REGULATING FOOD AND PHARMACEUTICALS IN THE EU: A COMPARISON OF STYLES OF GOVERNANCE

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A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of a Master of Arts in the Department of Political Science, Concentration Trans-Atlantic Studies.

Chapel Hill

2007

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ABSTRACT

SARA DUDLEY: Regulating Food and Pharmaceuticals in the EU: A Comparison of Styles of Governance
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The spread of Mad Cow disease (Bovine Spongiform Encephalopathy) across Europe revealed critical flaws in European health regulation. In 2000, the European Commission attempted to indulge public perception by establishing strong, proactive and coherent risk regulation policy, as set down in their 2000 Communication on the Precautionary Principle. However, the Precautionary Principle does not apply to all industrial sectors equally. This thesis compares food safety regulation to pharmaceutical regulation. It clearly shows that each system of regulation is governed by a different mode or ‘style’. These different styles of governance predate the 2000 Communication but have also continued unchanged since then.
ACKNOWLEDGEMENTS

I would like to take this opportunity to thank Dr. Gary Marks for his extensive guidance throughout this entire research project. He was essential for helping me to hone my research from its inception. I would also like to thank Mr. Francois Lafond for introducing me to the subject area of risk regulation and directing me to my initial sources.

I would also like thank my two separate systems of support: Dr. Sarah Hutchison and Dr. John Stephens from the TAM program, and of course my parents and family.
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CHAPTER ONE

INTRODUCTION

In the wake of the Bovine Spongiform Encephalopathy (BSE) crisis in Europe, many including the European Parliament criticized the handling of the epidemic by the Commission. There was, and there remains, a strong fear that the next crisis could equally catch policymakers just as un-prepared. Before the spread of BSE, most public health officials could not have foreseen that food for human consumption and feed for animal consumption might have such potentially devastating effects. The next crisis could be equally as unpredictable. In response to this fear, the critics of past policies wanted to create a ‘fortress-like’ regulatory institution. They advocated for less fragmentary health policy regulation and one centralized regulatory agency, like the American version of the FDA, to enact concerted legislation for all sectors.¹

The 2000 Communication by the Commission on the use of the Precautionary Principle (PP) can be considered an embryonic step to presuppose at the very least a strong position on health regulation. The Communication attempts to represent the collective preferences of European citizens as demanding a high level of protection. The Precautionary Principle (PP) is thus meant to establish a strong proactive stance in the face of scientific uncertainty during risk analysis.

Risk analysis involves three coordinated steps: risk evaluation or assessment, management, communication. After performing a scientific evaluation where degrees of uncertainty are identified at each stage, the PP should frame the risk management phase. To quote the Communication: “Judging what is an acceptable level of risk for society is an eminently political responsibility”.\(^2\) In other words, the PP arms the political decision-maker with the legislative tool to conduct risk management.

This effort to underwrite a health policy that avoids the coexistence of divergent visions for different industrial sectors is belied by some internal contradictions. The Communication is primarily focused on expanding the PP from environmental policy to food safety. However, it also makes special mention of ‘a priori’ dangerous goods, like drugs in the pharmaceutical sector. It argues that the system practiced by most developed countries for pre-market approvals “is one way of applying the PP”.\(^3\)

I would argue that the PP does not logically apply to the pharmaceutical sector. Drugs from the outset have been considered dangerous goods, which has fundamentally affected the evaluation of their risk and their management. By likening the atypical process of risk assessment for food to the more standard process of pre-market approvals, it would appear that the Commission is attempting to obscure, or downplay, the exceptionally political nature of food safety regulation. It presents a pretext of ‘business as usual’ by claiming that drug regulation is equally as ‘precautionary’. The next logical conclusion would be, if it is standard practice for drugs, why not food?


\(^3\) Ibid., 20.
The motivations in making food safety similar to pharmaceutical regulation in the Communication are most likely diverse. The PP has garnered critical international attention in the media, and through trade disputes arbitrated by the WTO. The Communication can be seen to provide a defensive response in addition to concerted health policy. The fact remains that the precise implications of the PP are undetermined and the principle remains substantially fluid. An informed discussion by different parties, like the WTO and other national governments, can only be held if all sides at least acknowledge they are using different working definitions and agree on a common principle. The 2000 Communication is an attempt on the Commission’s part to assert their definition.

The different approaches in food safety regulation and pharmaceutical regulation will be further confirmed in considering the EU’s planned research for 2007-2013. The 7th Research and Development Framework process is an outline of strategies with regard to emerging biotechnologies. The EU has gone to incredible lengths to define a European-wide ‘knowledge based Bio-economy’ in order to compete with the US, China and Japan. From nanotechnology to cloning, some of the most interesting and lucrative science is being done in this field. For our purposes, both food and pharmaceuticals stand to be radically changed by biotechnology. Genetically modified foods or organisms (GMOs) and new bio-engineered drugs engender very different responses, in terms of research and institutional arrangements. This subsequently affects their risk analysis. If one takes a closer look at various EU position papers dealing with biotechnology, one will see some rhetorical back-pedaling on the Commission’s part about their support of the PP. The language and terminology used are subtly different from those used in the
2000 Communication. This also further confirms that regulatory approaches and capabilities are remarkably divergent between the two sectors of food safety and drugs.

The following sections will outline these differences by detailing the respective processes of risk evaluation and risk management for food products and pharmaceuticals. GMOs and bio-engineered drugs will be then used as case studies to illustrate how the general principles behind each respective form of regulation hold up with regards to more contentious and novel products. I will then propose possible implications and draw some tentative conclusions about the status of health policy regulation in the EU.
CHAPTER TWO

Food Safety Regulation

History

The BSE crisis provided the critical “triggering event” for policy innovation that has since paved the way for food safety health regulation. In 1986, BSE, commonly known as mad cow disease, was identified as a possible disease to be found in cattle. One year later, the UK created a database to track the disease in livestock. In 1988, ruminant-derived proteins found in livestock feed were identified as the infectious agent and as a result, the feed was banned for domestic consumption within the UK. However, the contaminated feed was still exported to other countries. Slaughter of infected cattle also became mandatory. Farmers were compensated initially at 50% of their losses and then later at 100%. The number of reports then jumped dramatically when compensation was increased, which provided circumstantial evidence of prior under-reporting. Ten years later from the identification of BSE in cattle, a new variant of Creutzfeldt-Jakob (vCJD), a neuro-degenerative disease, was reported in ten human cases. By 2007, 160 people had died of vCJD, and just over 183,000 cases of BSE had been reported in livestock in the UK alone.

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The scandal provoked by the BSE crisis was more than a simple reaction to the death count. It was a function of the systematic breakdown of governance. Investigations became premised on detailing how much governing officials knew about the impact of the disease and when they knew it. BSE infected livestock globally but European countries including the UK, France, Portugal and Spain received the brunt of the damages. This therefore entailed not only a systematic breakdown of governance in Member States of the EU but also a severe malfunction at the supra-national level.

The European Parliament as an institution has been the most vocal critic of those they consider responsible for the BSE crisis: namely, the European Commission and the Conservative British administration of the 80’s and 90’s. In the case of the UK, the EP accused officials at the Scientific Veterinary Committee of acts tantamount to corruption. The investigatory report commissioned by the EP and led by MEP Ortega Medina laid these several accusations at the UK’s feet.\(^6\) To begin with, Medina pointed to evidence that clearly showed officials were worried about the existence of BSE and the spread of the infection through the livestock. In 1988, this led to the feed being banned for use within the UK. However, exports of the feed were increased to other countries at lower costs and could therefore be considered a case of trade dumping. This increase in exports is also alleged to have spread the disease across the continent. To be noted, the disease was supposed to have originated in Britain because of previous deregulations in the criteria for creating the feed. British officials responded to the accusation of unethical activities by claiming that international trade regulations were a matter to be dealt with by the EU, then known as the European Community. They claimed to have voluntarily

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written other countries warning about the possible deleterious effects of the feed while they maintained their exports.

The British were also accused of mismanaging the tracking system for the containment of the disease. Due to inadequate labeling restrictions, affected cattle were hard to track, and cross border trades exacerbated the infection.

Finally, the British stood to be most guilty of neglecting consumer health by way of critical deregulations due to profit incentives. At several junctures, British officials neglected to act proactively in the face of foreboding, albeit inconclusive evidence. In the minds of the EP, scientific uncertainty was not a legitimate barrier to action, especially when potential consequences were irreversible, immediate and so severe.

In terms of the Commission’s culpability, the EP charged them of not curbing the UK’s authority. Chief UK Veterinary Officer, Mr. Keith Meldrum, reportedly stated that “Commission inspectors had no authority to investigate BSE matters…that BSE was not a technical but a political matter”.7 Mr. Meldrum’s comments implied that the Agriculture and Environment Commission had competence only in technical decisions. The Commission’s later justification of having “no suitable legal basis” to act supports that claim.8 Furthermore, the Commission is blamed for being influenced by a preponderant amount of British thinking. Its BSE subgroup on the Scientific Veterinary Committee included an average of 4 British experts out of 9 members. The EP thus

7 Ibid., 9.
8 Ibid., 9.
accused the Committee of making a “partial and biased reading of the advice and
warnings of scientists”.9

In summary, the BSE crisis revealed very specific issues of governance for both
the national and supra-national level: a lack of inter-state communication and knowledge
sharing, a grey zone of accountability between the national and supra-national levels, an
opaqueness in decision-making, a biased collusion between experts and politicians
without proper consideration of scientific opinion, and a reactionary versus proactive
attitude to scientific uncertainty.

The Precautionary Principle (PP) and the European Food Safety Authority
(EFSA) were both implemented to respond to these several issues. In many ways, the PP
and the EFSA are symbiotic and mutually reinforcing. The following section will detail
how during the initial step of risk evaluation, the EFSA delivers the preconditions for the
risk management that the PP requires, as outlined in the 2000 Communication.

Creating the right conditions: Risk Evaluation in the EFSA

It became clear after the BSE crisis that it was necessary for the European polity
to have an independent institution capable of providing risk assessment, in order to
“enable Community institutions and Member States to take informed risk management
decisions”.10

There were several purposes behind moving decision-making from the
Agriculture and Environment DG within the Commission to an external regulatory

9 Ibid., 11.

10 Council of the European Union and the European Parliament. “…Laying down the general principles
and requirements of food law, establishing the EFSA and laying down procedures in matters of food
agency. Foremost in the minds of regulators was regaining the lost trust of consumers with regards to food safety. This was started with the very clear assertion that issues of public health outweigh economic considerations. This strategy has entailed a lot of rhetoric about civic participation in decision-making. The 2000 Communication goes further, by claiming that the precursor step to risk assessment for food, the identification of a potential hazard, is consumer driven: “it may be for the user, a private individual, a consumer association, citizens or the public authorities to demonstrate the nature of a danger and the level of risk posed by a product or process”.\textsuperscript{11} We will see later how this premise of tailoring policy to consumer demands acts as an essential frame to the health regulation of the EU.

\textit{Making Scientific Assessment Public}

The first step for inserting the public into deliberations is to make ‘room’ for them. This entails making the process understandable and transparent for civic stakeholders. In this way, they may begin to contemplate how to incorporate their own voices within the process. The process of comitology was not well suited to the criteria of transparency, with its dense internal networks of committees and sub-working groups. Thus the EFSA currently chairs its own scientific review with several committees having clear portfolios. Each committee is constituted of experts of various nationalities, where their positions are filled by open bids, their credentials and biographies are listed, and their vested interests are stated at the outset. This is a clear response to the charge of preponderant power by one Member State. The EFSA, while chairing its own committees, can be asked by the Commission to give a scientific opinion or to give

assistance but only when “involving the application of well-established” practices.\(^\text{12}\) The EFSA is also in charge of commissioning studies with outside agencies, and is thus meant to act as the center of a network of national scientific bodies. However, the fact remains, that even by 2005 the Commission still listed the required integration of the national and supra-national authorities as a future priority.\(^\text{13}\)

The second step to ‘publicizing’ scientific decision-making is to create actual open communication between the EFSA, as the major Community institution, Member states, and individuals. Communication with Member states involves the above-mentioned networking with national authorities, which has the added benefit of harmonizing best practices and reducing barriers to trade. As David Vogel and Christopher Ansell state, health regulation, especially in terms of food, remains one of the largest stumbling blocks to integration. Communication with individuals is listed as a priority in the 2000 Communication. One of its core functions is within the third step of risk assessment, namely risk communication, which involves the rapid alert system during times of contamination. The EFSA is also charged with disseminating “objective, reliable, and easily accessible information”.\(^\text{14}\) The format or mode of disseminating this information is left vague.

The EFSA’s criteria of transparency and open communication are perhaps misleading. While they are conducting science publicly, in the way that their methods


are understandable and the sources of their opinions are stated, this transparency does not invite active participation by citizens in the evaluation process. Instead, they are preparing civic voices for participation for the second phase of risk assessment, risk management.

If one remembers, for food products especially, the Commission claims to depend on consumers to identify potential hazards. If consumers are included at the outset, it would be very difficult to shut them out of the process for the subsequent phases. The EFSA’s objective is to allow consumers the privilege of ‘following along’.

The EFSA is also responsible for building up methodology for evaluating the risks involved with food safety. As the safety of food is affected through the process of ‘farm to fork’, the EFSA has a lot of catch-up work to do in order to be able to establish accepted testing methods for seeds, animal feed, as well as products for direct human consumption. The EFSA is also in charge of implementing traceability requirements as outlined in Directive No 178/2002. Traceability is essential for curtailing the spread of infection during crises, but is also a key element of coping with the GMO issue. It means that farmers are held accountable for the type of materials they choose to use and consumers can also make informed choices.

If one considers the entirety of the EFSA’s functions, one can begin to appreciate the institution as political tool for decision-making. I reiterate the word ‘tool’ because the EFSA as an institution complements decision-making or risk management rather than substitutes or competes with it. It provides scientific opinions, it collects data, and it even assembles minority opinions about divergent practices. It does not ever make binding decisions. While there might be a desire for strengthened “links between risk assessors
and risk managers”, there remains a clear separation between the two practices.  

Risk evaluation remains a technical process and an instrument for improving governance. Risk management, as we will now explore further, remains “an eminently political responsibility”.  

Risk Management

As previously stated, the Precautionary Principle has been deemed by the Commission to be the unique policy tool in managing identified risks. The fact remains however, that the PP is a fairly fluid concept and could easily have different implications for different participating institutions and organizations. For the case of the environment, the application of the PP results in taking preventative positive action even when potential harmful effects have been demonstrated, but not conclusively. In the case of food safety legislation, it requires implementing restrictive measures even if no harm has been shown. As the Communication states, the PP can involve taking the worst case scenario as its premise for action. However, the potential consequence of presuming the worst case scenario is that “when such hypotheses are accumulated, this will lead to an exaggeration of the real risk.” The benefit of this position is that it “gives a certain assurance that it will not be underestimated”.

The decision-making process as part of risk management involves the theoretical consideration of what in bio-tech terms is called the ‘innovation triangle’: comprised of

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17 Ibid., Annex III.
18 Ibid., Annex III.
science, society, and the economy.\textsuperscript{19} The Commission clearly outlines that multiple perspectives must frame risk management: “scientific assessment alone cannot…provide all the information”.\textsuperscript{20} This means that the empirical data that frames the quantification of scientific certitude is in turn interpreted by interested parties with qualitative concerns. The decision of how to act is not technocratic. Jacques Delors when talking about food safety regulation on a European wide scale used the term “the culture of risk”.\textsuperscript{21} This is in line with the notion of collective preferences often spoken about by the Commission. It involves a pre-supposition that the EU polity is uniform and consistent, and that it can be represented. In this sense, the idea of protecting a people from risk no longer involves a mere scientific assessment. It becomes another symbolic element meant to reinforce this act of representation at the supra-national level.

There are several consequences in including the public during the initial risk management. In general, risk assessment done prematurely during the scientific process, i.e. when a procedure or product has been identified as being new and as having potential effects but little else has been concluded, potential risks can be inflated. As Olivier Godard puts it, preventative measures must be proportionate to both risks and potential \textit{benefits}. Furthermore, not all potential risks should be accorded the same weight and this too should affect the evaluation. Godard calls this type of risk management apocalyptic and reasons that the lack of proportionate consideration of plausible possibilities could


\footnotesize{\textsuperscript{21} Delors, Jacques. “Avant Propos”. In \textit{La Creation de l’autorite Alimentaire Europeene} by Francois Lafond. 2001.}
lead to economic and political crises. However, decision-makers are in a bind when it comes to instituting cautious health regulations and catering to the needs of the public. There has been a growing trend in public involvement leading to what can be termed the ‘abstention rule’ or what essentially involves the eradication of all risk. This is understandably borne out of a lack of trust; trust that was lost during events like the BSE crisis. A strong fear was tripped when an innocuous product had such ruinous effects. David Vogel names this ‘bind’ that decision-makers deal with another way: contested governance. Contested governance is an event that transcends the typical policy conflict that most sectors face. It is characterized by the deep and broad battle between stakeholders over the fundamental style of governance. In the case of food regulation, the existence of a valid scientific methodology is not sufficient to ensure public safety. The public demands of government something more, an extra element of man made protection. This is what the PP is meant to offer.

The Case of Genetically Modified Foods

Genetically Modified foods have been the source of a contentious trade debate between the EU and the US and Canada since the early nineties. Historically, the American FDA decided to approach GMOs as roughly on par with more conventionally produced foods and did not require special legislation. The EU, on the other hand, has consistently approached GMOs as a novel good and passed specific legislation dealing with it. As Grace Skogstad claims, this very early distinction of ‘novel’ was in part due to the influence of environmental groups. Furthermore, the DG responsible for the

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environment took over legislation in 1986. The Commission’s decision to authorize several types of bio-engineered maize resulted in several national Member States invoking the ‘safeguard clause’ and banning any imports. In 1999, a de facto moratorium was placed on all genetically modified products and only eventually replaced with less stringent measures in 2003. To date, GMOs in the EU are subject to compulsory traceability and packaging requirements, and a case-by-case approval process undertaken by the EFSA before they can be admitted into the market.

The divide between the EU and North America is more obvious for GMOs simply because other areas of biotechnology have seen a growing trans-Atlantic collaboration. The EU has participated in the joint EU-US task force on biotechnology since June 1990, and has funded over one billion euros of research between the years 2003 and 2004 alone. Three key projects that are being developed by the Commission include: the “NOFORISK” research project aimed at improving quantitative risk assessment methods to reduce scientific uncertainty, the “SAFEFOODERA” aimed at creating an open dialogue between producers and consumers, and the “SAFE FOODS” where new assessment criteria are created for new practices. The titles alone of the projects are very much in line with the rhetoric of the PP in the 2000 Communication. There seems to be a public relations aspect aimed at assuaging consumer fears but also with names like “NOFORISK” projecting a strategy of eradication of risk.

However, if one consults much of the literature that the Commission disseminates about bio-technology, the impetus for this type of restrictive regulation does not originate

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with them.\textsuperscript{25} The Commission, in concert with the Competitiveness in Biotechnology Advisory Group of Industry and Academia (CBAG), stresses that it is for Member States to implement the more stringent measures of traceability requirements and prior approval for GMO products. The semantics involved are interesting, however. The Commission was forced to regulate the industry with a pre-market type case-by-case approval of GMOs which is typically only done for \textit{a priori} goods like pharmaceuticals. The alternative was the over-regulation of the industry with individual ad-hoc Member-State bans. Throughout the document, the Commission stresses the recalcitrant bargaining position of the Member States in Council and their inability to pass their own legislation through qualified majority voting. The Report is essentially an admonishment to Member States arguing that they had better show greater willingness to collaborate. The heart of their criticism lies in the fact that Member States “demanded” these measures and therefore “subsequently committed themselves to them”.\textsuperscript{26}

The language of the Report is also rhetorically dramatically different from the few occasions that GMOs are mentioned in the 2000 Communication on the PP. Their right to impose ‘high levels of protection’ is not as eagerly stressed in the report. The prerogative of safety is replaced by more economic appraisals of costs and benefits. The Commission seems aware of the costs on a European scale of not competing with the US


in this emerging market. The benefits must accrue to individual Member States as they are the most active proselytizers for restrictive measures.

The Commission also makes it very clear that they have taken into account popular opinion. A 2006 Euro-Barometer makes it apparent that EU citizens do not greet GMOs in the same fashion as other forms of biotechnology. However, the Euro-barometer and the Report once again do not focus on protective regulatory measures. As the Report on biotechnology states: “Recent public analysis clearly suggests that consumer’s reluctance towards GMOs is caused not so much by perceived risks rather than the lack of perceived benefits”. The use of the PP therefore seems inappropriate. The PP is labeled as a tool for consumer protection not an instrument to cater to consumer perception. This makes one wonder whether it is appropriate to talk of European collective preferences for health and safety under the premise of a scientific regulatory system. It would seem that economic and consumer considerations rather than ones of health are the larger issue.

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CHAPTER THREE
PHARMACEUTICAL REGULATION

History

Drugs have historically been perceived as a unique good. Drug regulation predates post-materialist concerns about the environment and certainly ones over food safety. Their a priori distinction in the 2000 Communication differentiates it from other products like food products. The burden of proof is reversed. Decision-makers assume that a product is hazardous until the opposite is shown. This means that no public agitation is necessary to point out possible negative effects. From the initial step, the identification of potential risks, the process of risk analysis is very different for pharmaceutical regulation.

The perception of the deleterious effects of drugs crested significantly in both the US and the EU during the thalidomide crisis during the early 60’s. Thalidomide was formulated by a German company and used extensively throughout Europe and the US to treat morning sickness in pregnant women. Due to improper testing, its potential effects on the fetus were not discovered until tens of thousands of birth defects and possible abortive deaths resulted.28 Like in the case of BSE, the crisis demonstrated some clear breakdowns in governance. It reminded the public about the risks involved in

pharmaceuticals. Industrial self-regulation needed to be complemented by governmental intervention. This resulted in the creation of regulatory agencies with government mandates to be theoretically independent of the pharmaceutical industry. They were entrusted to maintain the balance between commercial interests and public health. These agencies were required to check the efficacy, safety and quality of new drugs on the market. A regimented procedure was also put into place in order to verify a firm’s scientific investigations consistently and accurately. The procedure followed as such: chemical and laboratory analysis, non-clinical pharmacology and animal toxicology, Phase I trials with health human volunteers, Phase II clinical trials with small numbers of patients, Phase III clinical trials with greater patient numbers, and Phase IV post-marketing pharmacovigilance. The use of individual case studies and anecdotal evidence by physicians was replaced. The use of clinical studies with larger survey populations allowed for statistical analysis and thus a more refined presentation/evaluation of the risks associated.

Risk Evaluation: national regulating authorities and the role of the EMEA

In the case of Europe, national authorities across the board developed very different approaches to pharmaceutical regulation. Many of the national agencies tended to reflect the style of governance particular to any one country. Germany, for instance, had a very paternalistic approach to regulation where the government felt it was its duty to impose strict restrictions on the industry. In Britain, commercial interests played a larger role in shaping regulatory institutions and government and industry maintained

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close contacts. The process of drug licensing was therefore streamlined in order to maximize profit incentives.\textsuperscript{30}

However, as a European space opened up, the custom’s union allowed for cross-border licensing of pharmaceuticals. Two policy effects were triggered. First, national authorities began to charge the pharmaceutical companies licensing fees in order to become self-sustaining. This meant that agencies began to have to compete with other national authorities in order to attract evaluation and licensing contracts. Models like the German case could not compete with more industrial friendly ones like the British agency. Different national models therefore converged. In countries like France, this meant that the Health Minister was no longer needed to even sign the approvals of new drugs. This became tell-tale of a new mode of regulation. Government was stepping aside in order to become more responsive to commercial interests. Thus, “[the] strictly scientific, [was] unburdened by economic considerations and protected from any discretionary intervention by official policymakers so as to guarantee its credibility”.\textsuperscript{31} These independent regulatory agencies, comprised of experts, convening with industrialists, were now in charge of undertaking the three staged process of risk assessment.

The second effect involved the creation of the European Medical Evaluating Agency (EMEA). When the European space for market approvals opened up, the European Federation of Pharmaceutical Industry Association took up office in London and Brussels to make the system work to their advantage. This has fundamentally shaped


the EMEA. The influential role of the pharmaceutical industry makes the EMEA’s initial claim that its creation was “firstly a benefit for the European patient” unlikely.\(^{32}\) The fact remains that approval systems needed to be improved as drug registrations slowed down, applications were increasing, and the requisite knowledge for decision-making became more scientific and technical.\(^{33}\) The EMEA’s priorities were to remedy these specific problems at the request of the pharmaceutical industry.

The EMEA was thus designed to act as an arbiter between competing national agencies. The process of European wide licensing currently requires one host Member country to evaluate a new drug, then a second Member State to either support or reject an approval in their country. If the second Member-State supports the approval, the drug can be marketed across the Union. If the second Member State rejects the approval then the EMEA appoints a third rapporteur Member State (unofficially the pharmaceutical client gets to choose) to arbitrate between the divergent opinions. Similar to the EFSA, the EMEA has the effect of harmonizing practices between Member States. No Member State wants to be identified as having radically divergent practices or gain the reputation of being overtly difficult. Unlike the EFSA, the EMEA can make binding decisions and this cuts down on time taken for litigation. This also means that the decision-making style of close collaboration between experts and industrialists is preserved on the supra-national level.

The evaluation process is greatly framed by the notion of ‘burden of proof’. The a priori distinction means that over time a sophisticated procedure for testing

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pharmaceuticals has evolved. There is a very clear and well established regiment for proving a drug’s safety and efficacy. If we recall, methodologies for testing food products, or non \textit{a priori} goods, are still inchoate. The EFSA is charged with solidifying these methods presently. However, as public perception plays a key role, products like GMOs can later be called on to prove that their goods are not dangerous. This belated burden of proof forces them to undertake voluntary research or wait on the EFSA and their network of labs to catch-up. Therefore, \textit{a priori} goods benefit oddly from their categorization as they are much better prepared to handle their own burden. They have a clear institutional road-map to follow, and can benefit from experts who have standardized means of testing. Furthermore, this burden of proof quickly shifts in the European market once one Member state gives its approval. Once the product is approved in one state, the second state must collect a large amount of data to be able to support a rejection.

Of course, profit margins further aid pharmaceutical companies to meet their charge. Ten years can pass between a discovery and licensing, with upwards of billions of dollars being spent to fund the necessary research. The cost of the entire testing phase and the loss of potential revenue from delays put extreme pressure on regulating agencies to cut down their times of approvals. Putting a new drug on the market is therefore quite risky, there always being a chance of rejection and wasted time and resources. However, the huge profit margins after hitting the market are the best incentive to force this kind of extensive preparatory groundwork. Beef importers and farmers are by no means small industries. They also mobilize a great number of resources and they have close links with government support. However, they do not enjoy the same economies of scale as
pharmaceutical industries. Their profit margins lack the hyperbole necessary to recuperate those types of prohibitive costs.

Risk Management

To begin with, the separation between assessors and managers does not exist in the same way as those who regulate food safety. Pharmaceutical regulation is a closed loop that does not ever devolve to the Commission or national health ministries. Furthermore, the public is not included at the outset of the process nor are they ever given the chance to become involved later. The risk evaluation involves pharmaceutical companies bringing their own data to independent authorities and meeting with experts. Their sophisticated data facilitates the risk management phase, perhaps constraining the anarchical element of scientific uncertainty to a more appreciable quantitative assessment. More importantly, however, the process allows for a close collaboration of experts and industry to decide what becomes a more technocratic and less political decision.

This close collaboration is part of the trend termed ‘the privatization of science’. This phenomenon is the exact opposite of the concurrent trend for food safety to publicize science. Perhaps as the thalidomide crisis is much older than the BSE crisis, government is less interested in regaining public trust in terms of pharmaceuticals. Furthermore, the thalidomide crisis predated the political emergence of the EU. Thus the supranational level did not have to be accountable to the public. This lack of public responsiveness continues to date.
The pharmaceutical industry’s ability to innovate has led to what are now called ‘blockbuster drugs’, i.e. drugs like Lipitor or Viagra. People have become accustomed to powerful medications improving a wide variety of ailments. Drug companies have in return seen their profit margins explode. This profit incentive has led to a stakeholder attitude towards knowledge where Intellectual Property restricts the access of information. This has led to research institutions either being performed by universities under strict confidentiality agreements or private research facilities becoming more prominent. Pharmaceutical companies have become the ‘owners’ of their data. This entails them being given the ability to select what materials they want published and/or patenting their discoveries so that others must pay to use their methods and products. Perhaps indicative of the lucrative nature of Intellectual Property and its importance for medicines, the European Patent Office is the only regulatory institution other than the EMEA to be able to make binding decisions.

If we consider this institutional arrangement and the process of risk evaluation and risk management, where exactly does the PP come into play in terms of pharmaceutical regulation? Perhaps, the best term used to describe the sphere of pharmaceutical regulation has been ‘entrepreneurial politics’. When regulating agencies compete with each other for self-sustaining fees, corporate attitudes transform applicant companies into consumers. To be noted, the EMEA derives the majority of its financing from fees as compared to the 15% of the FDA derived from industry. This has led to what the head


35 Ibid., pg. 137.
of the European Federation of Pharmaceutical Industries and Associations calls a “partnership” whereby it is “not a case of the regulator versus the regulated”.36

The case of innovative medicines and bio-engineered drugs

In its most basic form genetically engineered drugs have become a staple in health care provision since 1982. Insulin for treatment of patients suffering from diabetes was originally animal derived, however, the technology of bio-engineering allowed for synthetic versions to replace porcine ones. Presently, slightly less quotidian uses for bio-engineered drugs are slated for either continued research or even approval. Bio-pharmaceuticals, involving larger molecules of proteins, are being studied for targeting underlying mechanisms of diseases. Bio-engineered micro-organisms like modified versions of E.coli are also being tested for sources of antibiotics and insulin. The bio-drug Herceptin is the first of its kind with matching diagnostic tests to profile the genetic makeup of patients to be approved. The fact remains that more novel applications for bio-pharmaceuticals are set to be explored and implemented.

The Commission has begun to use the Lisbon Employment Strategy to frame their arguments pro-biotechnology. They claim there is a “recognized need” for bio-technology to help them reach their targeted goals of “economic growth, sustainable development and environmental preservation”37 With this aim in mind, the 7th R&D Framework has initiated several projects to facilitate research. The entire Framework has

36 Ross, W. “It’s no FDA-Maybe It Even Works a Little Better, an Interview with Brian P. Ager, Director General of the European Federation of Pharmaceutical Industry and Associations”. In Medical Marketing and Media 2000, 35 (8), pg. 61-7.

a budget of 50 billion euros for the year 2007 through to 2013. The perceived need for these strategies was great enough that the 7th Framework received a 150% increase from the budget of the 6th Framework.

Due to the constraints placed on GMOs by Member States, the 7th Framework focuses largely on improving research and production in the pharmaceutical industry. The 7th Framework outlines two distinct approaches. The first one involves introducing a type of “risk-sharing finance facility”. In layman’s terms this means a funding project undertaken by both private and public stakeholders. The project, termed the Joint Technology Initiative on Innovative Medicines (IMI JTI), will be co-funded by the European Federation of Pharmaceutical Industry Association and is meant to “reinvigorate the industry”. The implications of this co-financing involve reinforcing the relationship between regulators and those who are regulated. Once again, the governing style is entrepreneurial politics. Costs and revenue dictate a type of relationship that is not conducive towards public participation. The gaps between regulators and industry are being tightened, not widened by civic participation.

This proclivity towards industry is confirmed by the second goal. The Commission, along with the Competitiveness in Biotechnology Advisory Group (CBAG), is advising that regulators need to streamline the approval process.

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Deregulation is outlined as a major priority, in order to remove barriers to competition for Small to Medium Enterprises (SMEs). The 7th Framework is meant to focus on ways that the EMEA can become less costly, more efficient, and give faster approval times: “It should ensure the maximum utilization of research results and data, and rapid uptake into industrial, clinical and regulatory practice.”\(^\text{41}\) The Commission includes the note that faster approval times will also benefit European patients in terms of better access to medicines. However, the fact that the entire project is framed by the Lisbon Agenda means that ways for improving competitiveness are meant to be the main priorities.

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I would like to frame this concluding section with one initial personal impression. Over the course of studying both food and pharmaceutical regulation within the EU, it seems remarkable that the two are very rarely discussed together in the lengths of journal articles, books, or legislative/government documents. This is not the case for the American situation where both types of regulatory capabilities are routinely discussed within the framework of the Food and Drug Administration. For the European geopolitical space, the academic and theoretical tendency to separate the two seems logical.

As this thesis shows, the two sectors engender different stakeholder attitudes and institutional responses. The regulation of food safety is very much oriented towards the public. Its criteria for openness and transparency in order to facilitate democratic civic participation means that regulators are required to flex their political muscles. They cannot engage in technocratic, elitist, and opaque decision-making. The EFSA reflects this type of governance style. Pharmaceutical regulation has purposefully evaded this type of civic activity. National regulating authorities and the EMEA have endeavored to maintain close connections with the pharmaceutical industry. The fact that national regulating agencies collect licensing fees from pharmaceutical companies means that this type of governance style can accurately be termed ‘entrepreneurial politics’.
These differences in styles have meant that academics, bureaucrats, and politicians tend to deal with each system of regulation as being separate. The trend towards separating the two makes the 2000 Communication’s attempt to link them singular and note-worthy.

Perhaps we need consider the historical context of the Communication of seven years ago to better understand its underlying motivations. Periodicals describe how it was politically advantageous for European officials, for example Romano Prodi as Commission President, to promise strong, proactive, and concerted health regulation. The 2000 Communication could be therefore considered to have been a road-map or a declaration of intentions on the part of the EU Commission. However, the rhetoric of political promise is belied by the fact that the two regulatory schemes were on two different strategic tracks. While both were meant to meld the fields of science and policy, one has led to the ‘publicization’ of science and the other the privatization. The 2000 Communication at no point interrupted this divergence. It in fact encouraged the split by creating the legal wherewithal to open the debate for food safety, and failing to do so for pharmaceutical regulation.

By way of the two case studies, bio-technology seemingly exposes the root of a contradictory health regulatory policy. Clearly, divergent visions for different sectors exist. It makes one question what is the problematic part of biotechnology: the process or the product? Clearly, the process is heralded as being potentially lucrative and advantageous. However, it is not simple enough to say the product is the problem either. A cold empirical and scientific analysis has not alluded to any negative side effects for GMOs, as of yet. A cultural factor, where ‘collective’ preferences are constantly referred to, is at play. Furthermore, the language of legislation for GMOs has a cost vs. benefit
component. The economic terms certainly detract from the scientific aspects of risk analysis. Within trinity of stakeholders, society, the economy and science, who is the protagonist and who is the bit player? It is tempting to say that the economy wins out. As the Third Annual report states, it is about consumer perception and not protection. The lack of clear benefits is more salient than the existence of potential risks. It is appropriate to question whether the PP is just a guise to do a cost vs. benefit analysis without tripping the ‘protectionist’ flag.

For pharmaceuticals, the opposite can be said. The industry, including the emerging biotechnology contingent, is rapidly growing and one of its main supporters is the Commission. As during the initial creation of the EMEA, this rapid growth cannot come at the price of appearing to forsake consumer protection. However, ties between industry and government are quickly becoming closer, and are doing so at the behest of ambitious and well-funded research strategies. It is clear that the societal stakeholders do not have an overriding influence.

An interesting implication to this debate over EU health regulation is the future of the biotechnology field. I would contest the assertion that “the European dispute over GM foods may establish a precedent for how societies will debate and regulate novel technologies that present complex ethical and scientific questions”.

The presently divergent practices give a prescient indicator that one cannot generalize about emerging biotechnologies and, secondly, that these two sectors do not seem likely to ever converge. Furthermore, these practices are institutionally enshrined and, in the absence of another great policy ‘triggering’ event, are unlikely to change.

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Finally, we are left with the matter of the PP. The ability of the Commission to
promulgate its use of the Precautionary Principle is a source of contention. Its degree of
success as a domestic PR tactic to assuage the citizenry of their ‘high level of protection’
has not been studied. Certainly, the millennium cry for a fortress-Health Europe has not
been met. Whether any regret that fact presently also remains to be studied. Whether the
2000 Communication meant to seriously link together the divergent sectors of food safety
and pharmaceutical regulation is also unknown. Clearly, international audiences are not
convinced about the appropriateness of the PP as a legislative tool. With this in mind, the
PP as a policy approach has not created strong concerted health policy.


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