 2012–2017, was first established for a five-year period with the enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). It was reauthorized for another five years (2008–2012) under MDUFMA – the Food and Drug Administration Act of 2007. The bi-partisan votes in both houses, and the minimal debate that accompanied them, are rare and exceptional demonstrations of bi-partisanship in an otherwise dysfunctional Congress. But this Congress is also interested in job creation and maintaining the industry's international competitiveness. The amendment acknowledges the spectrum of past criticisms, ranging from the fast track 510(k) procedure, to stricter requirements for clinical studies, conflicts of interest issues, and better post-market surveillance. Accordingly, the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) would:

98 Challoner, *supra* note 80, at p. 2.

99 The two workshops were convened by the IOM and had a wide participation of academics representing a cross-section of expertise and knowledge, staff of the FDA and industry representatives. They provided information and presented commissioned papers. The final recommendations were approved by the 12-member Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process. In addition, fourteen reviewers and experts reviewed the final recommendations supervised by two experts (one from industry and one academic) appointed by the National Research Council.

100 These are The Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association (MDMA) and the Medical Imaging Technology Association (MITA).

101 FDA, "Understanding Barriers to Medical Device Quality", 31 October 2011, available on the Internet at: <www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM277323.pdf>

102 Statement by Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health, FDA, Department of Health and Human Services, Before the Subcommittee on Health of the Committee on Energy and Commerce, U.S. House of Representatives, 18 April, 2012. This hearing produced extensive comments on specific reforms.

103 Stewart Eisenhart, "FDA Unveils Elements of 510(k) Overhaul. Postpones Hot-button Issues", available from StewartEisenhart@Emergo.Group.com (received on 1 January 2011).

104 For an update of FDA's efforts, see William Maisel, *supra* note 34.

- “Allow the FDA more easily up-classify problematic devices so that subsequent, similar devices receive more scrutiny;
- Establish a timeframe for the FDA to finalize and implement regulations on unique device identification [to trace medical devices to patients];
- Add medical devices to the Sentinel initiative that was created five years ago as a mechanism to enhance post-market oversights of drugs;
- Codify the requirement that approval for high-risk devices is contingent on completing required post-market studies;
- Create a time line for so-called “522 post-market studies” for devices cleared by the fast track process; and
- Require the FDA to do more outreach to involve “non-conflicted” experts and groups in its recruitment efforts for medical device advisory committees.”¹⁰⁵

The current user fee program (2012–2017) covers about 20 % of the costs for reviewing medical devices in comparison to 60 % for reviewing drugs and would provide new revenues (\$595 million) as compared to the current (\$287 million) allowing for the hiring of 240 fulltime review process employees, including 140 reviewers specifically for devices over five years.¹⁰⁶ Most observers, both in and outside of Congress, consider a user fee program to be perfectly legitimate and effective; a minority is deeply concerned that user fees grant business undue influence over regulation.

Congress and lobbyists, representing diverse segments of the med-tech industry, continue to argue in

favour of fewer and softer regulations, faster approvals, and the continuation of FDA's two-pronged approach to the market – through pre-market notification (PMA) and the so-called 510(k) notification procedure. Privately, some circles do concede that a few areas need improvement and/or tailor-made regulation because of device-specific risks. Currently, a bi-partisan bill in the Senate, the Medical Device Regulatory Improvement Act (S1700), seeks to modernize the FDA's review process. AdvaMed is “especially encouraged to see the legislation's focus on clarifying FDA data requirements, streamlining agency management processes and its emphasis on the importance of attracting the best experts to FDA advisory committees.”¹⁰⁷ In addition, a legislative package of ten bills was introduced in the House that sought to “fix the FDA's medical device regulation.”¹⁰⁸ The on-going debates in Congress and inside the FDA since 2010 all indicate that they want the FDA to better serve in its role as protector of public health while upholding the principle of “least burdensome regulation.” While a few years ago the package of proposed changes would have been unthinkable, change is coming but it will be slow. Some regulatory issues require statutory action by Congress, others regulatory action by the FDA, and some problems require reducing discretionary decision-making in reviews by FDA staff.¹⁰⁹ Serious challenges are still ahead.

Concluding comments

This narrative pieced together the mosaic of device regulation from diverse source materials and interdisciplinary readings which enabled us to develop the main arguments about both the FDA and EU approach to medical device legislation and conclude that substantial legal and institutional differences should not be confused with superior performance of one system over the other. While we did not aspire to resolve the puzzles mentioned at the outset within the space of this contribution, we offered a number of striking observations on the EU approach from an U.S. perspective, and lessons learned from the U.S. experience of regulating medical devices since 1976. We also explored why and how the idea of an equivalence-based system emerged, where it came from, and who benefited from it. The essay offered insights into legislative-executive politics un-

105 Donna Young, “US Senate Adopts FDA User Fee Bill in Rare Bipartisan Move”, 25 May 2012, available on the internet at: <<http://www.rajpharma.com>> (received on 28 May 2012).

106 Representative Joe Pitts held a Hearing on Reauthorization Medical Device User Fee Act, 15 February 2012.

107 Vibha Sharma, “US FDA Consults on Creating External Expert Network for Emerging Medical Devices”, available on the Internet at: <www.rajpharma.com> (received on 5 May 2011).

108 Vibha Sharma, “New Bills in US House, Senate Aim to Streamline FDA Device Reviews”, available on the Internet at: <www.rajpharma.com> (received on 20 October 2011).

109 Comments by Public Citizen's Health Research Group on FDA 510(k) Medical Devices Working Group Preliminary Report and Recommendations authored by Jonas Zajac Hines, Peter Lurie, Eunice Yu, Sidney Wolfe, “Left to Their Own Devices: Breakdowns in the United States Medical Device Premarket Review”, 7/7 *PloS Medicine* (2010), available on the Internet at: <www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000280> (last accessed on 8 June 2013).

der a system of a balance of power within a legal system of checks and balances and critical debates in the U.S., and why patient advocacy groups, the American public, various scientific communities, including the IOM, are insisting that the FDA do a better job at protecting the public's health.

The FDA's status was described as that of a czar of medical device regulation in the U.S., but that domestic label does not make it a world leader, although the political discourse and the political culture in the U.S. and admiration mixed with apprehension from abroad reinforce such perception and assessment. In the future, the U.S. and the EU will continue to compete with each other for prominence, but the enormous legal and institutional differences will endure. Most observers recognize that the leverage that can be gained through testing drugs or medical devices for safety in pre-clinical and post-clinical trials should be enhanced. Neither the FDA-based regulatory pathway nor the pharma-style regulation of high-risk devices requested by the European Parliament and ENVI alone will secure that patients' and physicians' interests will be better served than in the past. It takes a great deal more vision to develop the right solutions and find common grounds to the satisfaction of each party and the respective publics than the well-known policy-making styles and traditional politics on each side have been able to achieve. One fact remains: what is doable in the U.S. is not necessarily doable in the European Union and vice-versa.

Why American and European lawmakers have tolerated a double standard for drugs and devices, more rigor and strict rules for drug approvals but less rigor and laxer rules for high-risk medical devices, is more difficult to explain. It could be that both were more interested in an innovation and growth agenda than in patient safety, but this can hardly be the entire explanation. Whatever other causes might explain such neglect, there are certainly causes unique to each case. A kind of "Washington consensus" supported the 510(k) clearance process, invented by the FDA and approved by Congress, and encouraged manufacturers to rely on equivalence data rather than on evidence from clinical trials. The announcement by President Obama and the leaders of the EU of 13 February 2013 that they would launch negotiations on a Transatlantic Trade and Investment Partnership soon, and also contribute to the development of global rules has raised hopes among the U.S. and

European industry for further cooperation and harmonization, despite similar initiatives in the 1990s petering out with little success.

Learning and communicating more about the underlying differences in the origin and development of policy and institutional legacies and their underlying rationale, including the relevant norms and the interpretation and application of the precautionary principle, would greatly pay off in finding common ground between the U.S. and EU approaches. But it takes some patience to understand how the legal differences in risk assessment can be reconciled to the satisfaction of each party. The leaders in global medical device regulation have a responsibility to leverage the momentum of the reforms toward more patient safety and leveling the playing field among competing regulatory objectives.

An abundance of bills before Congress, the upheaval over the medical device tax of 2.3% introduced as part of the Affordable Care Act of March 2010, and the current political climate in a dysfunctional Congress, discourage any speculation of how political pressures will bear on the final reforms. Neither is it possible to foretell how the record of the FDA-led reforms will end. For every argument in defence of the FDA's handling of medical devices, scholarship and empirical data suggest counterarguments. The moving parts on the EU side are no less complex and the level of complexity has increased since the vote by ENVI and later IMCO. How the law-making process between the European Parliament, the Council and the Commission will end in 2014, and which of the three options they will adopt, is anyone's guess. Certain developments are certain: the tools for implementation in the Member States will be strengthened, transnational public and private multilevel regulation in Europe will endure, as will institutional complexity of law – and policy-making and inter-institutional tensions and rivalries. Despite complicated structures, the EU has had success in bringing new innovative medical devices to physicians and patients earlier than the FDA has to American patients. It also has been successful in exporting its regulatory model or some of its elements to other countries around the world. Still, all in the EU medical device community recognize the urgency of the on-going reforms, which will be a combination of compromises by different stakeholders. The end result should be a substantially enhanced but possibly also a more complex regulatory framework.