The First Malcolm Carlisle Lecture

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"Device Regulation and Liability – Taking Things Beyond Criticism"

Professor Christopher Hodges[1]

It is such a pleasure and honour to be asked to give this lecture in recognition of Malcolm Carlisle, and to celebrate his outstanding achievements in the medical device industry. I am asked to emulate Malcolm's gifts to be insightful and provocative. But I start with an apology. Those of you who knew Malcolm will be well aware of his mischievous sense of fun, so you will relieved to know that I propose to resist the temptation to tell the Duck Joke, or the Polar Bear Joke, or any other kind of joke – much as I would like to. However, I am proud to wear Malcolm's Duck Tie as a symbolic reminder not to take ourselves too seriously.

I was privileged to know Malcolm as friend and colleague for over 30 years. Throughout that time, we worked passionately for fair, effective, balanced and sensible regulation and liability systems. In this lecture, I want to set out a summary of where we have reached in achieving those goals, and how to take things forward. Attempting to state an overview of these issues is only possible because one is able to review what has already been built, namely a pan-European system of regulation for medical devices and the emergence of a new European system for dispute resolution. In both of these areas—regulatory and liability systems—Malcolm's contribution was of very great significance. He played a leading role in EUCOMED's advocacy of the need for pan-EU regulation of devices, from a major conference in the 1980s, which led to agreement on the need for a legislative package (which helpfully coincided with the materialisation of the EU's 'New Approach' model for regulation of products), and he was intimately involved with negotiating the content of the Medical Devices Directive 93/42, and in guiding its implementation and development over the succeeding twenty years. His experience as General Counsel of a major manufacturer, Smiths Industries Medical Systems, perhaps unusually but also fortuitously with responsibility for oversight of regulatory

[1] Head of the CMS/Swiss Re Research Programme on Civil Justice Systems, Centre for Socio-Legal Studies, University of Oxford; Erasmus Professor of the Fundamentals of Private Law, Erasmus University, Rotterdam; Life Member, Wolfson College, Oxford; Solicitor of the Senior Courts of England and Wales.

affairs, and his long service as EUCOMED's Board member responsible for regulation, and similar work at member state level with ABHI, to say nothing of subsequently running Eschmann, gave him unique practical understanding of regulatory affairs, as well as experience of liability and insurance issues, both across Europe but also worldwide, and especially in the United States. His experience of liability issues formed the basis from 2005 of close involvement, ultimately as CEO of European Justice Forum, in lobbying for a balanced European system of dispute resolution, based on sound empirical evidence, obtained from independent research and fresh, objective thinking.

So, we now have a European regulatory system, and well-established liability systems, both of which are undergoing review. We are, therefore, in a position to take stock, but also to see how all the parts might fit together. In this lecture I propose to review where we have got to, note where the problems are, and identify ways forward. I will start by looking at the state of development of European regulatory systems, and then public enforcement and legal liability systems, and identify the major problems that need to be addressed. I will conclude by drawing the areas together and suggesting a way forward aimed at "Taking Things Beyond Criticism".

A. The Regulatory System

Regulatory theory[2] identifies two basic regulatory techniques for product safety:

- *Ex ante* controls: design, testing, manufacture, supply chain, marketing and user information
- *Ex post* controls: post-marketing surveillance (PMSD), collection and review of data; information, recall and revision systems

These techniques are in practice combined into a simple operational concept, the Quality System.[3] Manufacturers have used quality systems for many decades. A quality system provides an operational framework within which the *ex ante* and *ex post* control systems can be undertaken in a systematic, predictable and auditable manner.

All these techniques are crucial elements of EU regulatory systems. They can be illustrated by looking at the nature and historical development of regulatory systems enshrined in EU law for a series of product types. Regretfully putting on one side the interesting features of chemicals,

[2] C Hodges, *European Regulation of Consumer Product Safety* (Oxford University Press, 2005).
[3] ISO 9000 series; for medical devices EN 46000 series.

biocides, tobacco and cosmetics, I will just summarise the systems for medicines, engineered products and general consumer products:

- **Medicinal products**:[4] This regulatory system was the first to be introduced, from the mid-1960s, although crystallizing an approach that had been developed from at least the 1930s in America.[5] Since the concept of 'design' is less applicable to pharmaceutical compounds, the *ex ante* function consists of undertaking toxicology tests and clinical trials whose results are then critically evaluated by experts in both firms and public agencies, in order to determine the acceptability of the risk-benefit balance of a product and to define the safety information that needs to accompany it. But since at the licensing stage experience of the compound will be limited (to perhaps 3,000 human subjects), use of the product will be monitored throughout its commercial lifetime, feeding back adverse reaction data to aggregated pools that are constantly monitored by company and public experts, who revise the risk-benefit and safety information. It is commonplace for product information to be amended in the light of new information, and some products have to be withdrawn. But all of these steps are based on collecting accurate and adequate data, and its consideration within a consistent organizational framework.

- **The EU New Approach (1985) – New Legislative Framework (2008)**.[6] The same basic quality system approach as that for medicines was taken for all engineered products—machinery, toys, boats, weighing machines, pressure vessels, and so on—and, of course, medical devices. There are two main architectural differences from medicines. Firstly, authority to approve the marketing of a product is taken by its manufacturer, rather than by a public authority. This is justified by the twin considerations of the inherent (limited) level of risk of such products (it is in fact medicines that are exceptional in requiring state approval; the paradigm for every other type of product is that responsibility rests with the manufacturer). There is also the pragmatic consideration that the sheer number of products could not feasibly be reviewed by public authorities, at least not without huge cost, delay, chilling of innovation and access to innovative treatments. Secondly, in order to account for a considerable variation in the risk level between

[4] C Hodges, 'The Regulation of Medicines and Medical Devices' in A Grubb, J Laing, J McHale and I Kennedy (eds), *Principles of Medical Law* (Oxford University Press, 3ed, 2011).
[5] DE Carpenter, *Reputation and Power. Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton University Press, 2010).
[6] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93; Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC; Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

different types of devices, a classification system is used, which subjects different classes to greater or lesser levels of control. An audit-like assessment is required for higher classes, involving assessment by notified bodies. The post-marketing compilation of adverse event reports is, of course, efficiently undertaken as a system coordinated by public authorities. I will not go into the details of the 2008 extensions to the New Legislative Framework, or the 2007 extensions to the MDD and the currently proposed MDD revision, since they will be familiar to most in this audience. The MDR proposal introduces much tougher requirements for notified bodies, for post-marketing surveillance and vigilance, and will greatly improve transparency and provision of clinical evidence.

- **General Consumer Products**: The GPS regime (1992, revised 2001)[7] covers low risk products so imposes limited *ex ante* controls, but still relies on *ex post* vigilance monitoring. It is interesting that improving the post-marketing system is where a great deal of recent attention has focused. A 2011 report identified a number of issues that need to be improved in the current market surveillance system and to enable it to deliver "more rapidly, efficiently and consistently throughout the EU and which is also flexible enough to adapt to the challenges of globalisation".[8] The review of the current framework adopted by Member States (MSs) to deliver market surveillance and previously published review material found clear indications that the present system is no longer "fit for purpose". Particular issues highlighted are the following (and these should sound familiar):

  - Lack of resources clearly affects the impact of market surveillance in many MSs.
  - The need for co-ordination is recognized but as yet no solutions have been universally adopted.
  - Joint enforcement programmes are certainly not normal custom and practice.
  - Good practice is being followed in many Member States but is not being universally applied.

  There is very little performance information available regarding the market surveillance activities of Member States and accurate benchmarking is impossible.

  The report identifies some clear routes to improvement of service delivery including:

[7] Directive 2001/95/EC on general product safety.
[8] *The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive*, (BSI, 2011), available at http://ec.europa.eu/consumers/safety/projects/docs/final_report_the_future_of_market_surveillance.pdf.

- The advantages of scale can be a benefit when utilised within MSs and increasingly so when resulting from coordinated programmes between MSs.

- The main requirements will always be sufficient if there are assured funding and numbers of qualified inspectors working within a framework that incorporates as many aspects of best practice as possible with reasonable access to accredited testing facilities.

- A wider range of information sources would allow for better targeting.

- RAPEX notifications need to be transferred quicker and greater efforts should be made to provide more actionable information.

- Information and advice to economic operators (especially SMEs) is a legitimate MS function that needs to be given a greater priority.

The review of best practice equally gave clear examples of procedures that would improve the effectiveness and increase the efficiency of current practice, including;

- Best practice should become the basic operating procedures of all MSs authorities.

- A balance should be found between reactive and proactive approaches.

- Better use should be made of consumer complaint and accident & injury data.

- Databases of risk-assessed economic entities should be created.

- Risk-based inspection programmes should be developed.

- Intelligence-led safety initiatives initiated with precautionary principle in mind.

- Enforcement policies should be accessible to the public.

- National Market Surveillance Coordination Committees should be established.

I want to make six points about these systems. Firstly, we see strong similarities in the architecture of the systems for medicines, engineered products and general consumer products, with convergence over time, and similar problems. The problems of any one product type, such as medical devices, are not unique. One can learn from looking at other systems, and one should also make sure that there is a coherent overall approach.

Secondly, it is important to note that the basic techniques of control of safety [and quality (for medicines) and performance (for devices)] are not at all controversial, but are universally agreed. They involve pre- and post-marketing controls within a quality compliance system. The only differences that arise relate to details, for which the decision is whether the cost of extra requirements is justified by the incremental increase in safety. It is ironic to note that since the

catastrophic financial crash of 2008, all global and European policymakers are now extending regulation of financial services beyond mere prudential regulation into conduct regulation. In other words, they are no longer trusting the banks and markets to get it right spontaneously, and regulatory controls are being pushed down more intrusively into operational levels and assessing individual products. Some of us got there 50 years ago.

Thirdly, the EU systems contain considerable flexibility to match the intensity of regulatory control to the level of risk associated with particular products, and so balance controls and protections with freedom to innovate and hence commercial health.

Fourthly, significant trust rests on individual operators throughout the system. Malcolm Carlisle constantly reminded us that a quality system and risk assessment are tools that have to be operated by individuals who are capable of exercising clear, objective and independent judgment and common sense. It is not enough to tick boxes, you have to think carefully about what risks in fact arise and how to deal with them. As John Ruskin (1819-1900) said, "Quality is never an accident. It is always the result of an intelligent effort." It also requires honesty—freedom from corrupting influences—on the part of everyone involved—researchers, regulators, notified bodies, manufacturers, and all their human operators.

Techniques that can support the effective and honest application of the systems include governance (oversight, involving all relevant stakeholders), transparency, and cross-checking (audit, or joint inspections).

Fifthly, looked at systematically, all of the systems—for medicines, New Framework, specifically devices, and consumer products—consist of *tiers of 'controllers'*, working together (public authorities, manufacturers, qualified persons, notified bodies, suppliers, professional users, and end-users). The system is built on collaboration in the allocation of responsibilities and the sharing of data.

This phenomenon is described in regulatory theory as 'meta regulation'.[9] Historical ideas about regulation viewed it as a vertical conception, in which state authorities 'commanded and controlled' private firms. Hence, the state set the rules, and imposed punishment on those who did not obey them. Over time, we have recognised that rules can be set not only by private sector bodies (standards) but also by firms (compliance systems). Further, outsiders can affect compliance

[9] N Gunningham and P Grabosky, *Smart Regulation. Designing Environmental Policy* (Oxford University Press, 1998).

behaviour (gatekeepers like notified bodies, insurers, investors, bankers, trade bodies, ethics bodies, commentators, customers).

Sixthly, all the regulatory systems have also evolved. One consistent development has been to increase the sophistication of the post-marketing vigilance systems. Post-marketing vigilance was stepped up in 1995 for medicines, 2001 for GPS, and 2008 under the New Legislative Framework. In 2013 proposals were made to create a unified post-marketing system, update it and bring all those in supply chains within it. Especially for many medical products, such as implants, you cannot know in advance exactly how well they will perform *in situ*, so you need a robust *ex post* vigilance system.

In summary, therefore, we have achieved a great deal. We have put in place robust controls for safety and risk assessment in design, manufacture, and product information, both before and after marketing. The systems are holistic and integrated. They are supported by controls within companies (quality systems) and external oversight and enforcement (competent authorities and notified bodies). The systems have wide geographical reach across the 500 million people of the EU. In theory, they *should* work. I emphatically do not believe that there is a case for major redesign of the regulatory architecture, such as by extending the pharmaceutical licensing regime *per se* to medical devices or any other product types.

So far, so good. What challenges remain to be tackled? We can learn a number of things from looking at case studies where things went wrong. We have quite a few to consider: the PiP breast implant saga, other orthopaedic implant recalls, and also related areas like mad cows and vCJD, ethanol in Austrian wine, dangerous cosmetic interventions, and the French *Mediator* drug scandal. Outside Europe, in the less regulated environment of say China, we have melamine in milk and toxic sofas that contain dimethylfumarate. We have many financial disasters, such as BCCI, Enron, WorldCom, rogue traders who hide unauthorised trades, systemic mis-selling of payment protection insurance (PPI), excessive lending against assets that are inadequate if the market turns down, prompting a massive global financial crisis. Things do go wrong, and can have serious adverse effects on large numbers of people, prompting public calls for more controls. These cases all involve bad practice that has predictably adverse effects, but is either undiscovered or unchallenged by both internal and external authorities. Do we just shrug and say “shit happens”, or do we look more closely at human motivations, and surveillance and investigation systems, and see why things went wrong, how can we improve behaviour, and how can we identify problems sooner?

Two points are worth remembering before we go further. Firstly, healthcare products (medicines and devices) carry inherent risk. Establishing a risk-benefit balance inherently involves complexity. It

is inevitable that this is done by professionals (whether public or private sector), and also that the public, media and politicians will not understand either the process or the decisions after something goes wrong. So complacency is not an option for this sector: we have to find solutions.

Secondly, a strong lesson from the case studies is that however good your *own* system might be, or *most* people's systems might be, *someone* might mess up, and this can lead to a collapse of consumer confidence and political calls to legislate for increased regulation. The fact that most manufacturers, notified bodies and regulators are doing the right thing will be forgotten in the spotlight of public concern. The inherent complexity of the system, with its multiple actors, will not be understood. The multiplicity of inter-connected actors is both a strength and a weakness. The cases highlight several important risks:

- There can be the isolated manufacturer who is fraudulent and goes to great lengths to hide wrongdoing: he can even have a reputation for doing the right thing (such as instigating a recall), but can in fact be operating with significant non-compliance.

- The inherent limitations of the assessment and auditing function of notified bodies. A notified body might do everything it was supposed to do, but still fail to detect non-compliance. Even a good notified body can be hoodwinked. Financial auditors have known that for many years. Within the devices sector, we have also known for some years that there are serious variations in quality in different countries, even within the same organisation.

- Regulators also have limits. A regulator may not have sufficient power to investigate, say in another country. This will be a particular problem if a foreign regulator is asleep, or is told of a problem but fails to investigate or take action. There is also the perennial problem of lack of resources.

- Problems for both notified bodies and competent authorities arise from the EU's decentralised structure. There can be variations in quality here, and challenges of achieving effective coordination. National regulators may face resource constraints.

How do we respond to these problems? Improvements that suggest themselves are:

- the need for a single, large, comprehensive pool of all safety data

- strengthening peer support of competent authorities and notified bodies, and doing joint inspections

- power to carry out random inspections, so that safety signals can be investigated swiftly

- channels and incentives for whistleblowing

- avoiding multiple applications, and forum shopping.

All these techniques are in the draft MD Regulation proposed by the European Commission (apart from whistleblowing). The EU proposals have got the approach absolutely right. Of course, the plan needs to be matched by implementation that is full and effective. But we might go further:

- Do we need 28 national competent authorities? We may need a national authority for constitutional and symbolic reasons, but cannot functions of surveillance and inspection, and even enforcement, be made more efficient, professional and effective if there were to be some rationalisation, or pooling or outsourcing?

- Do we need 70 or 80 notified bodies? Are their standards uniformly high enough? Should approval and oversight rest with national authorities, or should it be undertaken by an expert committee of Member States?

- We need to ensure full transparency of data, and make sure that the data is understandable by those who wish to scrutinise it. We need to learn from the *Bad Pharma* criticism of the pharmaceutical industry,[10] and make sure that allegations of lack of transparency, let alone cover up, cannot occur. Lack of transparency breeds lack of trust. People who are suspicious of the results or of selling practices will mistrust the reliability of the industry as a whole. I commend here the work of the EUCOMED and ABHI Codes of Practice arrangements.

I now turn to other legal consequences when things go wrong.

B. Enforcement of Regulatory Law

People do not often talk about the enforcement of regulatory law. Firstly, it is in fact a rare phenomenon in relation to medical device and pharmaceutical companies—and that indicates that

[10] B Goldacre, *Bad Pharma. How Drug Companies Mislead Doctors* (Fourth Estate, 2012).

standards of practice and compliance are generally consistently high. Only rarely are bad apples involved. Secondly, under EU constitutional rules on subsidiarity and national autonomy, matters of enforcement are issues for each Member State, the only general requirement being that enforcement and sanctions should be "proportionate, effective and dissuasive". But effective and consistent public enforcement is on the wider agenda, and those responsible for this industry should spend some time thinking about it.

What we need is:

- research on the powers available to national authorities, and on the circumstances in which they are used;

- development of a consistent policy and practice on enforcement across all national authorities (to avoid forum shopping to find the most lax jurisdiction). One element would be criteria for public regulators, building on precedents such as the UK Regulators Compliance Code,[11] Penalty Principles[12] enshrined in the Regulatory Enforcement and Sanctions Act 2008. The UK principles for economic regulation specified: accountability (including independence from government), focus, predictability, stability, coherence, adaptability, efficiency and proportionality.[13]

- an approach to regulation and enforcement that builds on meta regulation, and effectively integrates public, in-house and stakeholder pressures to maximise compliance.

Let me give a quick illustration of one problem, which arises out of different models of enforcement. This is a subject that is highly contentious in some other sectors, and the public and private actors in this industry should put in their views. Theories of enforcement can roughly be categorised into four approaches, which have ebbed and flowed during history.

- Deterrence theory is that people obey law if they fear the imposition of sanctions for wrongdoing. It is a punitive approach, which is pretty simplistic and primitive.

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[11] *Regulators' Compliance Code: Statutory Code of Practice for Regulators*, at http://www.berr.gov.uk/files/file45019.pdf, made under section 22 of the Legislative and Regulatory Reform Act 2007.

[12] Based on R Macrory, *Regulatory Justice: making sanctions effective* (HM Treasury, 2006); reprinted in R Macrory, *Regulation, Enforcement and Governance in Environmental Law* (Hart Publishing, 2010).

[13] *Principles for Economic Regulation* (BIS, April 2011) available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/p/11-795-principles-for-economic-regulation

- Economists (initially centred on Chicago post-WWII) developed a model that everyone, and especially companies whose *raison d'etre* is to maximise profits, makes decisions based on a rational assessment that compares the benefits to be gained from breaking the law as against the losses. So if the risk of discovery and of attracting large fines are high, potential gains will be lost and a rational actor should refrain from breaking the law. This theory can be ctitisised on many grounds, for which there is not space here. One problem is that the approach needs constant surveillance, investigation and imposition of sanctions. That demands a great deal of resource to be successful, and leads to a culture of constant suspicion, adversarial challenge and punishment. A second objection is that most people just do not behave as 'rational profit maximisers', at least not all the time. However, this theory is widely influential in U.S.A., and is adopted by EU competition authorities. I suggest you should take action to object to it spreading further.

- Empirical research led by Australian and British scholars over the past 40 years has illustrated how enforcement officials actually operate, across wide contexts, such as care homes, environmental pollution, juvenile crime, health and safety in the workplace, and technical areas such as telecoms. This finds a consistent approach by enforcers, who, if they have a sufficiently well-stocked toolbox of powers, operate on a pyramid model. Most activities occur at the bottom of the pyramid, where 'enforcement' is informal, and the emphasis is to improve compliance by persuasive or negotiated means. More serious matters can be dealt with by escalation to more serious sanctions, such as infringement notices, improvement notices, civil sanctions. The system will be most effective if there exists an ultimate sanction at the top of the pyramid, which is very rarely used, such as imprisonment, disqualification as a director, revocation of an authorisation. There should in fact be several pyramids, one covering a company's activities, and one covering the human actors involved, and pyramids can be both external (public) and internal (employee discipline). More thought needs to be given to how such pyramids should be integrated.

- Much research finds that large corporations are far better at compliance (and investment in compliance) than SMEs.[14] This issue needs to be confronted not just by public regulators but

[14] *Empowering and Protecting Consumers. Consultation on institutional changes for provision of consumer information, advice, education, advocacy and enforcement* (Department for Business Enterprise and Skills, 2011), at http://www.bis.gov.uk/Consultations/empowering-and-protecting-consumers; http://www.bis.gov.uk/assets/biscore/consumer-issues/docs/e/11-970-empowering-protecting-consumers-consultation-on-institutional-changes.pdf. A study found that businesses, in particular SMEs, often lack clarity about how to comply, and that evaluation and feedback remain weak elements of public regulatory

also by dominant firms. How can you help smaller enterprises understand and achieve what they need to do in order not to create problems that impact everyone else?

- Research in social and behavioural psychology has identified highly important information about how people behave, which urgently needs to be integrated into the debate on enforcement, and into the design of regulatory systems.[15] Crucial findings are that people obey rules if

  a. The rule confirms to the individuals' own internal ethical values;

  b. The process of making and enforcing rules is fair;

  c. they are (as many are) highly influenced by peers: compliance within regulated enterprises is repeatedly shown to be socially constructed.[16]

These findings suggest how we should design systems for public regulation and corporate structures. Important elements are;

- statements of corporate and public ethics

- creation of peer groups that can strengthen ethical behaviour and challenge undesirable behaviour, such as committees of regulators, notified body assessment, peer review, associations of professionals (in regulation, management, marketing, regulatory affairs). An important lesson from cases such as PiP and Enron is to be able to identify who is *not* active

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management: *Delivering regulatory reform. Report by the Comptroller and Auditor General* (National Audit Office, 2011).

[15] See generally T Gilovich, D Griffin and D Kahneman (eds), *Heuristics and Biases: The Psychology of Intuitive Judgment* (Cambridge 2002) (compiling research on how people make judgments); D Kahneman and A Tversky (eds), *Choices, Values, and Frames* (Cambridge 2000). An accessible form is D Kahneman, *Thinking, Fast and Slow* (Allen Lane, 2011). Some of the more detailed works are: D Kahneman and A Tversky 'Prospect Theory: An Analysis of Decision Under Risk' (1978) 47(2) *Econometrica* (1978) 263-290; J Darley, TR Tyler and K Bilz, 'Enacting justice: the interplay of individual and institutional perspectives,' in M Hogg and J Cooper (eds), *The SAGE Handbook of Social Psychology* (London: Sage, 2003); JT Jost and B Major (eds), *The Psychology of Legitimacy* (Cambridge: Cambridge University Press, 2001); TR Tyler, *Why People Obey the Law* (Yale University Press, 2006); TR Tyler and SL Blader, *Cooperation in Groups: Procedural Justice, Social Identity, and Behavioral Engagement* (Philadelphia: Psychology Press, 2000); TR Tyler and SL Blader, 'Can businesses effectively regulate employee conduct? The antecedents of rule following in work settings' (2005) 48 *Academy of Management Journal* 1143-1158; J Jackson, B Bradford, M Hough, A Myhill, P Quinton and TR Tyler, 'Why Do People Comply with the Law? Legitimacy and the Influence of Legal Institutions' (manuscript, 2013) (a survey of 7,434 respondents' attitudes to the police and the criminal law in the United Kindgom).

[16] RA Kagan, N Gunningham and D Thornton, 'Fear, duty, and regulatory compliance: lessons from three research projects' in C Parker and VL Nielsen (eds), *Explaining Compliance. Business Responses to Regulation* (Edward Elgar, 2012), 37; BM Hutter, *Compliance: Regulation and Environment* (Oxford: Oxford University Press, 1997); LB Edelman, S Petterson, E Chambliss and HS Erlanger, 'Legal ambiguity and the politics of compliance: affirmative action officers' dilemma' (1991) 13 *Law & Society Review* 73-97.

in such networks, and to provide means of supporting individuals who are worried that their employers are engaged in serious non-compliance or fraud, such as whistle-blowing channels.

C. The Liability and Compensation System

When faced with a potential problem over an implanted device, what is it that *people need*?

- Reliable information on which products they have in them (there might not be a problem with what they have)
- up-to-date information about risks (remembering that information may evolve)
- advice on treatment options
- ongoing monitoring
- appropriate revision
- reimbursement of expenses.

Traditionally, these disparate functions fall between multiple players: surgeons, clinics, manufacturers, lawyers, courts, magazines and the media. Can we not devise an integrated system, which improves patients' experiences and so ensures adequate trust in industry, technologies, national health systems and governments?

The solutions we should be considering include:

- Providing product traceability, including with Unique Device Identifiers,[17] and a single register of products, suppliers, professionals and patients (the MD Regulation amendments will achieve this);

[17] Commission Recommendation of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union (L99/17: OJ, 2013), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF

- A readily-identifiable and accessible network of sources of reliable, independent advice and support;[18]

- Integrated systems for information, investigation, revision and reimbursement, which deliver quick and adequate results.

How should we process claims for compensation for loss or injury? The classic approach relies on state-defined rights (breach of contract, negligence or strict product liability) that are enforced by victims having to consult lawyers and bring an action in a public court, which ends in the claim to breach of a right being either vindicated or rejected, and, if the former, an award of damages that then has to be enforced in further proceedings unless payment is made voluntarily. This is an adversarial system, being basically a state-sponsored mechanism that is better than 'taking the law into one's own hands' and exacting revenge on the perpetrator.

As we all know, hiring lawyers and accessing courts involves time and money.[19] This is especially true in the USA. Some countries have found quicker and cheaper solutions.

People have also moved beyond the legal standard in their expectations – liability law is merely a minimum requirement. The law sets a standard for liability, which triggers (full) compensation. But people now expect to be *cared for* when things go wrong, and reputable companies both need and want to meet their customers' expectations. So we have to establish ways of delivering more than the law covers. The traditional tools of injunctions and damages, to say nothing of civil procedure systems, do not respond to the issues.

Two reforms are needed. Firstly, we need to adopt far more modern means of resolving disputes. Secondly, we need to involve the complaint/dispute resolution process in a quality system approach to the legal and regulatory system.

[18] Access points need to be readily identifiable, and that means that systems need to be simple. This is a feature of various Nordic states. The UK has radically reformed and simplified the landscape for general consumer advice and protection (annual consumer detriment from unfair trading is estimated at £6.6 bn), focusing advice on a network of Citizens Advice and enforcement on Local Authority Trading Standards Services: Key findings of a NAO study were the need for agencies to work collaboratively and strengthen cross-border working: *Department for Business, Innovation and Skills, the Office of Fair Trading and Local Authority Trading Standards Services. Protecting consumers—the system for enforcing consumer law. Report by the Comptroller and Auditor General* (National Audit Office, 15 June 2011) http://www.official-documents.gov.uk/document/hc1012/hc10/1087/1087.pdf.

[19] C Hodges, S Vogenauer& M Tulibacka (eds), *The Costs andFunding of Civil Litigation: A Comparative Approach* (Hart Publishing, 2010).

Let us look at these ideas. Firstly, far better ways of resolving personal injury disputes are available than through courts and lawyers. In fact, a revolution is currently underway in Europe in dispute resolution, towards the techniques of voluntary solutions, alternative dispute resolution (ADR), and restitution assisted by regulators.

For example, the area of consumer-to-business complaints in Europe is about to undergo major change with a shift towards 'Consumer ADR' (CDR) or ombudsmen systems. The EU has just adopted a Directive on CDR, which requires all traders to belong to CDR systems by 2015 and specifies quality criteria for CDR entities, and a Regulation to create a pan-EU online dispute resolution (ODR) platform through which cross-border disputes can be sent.[20] These systems will be transformative.[21] For example, the Financial Ombudsman Service in UK handles 300,000 disputes and 1.5 million consumer queries against banks a year—as many as the total number of non-family cases in courts of England and Wales (which is falling). Other important examples are the German Insurance and Transport Ombudsmen, the French Financial and Energy médiateurs, the Swedish ARN, and the Dutch geschillencommissie.

Health disputes are, for the moment, excluded from the new EU legislation, but attention is turning to them. Personal injury cases have particular requirements that need individual assessment in every case: expert medical investigation and attribution of causation, as well as assessment of particular needs and responses. Various good examples exist, which we should extend across Europe and integrate:

- In the Nordic states, a series of injury compensation schemes exist. An application triggers a paper-based investigation by the national Board, assisted by any necessary external medical experts. Importantly, a series of schemes exist alongside each other, to which injuries can be allocated depending on the causation (road traffic, medical or drug). This wide coverage is essential.[22]

- In France, the ONIAM system operates on a regional network of investigatory committees, which decide causation. In cases in which fault is found, the medical or manufacturer's

[20] Directive 2013/xx on alternative dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Directive on consumer ADR)'; Regulation (EC) No 2013/xx on online dispute resolution for consumer disputes (Regulation on consumer ODR).
[21] C Hodges, I Benöhr and N Creutzfeldt-Banda, *Consumer ADR in Europe* (Hart Publishing, 2012).
[22] C Hodges, 'Nordic Compensation Schemes for Drug Injuries' (2006) 29*J Consumer Policy*143-175.

insurance must make a reasonable offer within a specified time, failing which penalties apply, and in cases not involving fault, the state funds make payments.[23]

- In Ireland, the Personal Injuries Assessment Board, established in 2004, has been a tremendous success. All personal injury claims must be assessed by the Board before legal proceedings are instituted. It delivers an opinion on quantum and facilitates settlement. It has reduced court claims by two-thirds, is fully self-funding from low access fees, has reduced the overhead costs of claims from 46% to under 9%, and reduced the average time from consent to award from 36 months under litigation to 7 months.[24]

Compensation schemes can be established in response to specific events, such as vaccine damage[25], various diseases of miners,[26] medicines (one from the 1970s was ICI's Eraldin), or funds for creditors of failed financial institutions,[27] or policyholders in Equitable Life.[28] They can be generic or established by a single company—a notable recent example of the latter was that of Johnson & Johnson in relation to the ASR hip prosthesis product: a global programme of monitoring, revision and reimbursement of expenses, with a grid of fair damage payments.[29]

Patients and companies waste far too much time and money on making, investigating and processing compensation claims. I would take unnecessary intermediaries and costs out of the system (i.e. lawyers). We should learn from the Nordic, French and Irish approaches and redesign a system in which the initial scrutiny (triage) and investigation phases are undertaken by independent experts (like the ombudsmen model) and valid claims are automatically paid through standing insurance arrangements. In other words, this would be a system backed with standing compensation funds.

The UK government has in fact recently announced its intention to adopt a similar system by extending the remit of the Parliamentary and Health Service Ombudsman (PHSO) to cover all public

[23] L' Office National d'Indemnisation des Accidents Médicaux: http://www.oniam.fr/oniam/presentation-oniam/. This was created under Code de la santé publique: see http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20111107.
[24] *Personal Injuries Assessment Board. Strategic Plan 2012-2016* (2012).
[25] Many countries have these. In UKM the Vaccine Damage Scheme provides a one-off tax-free payment of £120,000.
[26] Schemes include noise induced hearing loss (NIHL), some asbestos related conditions, pneumoconiosis, chronic obstructive pulmonary disease (COPD) and vibration white finger (VWF): see http://www.decc.gov.uk/en/content/cms/funding/coal_health/coal_health,aspx
[27] In UK, the Financial Services Compensation Scheme, at http://www.fscs.org.uk.
[28] A special fund, arranged by HM Treasury after pressure from the PHSO.
[29] Presentation by L Ködderitzsch at the "Building Effective Markets - The Role of an Integrated Legal System " conference, 29-30 January 2013, Swiss Re Centre for Global Dialogue, Rüschlikon, Zürich, Switzerland, available at http://www.csls.ox.ac.uk/documents/EXECUTIVESUMMARY.pdf

and private sector health disputes (I confess that was my idea).[30] In order to make this happen, the PHSO system requires significant modernisation; a great deal of thought on modelling what the trigger should be if the system is to avoid being flooded by complaints (negligence, strict liability, accident (New Zealand), unexpected event (Nordics), or something else); and the development of responsive payment and insurance mechanisms by each of the major sectors (NHS, private clinics, physicians and surgeons, manufacturers, pharmacists, dentists, cosmeticians and so on). It may well be wise to undertake pilots before mass roll-out and advertising.

Within such a comprehensive national structure, reputable groups might create mutual pools of insurance as long-stops to cover catastrophic failures in cover, such as the German pharmapool, and the UK ABTA travel agents' pool,[31] or, as the UK Keogh Report recently recommended, a pool of medical device manufacturers.[32] These should not cover everyone who might be liable, so as to avoid the risk of 'moral hazard' (removing the incentive to maintain high standards, and allowing rogues to free ride on reputable businesses), but availability should drive consumer choice towards reputable businesses.

We can make the system do more for us, if we collect all the data from complaints, disputes and all other sources, and feed it back in a holistic quality system that can inform improvements in practice – i.e. within the PMS. This coordination feature should be included in the architectural design from the start, even if it is not fully functional until later on. The submission of the PHSO to the Public Administration Select Committee's inquiries in June 2013 includes this idea of moving to a quality system in relation to the public sector (my idea as well).

I have been speaking of national models. But we should also be thinking whether it is possible to design an integrated pan-EU model of advice, investigation, redress and compensation, for both cross-border and national efficiency reasons. The medical device sector should not 'go it alone' here, but should coordinate with pharmaceutical, medical and other interests, although this sector could play a leading role.

[30] *Review of the Regulation of Cosmetic Interventions. Final Report* (Department of Health, 2013), recommendation 34.
[31] Airline and package travel operators are required to hold one of a number of specified insurance arrangements to cover the cost of repatriation: The Civil Aviation (Air Travel Organisers' Licensing) Regulations 1995 and the Civil Aviation (Air Travel Organisers' Licensing) Regulations 2012/1017 and The Package Travel, Package Holiday and Package Tours Regulations 1992/3288, implementing Directive 90/314/EEC.
[32] *Review of the Regulation of Cosmetic Interventions. Final Report* (Department of Health, 2013), recommendation 38.

D. Going Beyond Criticism

It is, of course, an unattainable goal to be beyond criticism. Anyone who believes they are unassailable becomes complacent, and standards suffer. But there are things that we can do to improve things.

- The regulatory architecture is in place and is fit for purpose and robust, but it needs added robustness to cater for identifying failures swiftly and putting things right; we need to anticipate that some people will cause problems, so we need to be able to maximise compliance, and spot non-compliance more quickly.

- The public enforcement system needs to be placed on a coordinated, coherent, principled, effective and efficient basis.

- The way we respond to patient problems, which will inevitably arise, needs to be redesigned on more responsive and efficient lines. We need to put in place efficient compensation arrangements, as part of both an integrated system of compensation arrangements and as part of a wider system of responsive care.

Underlying all this is the goal of ensuring a high level of trust – because simplicity and transparency works, and delivers speedy, low cost and effective solutions. I have referred to shifts in the expectations of citizens in modern European markets and polities about what they expect by way of higher standards of responsive care when things go wrong.

A number of scholars have noted that regulation has three components, emanating from three distinct types of risk: actuarial, socio-cultural and political.[33] Regulation in this sector (and hence business) is basically focused on only one risk: safety (actuarial risk). Regulators, in particular, also have to be aware of political risk. But if business is driven by profit, it is in business' interests to pay attention to the other two aspects: socio-cultural and political.

Given the inevitability of risk, when an event occurs, it triggers responses in all three licences. Often the reactions in the social and political spheres appear irrational, illogical and disproportionate—

[33] N Gunningham, RA Kagan and D Thornton, Shades of Green: Business, Regulation and Environment (Stanford: Stanford University Press, 2003) 20-40; N Gunningham, RA Kagan and D Thornton, 'Social licence and environmental protection: why businesses go beyond compliance,' (2004) 29 Law and Social Inquiry, 307-341; F Haines, *The Paradox of Regulation. What Regulation Can Achieve and What it Cannot* (Edward Elgar, 2011).

when viewed from the perspective of the legal sphere. But they are (usually temporarily) highly powerful forces and have to be addressed.

The political concern with what appears to be unacceptable and uncontrollable risk (for example in relation to vCJD in beef) is the precautionary principle. The precautionary principle is, in fact, entirely logical, but it is a *political* response to risk, not a scientific one. It says that if we are faced with uncertainty, we should avoid taking risky steps. Scientists might well not adopt that approach: instead, they might take (perhaps measured) risks in experiments and trials designed to advance knowledge about the underlying problem. But a politician would lose credibility—and employment—if he advocated taking a risk that has lodged in the public consciousness.

The lessons here for industry and civil servants are to aim to remove uncertainty. Anticipate the social and political risk; obtain data to frame, if not quantify, risk; make sure that you have independent friends who the public will trust to frame and rationalise the debate. Let us repeat, some medical devices can be predicted to give rise to social and political risk, especially implants, those dealing with fertility, and those incorporating biologics and nanotechnology.

These insights explain why just complying with the rules is not enough. Ticking the box (as Google and others recently found on tax avoidance arrangements) does not satisfy the social licence. It only takes one fraudulent PiP to put the social and political licence of the whole European device industry at risk.

Thus, if business, regulators and healthcare professions are to put themselves in a better position, it will be necessary to pay attention to issues such as:

- Thinking fully and objectively about risk assessment, involving extending peer review and peer support
- Expanding meaningful Corporate Social Responsibility
- Looking after patients/customers: delivering integrated and trustworthy advice, revisions, and injury schemes
- Preparing for public issues: thinking about what politicians and the media need in a crisis
- Ethical promotion and marketing.

Compare these two extremes of responses to problems:

- Too many cosmetic interventions and the PiP breast implant situation gave rise to questions like: What have I got in me? Is it dangerous? Where can I get advice? The clinic has gone into voluntary liquidation (but reopened under another name), so I have no source of advice, support, compensation or insurance. Who can I rely on? Who is accountable? Who is to blame?

- Spontaneous campaigns such as J&J's famous Tylenol recall and ASR hip revision scheme were aimed at delivering practical help, and sent the message "We care about our customers and patients". But three questions arise. The expense was colossal: how can it be reduced, while still maintaining effectiveness? Second, how can we deliver results that are currently in disjointed pathways (such as medical, regulatory, legal, insurance) in more integrated packages? Thirdly, these were problems with the company's own products, but how can the sector respond collectively to others who let the side down?

I suggest that a number of important answers lie in ethics. Major healthcare companies are good at setting internal moral standards, and these should be supported and spread externally. After all, patients, employees and external commentators expect healthcare companies to 'do the right thing'.

Remember the key findings of social psychology research that people will internalise legal compliance if the standard conforms to their internal moral standard and they regard the process as fair. We need to spread that idea throughout this sector, and beyond, not only in practice but also in reviewing our regulatory and compliance systems.

That's why anyone who pursues personal advantage (or commercial profit) who just abides by the letter of the current rules will always be at risk of "not getting it". Society expects more, whether it is bankers who seek to justify huge bonuses, MPs who claim unjustified expenses, or multinationals who take advantage of international tax rules to minimise contributing to the public finances of the countries in which their customers live. In all these examples, the internal evaluation of conduct and what the operator is worth is out of line with the views and expectations of the outsiders whom they serve and who ultimately pay them.

Society now expects people to abide by ethical norms of fairness and collaboration, and not to seek to rely just on the letter of the law. People expect something more, and will punish businesses in the marketplace if they do not find it. Business theorists call it business ethics. Contribution to society is

important. The French call it solidarity. Christianity calls it loving your neighbour. Humanists might call it ‘doing the right thing’.

To sum up. It is inherent in the nature of healthcare that things will occasionally go wrong. So how can we reduce the incidence, identify problems quickly, and respond most appropriately? We need to think about

- maintaining high standards, not just within our own organisations but in others. This will involve transparency, ethical approaches, and exceeding minimum standards – going beyond compliance

- designing integrated response systems that care for people’s various needs—information, advice, support, care, revisions, money—and making sure that we capture the information and learn from it.

These are noble but ambitious aims. Malcolm Carlisle would expect nothing less.