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After "the Regulatory Moment" in Comparative Regulatory Studies: Modeling the Early Stages of Regulatory Life Cycles

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After "the Regulatory Moment" in Comparative Regulatory Studies: Modeling the Early Stages of Regulatory Life Cycles

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ABSTRACT *Regulation has been the subject of a significant amount of scholarship, mostly debating the necessity of regulatory action or examining the phenomenon of capture. Less attention has been paid to the early stages of regulatory development, during which the structure of the regime is defined. By revisiting the life-cycle analogy of regulation first proposed by Bernstein in 1955, we offer a new model that explains the development of these early stages in greater depth. This model is then applied to case studies of several sectors in the US and UK to highlight the general pattern of early regulatory regime development.*

Introduction

Regulation of private markets has been the subject of a significant amount of academic scholarship, mostly aimed at arguing whether or not regulation should be employed in the first place (e.g. Demsetz 1968) or examining the mature stages of a regulatory body in which regulators have been "captured" by the industry they were intended to control (e.g. Dal Bo 2006). Much less attention has been paid to the early stages of the development of a regulatory regime, including the circumstances leading to the formation of a regulatory agency, as regulatory standards develop in a specific sector or issue area. While narratives have been drawn to describe specific instances or areas of regulatory activity (e.g. Bernauer 2003; Carpenter 2010), attempts to derive a general pattern of early regulatory development, such as that undertaken by Eisner (1994), have been less common.

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This article proceeds in two parts. First, we re-examine the life-cycle model of regulatory development first proposed by Bernstein (1955) in his classic text on independent regulatory commissions. After considering later and more recent scholarship on patterns of regulatory development, we propose a new model that is better able to explain the early stages of regulatory activity. Second, several cases of American and British regulation from the existing secondary literature are investigated, in order to illustrate the model's applicability. We find that a genealogical model such as the one proposed here not only provides an accurate description of the critical early stages of regulatory regimes development but also helps enable researchers to more effectively tackle key questions like what drives movement through the process, and why different areas move at different speeds in their regulatory development.

The Temporal Dimension in Regulatory Activity

Regulation can be used in a virtually limitless variety of sectors and can take on many forms, some of which appear quite different. Regulation can come directly from government, from a designated government agency, from an independent commission, or even from a trade association, as has been the case with prisons in the US (Lilly and Knepper 1993). There are voluntary regulatory regimes with no legally binding rules (Whitford and Tucker 2012), regimes with activist government regulators who are eager to create new rules (Bamberger and Mulligan 2011), and regimes in which industry benefits from a captured regulator (Croucher 2011).

Our concern here is with public sector regulation. This can be usefully defined as "a process or activity in which government requires or proscribes certain activities or behavior on the part of individuals and institutions, mostly private but sometimes public, and does so through a continuing administrative process, generally through specially designated regulatory agencies" (Reagan 1987: 17). In this view, regulation is a prescription by the government, which must be complied with by the intended targets; failure to do so usually involves a penalty, sometimes financial but also often involving possible incarceration. While some regulations are laws enforced by the police and judicial system, most regulations are administrative edicts created under the terms of enabling legislation and administered on a continuing basis by a government department or a specialized, quasi-judicial government agency (Rosenbloom 2007).

Regulations generally evolve into "regimes" in which sets of practices and roles are routinized and institutionalized. According to Eisner (1994), this application of the term "regime" to regulatory activity is intended to convey the same sense that it carries in international relations theory: "implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations converge in a given area" (Krasner 1982: 186). A regulatory regime is an institutionalized (though not necessarily codified) set of behaviors on the part of regulators and industry in which actors understand the rules and abide by them.

Given the numerous configurations that regulatory regimes can take, it would not be surprising to find that each regime was somewhat idiosyncratic. Certainly national governments have the capacity to exert some control, and political cultures and similar variables may dictate regulatory policy to some extent, producing different results in different countries and in sectors within countries leading to distinct national styles of regulation (Fligstein 1996; Lindblom 1977; Burgess 2002). However, many studies have found that different countries adopt similar types of

regulation, resulting in theories of regulatory convergence (Holzinger et al. 2008) where regulatory practices are seen to converge across sectors, such as banking or steel production, and are not unique to particular countries (Majone 1999; Bovens et al. 2001).

This question of divergence and convergence in regulatory regimes is a subject of ongoing research. This has intensified in recent years as states must contend with the forces of globalization, which puts pressure on governments to produce similar regulatory regimes in some sectors (Cerny 1999: 16) and has no doubt led to some flattening of regulatory variation. However even the different regulatory arrangements found in specific countries can be thought of as existing as variations on the attributes of more general regulatory forms. That is, even if they might start for different reasons, different countries often proceed to regulate different sectors and activities in such a way that their regimes become lagged copies of each other (Majone 1999; Hills and Michalis 2000; Garcia-Murillo 2005).

This suggests that the temporal dimension involved in regulation may in fact be as important as, if not more important than, spatial criteria in understanding regime evolution and a long-standing tradition in regulatory studies has adopted this approach to the understanding of regulatory regimes and their trajectories. In his pathbreaking 1955 work, *Regulating Business by Independent Commission*, for example, Marver Bernstein noted the significance of time in the process of regulatory development and suggested that regulatory agencies, regardless of the nature of the activity they regulated, tend to follow a set pattern of evolution or life-cycle, one which roughly parallels a human life, with distinct stages identifiable by age (Bernstein 1955).

Bernstein (1955: 74–95) postulated that regulatory regimes go through four distinct phases: *gestation*, in which a public problem is first perceived by its relevant stakeholders, and organized advocacy for a solution begins; *youth*, in which an activist, autonomous, regulatory body will struggle to define its powers and jurisdiction amid legal opposition from industry groups; *maturity*, where a stable regime emerges whose powers and duties are agreed upon by all sides and in which the autonomous regulatory body acts mechanically as a tribunal of the regime; and *old age*, when an industry has fully captured the regime and the regulatory body's main role is to fight to retain the status quo. In Bernstein's model, the creation of an independent regulatory body occurs between gestation and youth, and regulatory capture marks the passage from maturity to old age (see Figure 1).

Some stages of Bernstein's regulatory regime life-cycle have been well-explored, while others have not. The moment of regulatory birth, for example, has been examined in studies focusing on the question of whose interests were served by the creation of a particular regulatory regime (Stigler 1971, 1975). Similarly, the stage of maturity has been examined by scholars of issues such as regulatory capture and the role of the judiciary in regulatory review (e.g. May and Winter 1999; McGarity 2001). The stages of regulatory decline have also been analyzed in works focusing on policy termination (Bardach 1976; deLeon 1983; Lewis 2002) or de-regulation (Derthick and Quirk 1985; Collier 1998; Lazer and Mayer-Schonberger 2002).

However, the immediate period between what Bernstein termed "gestation" and "maturity" – or what he called the "youth" phase of regulatory regime development – remains very much underexplored. This is a critical period, however, in which the agencies and rules which go on to comprise an often very long-lasting mature regime are created and put into place. As this article argues, understanding mature regime

Figure 1. Bernstein's genealogical model of regulatory regimes (1955).

Stage	Summary of Activity
Gestation	Problems are discovered or perceived by specific stakeholders in a particular area. Advocacy groups organize and petition government for a public solution.
Regulatory agency created by government	
Youth	Boundaries of regulation and legal jurisdiction are not clear; regulation is probably ineffective.
Maturity	Controversies are over. Regulation becomes institutionalized.
Regulatory capture occurs	
Old Age	Industry has fully captured regime. Regulatory agency exclusively fights for the status quo.

processes, as well as subsequent actions such as de- and re-regulation, requires an understanding of the forces and processes at work in these early stages of regime development immediately following the initial "regulatory moment" of regime creation.

Towards an Improved Model of Early Regulatory Regime Development

While Bernstein's model may provide a fairly accurate depiction of the typical overall trajectory of a regulatory agency's lifespan, it is inadequate in two ways: first, the model does not explain why a regulatory regime will pass from one stage to the next; and, second, Bernstein's own work concentrated heavily on the stages of maturity and old age, leaving gestation and youth relatively vague. The description of the activities involved in these stages in Bernstein's model is very general and provides little detail on this critical early period of a regime's evolution.

Fortunately some empirical work by observers and practitioners involved in several different countries in the very early stages of regulatory regime evolution in several issue areas, such as the emergence of environmental regulation in the 1960s and 1970s, does exist. This work can be used to develop a more detailed and robust description of the youthful stage of regulatory development. With a better model of the stages of development, as well, the nature of the forces driving a regulatory regime through the various stages become more apparent, as does the content of the stages themselves.

Drawing on their own experiences as regulators in the UK, for example, Otway and Ravetz (1984) proposed a three-stage model of the formation of a regulatory regime, suggesting it proceeded in a more or less linear fashion from the recognition of a hazard, through the development of some limit values or standards for hazard mitigation, and finally to the implementation of these standards. In this model, the various stages are defined in terms of specific kinds of regulatory activity, from collecting data to monitoring hazard occurrence and, finally, to the preparation of codes, implementation of inspections, and enforcement. The birth of a regulatory regime is equated with the identification of a hazard – itself a process which may take some time. The model then centers upon the creation and implementation of

standards to deal with a hazard or risk as the essence of early regulatory activity. This is an improvement over the previous model, in which the boundaries between stages may seem somewhat arbitrary by comparison.

Otway and Ravetz (1984), however, say little about the specific activities which take place in the critical middle "technical" stage of standard development following the identification of a hazard. In his work on toxic chemical risk regulation in Canada, Leiss (2001) argued that this stage could easily last 10–15 years and could involve several distinct activities. In his own version of a model of early regime development, Leiss argued that the technical period, in which permanent risk management standards are sought, can be divided into an early stage of general uncertainty and a middle stage of competitive lobbying from interest groups once more complete scientific data has become available.

Howlett and Migone (2012), based on work such as Borraz (2007a, 2007b), identified an additional component in the earliest stage of development, in which regulators attempt to adapt existing legislation and exhort industry to comply with voluntary measures.

We can combine the Bernstein-type genealogical labels with the additional stages and activities identified by Leiss (2001), Otway and Ravetz (1984), and Howlett and Migone (2012) to produce an improved life-cycle model of regulatory regime development. That is, Leiss' and Otway and Ravetz's work can be thought of as filling in the missing gaps between Bernstein's gestation and mature stages of development: to continue the genealogical metaphor, adding a stage of "childhood" missing in Bernstein's original formulation prior to his idea of a "youth" stage. To this Howlett and Migone add an "infancy" stage while, furthermore, this new model is enhanced by Leiss' and Otway and Ravetz's provision of additional detail on regulatory issues and activities at the youth stage (see Figure 2).

Figure 2. Revised model of the early stages of a regulatory regime life cycle.

Life Cycle Stage	Regulatory Activity
Gestation	Emergence of problem on the agenda as a threat, hazard or risk
	Public acknowledgement of issue
Infancy	Poor knowledge base
	Efforts at issue suppression
	Attempt to adapt existing statutes and rules to current problems
	Exhortation to encourage voluntary activity
Childhood	Desire to create new rules but no clear knowledge of what these rules/standards should be
	Large-scale research programs for hazard characterization and initial quantitative risk assessments
	Responding to lobbying
	Venue shopping
Youth	Smaller-scale, maintenance research
	Emergence of more direct, authoritative state regulation
	Development of standards
	Frozen issue frames
	Litigation

In this model it is expected that initial regulatory arrangements will undergo a number of changes prior to maturity, as a regime becomes more or less locked-in to the standards and processes developed in the pre-adult stages. In addition, the creation of an autonomous regulatory agency should occur within the childhood stage, as this is when more complete scientific evidence becomes available and initial demands for binding industrial standards become apparent.

There are several questions that arise from the above discussion. First, is the model valid as a generic picture of regime development across countries, sectors, and time periods? The purpose of modeling the early stages of regulation is to divine a general pattern of the development of regulatory regimes that transcends national borders and sectoral differences. Do regulatory regimes in different sectors and in different countries actually progress through the stages of development as predicted by this model?

Second, assuming that the stages are indeed generic and accurately described, can the forces that impel regulation through the stages described above be determined? In other words, is it possible to know why a particular regulatory regime would pass from one stage to another, and when?

Third, do all regulatory regimes pass through all stages? And do they do so at the same rates? Even with a general model, there is room for atypical behavior and attributes that are particular to specific regimes, and this may be where the national and sectoral differences found in some earlier work on regulation may come into play. In short, while the model may accurately and usefully predict the general pattern of development of a regulatory regime, it may not be able to account for temporal differences that are related to the idiosyncrasies of individual countries and industrial sectors.

In order to address these questions, seven cases of health and safety risk regulation in the US and UK will be examined. Because these case studies cover many different time periods in two separate jurisdictions, they help illustrate the general pattern outlined by the improved life-cycle model developed above and help answer some of the questions raised above.

Applying the Genealogical Approach to Early Regulatory Regime Development: Case Studies

Seven cases of health and safety risk regulation in the US and UK have been selected for investigation from the existing secondary literature. The US cases include regulation of prescription medication, automobile safety, polychlorinated biphenyls (PCBs), and genetically modified organisms (GMOs); the UK cases include food safety, occupational health and safety, and dangerous dogs. These cases cover a diversity of topics and time periods in two jurisdictions so as to maximize the evaluation of the generalizability of the model set out above.

First, the cases come from the US and UK, two jurisdictions in which regulation is currently and has historically been a popular and accepted policy instrument (Sunstein 1991: 609; Cuéllar 2005; Rothstein 2005). Therefore, the legal and constitutional mechanisms for instituting a regulatory regime ought to function fluidly in both of these countries, eliminating the complicating factors that would arise in the analysis of a jurisdiction that has used regulation less frequently or for a

shorter period of time. Moreover, although their legal systems are derived from a single common law tradition, the United States and United Kingdom have evolved very different legal structures which could produce divergent regulatory frameworks (Brewster and Goldsmith 2007). Thus, if the genealogical model can be shown to apply in both US and UK cases, it will have passed a significant hurdle of generalizability.

Second, these cases have been selected to cover a wide range of sectors and time periods. These cases run the gamut from health care to toxic substances to workplace safety, and an attempt has been made to represent as many areas of regulatory concern as possible. In addition, two of the cases (GMOs in the US and dangerous dogs in the UK) did not complete all the stages of regulation predicted by the model; these cases will thus add to the analysis of why regulatory regimes may, or may not, pass from one stage to the next.

In what follows the facts of each case are set out. The results of these case studies are then analyzed in a subsequent section.

US: Prescription Medication

Interest in the regulation of medication in the US began in the 1890s, when there was a growing concern that chemical additives to food products might have negative health effects. In order to enforce truth in product labeling and advertising for food and medicines, Congress enacted the Pure Food and Drug Act in 1906 (Temin 1985: 434). This set the stage for later regulation of medication (Schwartz and Goldberg 2005: 138).

From 1906 until the early 1930s, regulation of medicine was enforced through the 1906 Act, but it was not until 1930 that the US Food and Drug Administration (FDA) was created to enhance this activity. Even then, it had little power or responsibility until the Food, Drug and Cosmetic Act of 1938 (Schwartz and Goldberg 2005: 138). Throughout this period, as an increasing awareness of harmful food additives and medicines developed, the 1906 law had to be adapted to new regulatory situations. In 1937, after more than 100 people were fatally poisoned by "Elixir Sulfanilamide", the US federal government sued the manufacturer for mislabeling the product (Temin 1979; Carpenter 2010) – the only legal option available at the time, since there was no law that required manufacturers of medicines to test their products for toxicity (Schwartz and Goldberg 2005: 139).

Before 1938, although doctors could prescribe medication, a doctor's prescription was not required to purchase any kind of medicine. However, in 1938 the FDA was given the power to regulate drugs and it moved quickly to "sharply curtail self-medication and used an increasing proportion of its drug resources to enforce limitations thereafter" (Temin 1979: 97). After 1938, not only did manufacturers have to test for toxicity, but the FDA was also allowed to designate some drugs as prescription and others as over-the-counter (Schwartz and Goldberg 2005: 139).

In the 1940s the regulation of prescription drugs then entered a new phase of development, in which court decisions helped to shape the scope of the regulatory regime's powers. During this decade, the FDA attempted to prosecute pharmacies that were in violation of non-prescription drug regulation. One notable case (*US v.*

Sullivan) was decided by the US Supreme Court in 1948, and the court's decision – which favored the FDA – was written into law later that year (Temin 1979: 100).

US: Automobile Safety

Prior to 1950, it was very much accepted that deficiencies in skill or prudence of the driver were the real culprit in automobile crashes, and car manufacturers were not considered responsible in any way for the safe design or "crashworthiness" of vehicles (Claybrook and Bollier, 1985: 92; Mashaw and Harfst 1987). In the 1950s and 1960s, however, a growing perception emerged that manufacturers had some responsibility, and this was supported by some important court decisions in which car manufacturers were found responsible for damages resulting from collisions (Leonardi 2010: 257).

From the early 1960s onward, auto safety in the US existed as an area of self-regulation. Car manufacturers were encouraged to make automobiles safer, but ultimately it was left up to them and the market to do so. Safety packages were sold as optional upgrade items but were not very popular (Claybrook and Bollier 1985: 92–95). The need for manufactured vehicle safety standards was brought to the political agenda in these years, in part by the work of Connecticut senator Abraham Ribicoff (Mashaw and Harfst 1987).

Data emphasizing the seriousness of the hazard presented by automobile accidents, however, continued to grow. By 1965, 49,000 Americans were killed and 1.5 million more were injured annually in traffic accidents. Car accidents were the number one killer of people younger than 44 and had become the leading non-natural cause of death in the US (Claybrook and Bollier 1985: 95). This was representative of an upward trend in automobile fatalities and injuries that had occurred over previous years (Chirinko and Harper 1993: 270). This rise in car accidents, and the work of consumer advocates such as Ralph Nader to bring awareness to the issue of vehicle design safety (or the dire lack thereof), allowed the concept of enhanced regulation of automobile manufacturing to produce safer vehicles to become a politically salient idea. Ribicoff's congressional hearings and Nader's 1965 book on the unsafe designs of the Chevrolet Corvair culminated in the creation of the National Highway Traffic Safety Administration (NHTSA) in 1966, and the first set of industry regulations were handed down in 1968 (Peltzman 1975: 678; Claybrook and Bollier 1985: 96).

After 1968, the automobile industry settled into a period of judicial activity, when in 1968, for example, after the NHTSA had ruled that front seat headrests should be mandatory on all new cars, a manufacturer of headrest add-ons sued the regulatory agency on the grounds that this regulation would have a negative impact on their profitability. The NHTSA won in court and the ruling stood, opening the door for further vehicle safety action on the part of the NHTSA (Mashaw and Harfst 1987: 276).

US: PCBs

Polychlorinated biphenyls (PCBs) are a group of organic compounds that have a variety of industrial applications, mostly as stable and relatively inert chemical

lubricants. In the 1960s, the first scientific reports emerged about the dangers to humans and animals of exposure to PCBs (Cairns and Siegmund 1981). At this time the problem of PCB exposure, especially through environmental buildup via bioaccumulation, was acknowledged but no actions were taken (Ashford et al. 1985: 426; Ross 2004: 278).

Although the Environmental Protection Agency (EPA) was created in 1970, it lacked the legal authority to regulate PCBs until the enactment of the Toxic Substances Control Act in 1976. From 1970 to 1976 an infant regulatory regime existed which attempted to operate a system of voluntary self-regulation as it undertook to develop risk and hazard standards for toxic chemicals (Ashford et al. 1985: 432; Ross 2004). In the mid-1970s, the US Food and Drug Administration conducted a significant amount of scientific research on the hazards and exposure levels of PCBs, and regulatory efforts during this time included temporary recommendations rather than industry-wide regulation (Cairns and Siegmund 1981).

From 1976 to 1980, regulation was still under development as the EPA conducted serious scientific research and issued periodic guidelines for industry use. Memory of a major poisoning incident in Japan in 1968 (Ross 2004: 278) and several smaller incidents in the US enabled serious action to be taken as the emerging scientific data bolstered the perception of PCBs as a dangerous and environmentally persistent chemical (Cairns and Siegmund 1981). In 1979, the EPA banned the distribution of PCBs, and in 1980 prohibited its manufacture (Ashford et al. 1985: 432).

After the 1979/1980 ban, a series of legal actions in the early 1980s further defined the boundaries of the EPA's regulatory regime. This included the authority to regulate PCB disposal, even over local governments' objections to disposal sites in their municipalities (Trost 1989: 126–128; Florio 1995: 1356), as well as the constitutional authority to enforce its fines and penalties (Trost 1989: 133).

US: Genetically Modified Organisms

The first discussions of research into the health hazards of genetically modified organisms in the US were initiated by the National Institutes of Health between 1973 and 1976, but a consensus on a course of action did not emerge (McHughen and Smyth 2008). Until the early 1980s, the main government body that was tasked with monitoring GMO research was the National Institutes of Health's Recombinant DNA Advisory Committee, but it did not have any major regulatory responsibilities (Marden 2003: 737).

After an interest in the health risks of GMOs surfaced in the 1970s, however, the National Institutes of Health issued guidelines about what could and could not be released into the environment – but again, no legislation or regulation was enacted (Shapiro 1990: 13–14). This remained the case for some length of time. Only in 1984 was the Office of Science and Technology Policy given jurisdiction for potentially regulating GMOs, but even then it was decided that these biotechnology products should "be regulated under the existing web of federal statutory authority and regulation" (Marden 2003: 738).

At present, the FDA, the EPA, and the US Department of Agriculture all have jurisdiction to make rules regarding GMOs and genetically modified crops, but the

regulatory regime is content to use existing food and agriculture regulations, and voluntary action for this purpose remains the norm (Marden 2003).

UK: Food Safety

After many decades of growing scientific concern over food safety in the UK, not much had been done in terms of overall policy or centralized regulation (Lang et al. 2001: 539). Between 1960 and 1999, food safety policy in the UK was secret, highly politicized, and laden with institutionalized conflicts of interest, as many policy decisions were based on advice from companies it directly affected (Millstone and van Zwanenberg 2002). This was not a case of regulatory capture, as there was no autonomous regulatory body to be captured – food safety policy was directly controlled on an ad hoc basis throughout this time by the Ministry of Agriculture, Fisheries and Food (MAFF).

The situation came to a head in the decade-and-a-half after 1980, when a series of food scares garnered significant public attention. These included salmonella in British eggs, Listeria in British cheese, bottled water contaminated with benzene, and patulin in apple juice (Lang et al. 2001: 538; Krebs 2004: 394). In response to these events, MAFF set up a Food Safety Directorate in 1989 and a "Consumer Panel" in 1991 to deal with increased concern over food safety, but this did not result in significant policy changes. In 1996, MAFF made some further, but minor, reforms, such as requiring some of its expert advisors to declare their funding sources or shareholding links to companies in the food sector. However, these reforms "did not fundamentally alter the decision-making practices or the policy outcomes" in the area of food safety (Millstone and van Zwanenberg 2002: 601).

In 1996, Britain experienced by far its most significant food-related crisis since World War II. Although bovine spongiform encephalopathy (also called BSE or more familiarly "mad cow disease") had been identified earlier, in March of 1996 the UK government released a statement that the cattle disease was linked to the fatal variant Creutzfeldt-Jakob Disease in humans. More than 100 human deaths in the UK have been associated with variant Creutzfeldt-Jakob, and the crisis generated by the 1996 announcement resulted in the destruction of millions of farm animals and severe economic repercussions for Britain's farming industry (Gerodimos 2004: 914).

As a direct result of the BSE crisis, there was an immediate urge to create an independent food safety inspector or commission, neither of which yet existed in the UK (Millstone and van Zwanenberg 2002: 602). This occurred in 2000 when, after much public debate, the Food Standards Agency (FSA) was created by statute. The FSA, which is answerable directly to the health minister, immediately launched an ambitious program of enforcement, awareness, and funding scientific research that has resulted in a measurable reduction in food-related illnesses (Krebs 2004: 391).

UK: Occupational Health and Safety

Workplace safety in the UK was largely governed by nineteenth century laws until well after World War II. Even after the war, occupational safety rules and regulations were extremely ad hoc and decentralized. This resulted in ineffective policy, as reported workplace incidents continued to rise throughout this time. In the 1960s, there were

600–700 workplace deaths per year and 300,000 reported accidents per year in the UK (Beck and Woolfson 2000: 37). A growing concern for occupational safety led the government to strike the Robens Committee, which reported in 1972.

The Robens Report did not recommend the establishment of an independent regulatory agency to oversee occupational health and safety. In fact, it advocated fewer statutory rules and a more collaborative process whereby employers and employees could create individual workplace safety arrangements (James and Walters 2002). In spite of this, and probably in response to the demands of the organized labor movement (Beck and Woolfson 2002), minor reforms were attempted after the release of the report. In 1972, for example, the Department of the Environment created guidelines for industrial hazard control and disaster prevention, but they were non-binding and relied on "local planning authorities" – literally town councils with no formal technical expertise (Irwin et al. 1982: 262–263).

In 1974, a chemical processing plant in Flixborough, England exploded, killing 28 people and injuring 36 (Sadee et al. 1977). In direct response to the Flixborough incident, the UK government established the Health and Safety Executive to oversee workplace safety issues. This led to the creation of firm regulations, such as the 1978 rules requiring the registration for bulk storage of hazardous materials (Irwin et al. 1982) and the 1977 regulations governing worker representation at employer safety committees (James and Walters 2002). Both of these regulations were expanded in the early 1980s (Baxter 1986).

UK: Dangerous Dogs

A final case examines regulatory actions pertaining to dangerous breeds of dogs in the UK. Until the early 1990s, legislation related to keeping dogs as pets had remained unchanged since the nineteenth (and in the case of licensing, the eighteenth) century (Lodge and Hood 2002: 4). In the late 1980s, a small number of dog attacks across Western Europe were perceived by the British media to be linked to a proliferation of relatively new large dog breeds, especially the American pit bull terrier (Baldwin et al. 2000: 288; Lodge and Hood 2002). This led to the 1991 Dangerous Dogs Act, which restricts the sale of some breeds and requires certain conditions (like wearing a muzzle) when in public.

One major failing of the dangerous dog legislation is that no systematic scientific research had been conducted prior to its enactment (Hood et al. 1999: 156). This has produced a regime full of inconsistencies and loopholes, such as the absence of Rottweilers and German Shepherds from the list of proscribed dogs, even though these breeds were involved in several of the high-profile attacks that inspired the legislation (Baldwin et al. 2000). Furthermore, the Act does not require owners to license dogs or to report dog attacks (Hood and Rothstein 2001: 46), which raises questions about the law's enforceability. Not surprisingly, the Dangerous Dogs Act remains an isolated piece of legislation, and no independent regulatory agency has been created.

Analysis: Summary of Cases and Key Findings

The genealogical model of regulation proposed in this study comprises four early stages of development: gestation, in which a problem arises and is publicly acknowledged;

infancy, which is characterized by exhortations to voluntary regulation and attempts to adapt existing legislation; childhood, in which an independent regulatory body is created; and youth, in which a stable regime begins to establish itself. These stages can be applied to the facts of the seven cases detailed above.

The most prominent feature of the case analysis is that five of the seven cases conform very closely to the model. In the cases of prescription medication, auto safety, PCBs, food safety, and occupational health and safety, the regulatory regime was found to proceed through the model's stages in order. In all of these cases, public acknowledgment of the problem led to voluntary regulations and adaptive experimentation, which in turn led to the creation of an independent regulatory body, which then produced meaningful and enforceable regulation. In this sense it appears that the model has some validity.

More interestingly, it appears from all seven cases that the accumulation of scientific or statistical evidence is required to move from the gestation stage to infancy. For example, after ten years of research on the hazards of PCB exposure to humans, voluntary regulations were produced between 1970 and 1976. Likewise, documented statistics on workplace accidents in the UK and automotive deaths in the US led to voluntary regulations in both of those cases. Notably, inadequate data in the case of dangerous dogs in the UK failed to produce either a voluntary regime or adaptive use of existing legislation.

Similarly, all of the cases suggest that a public crisis, real or perceived, is necessary for the creation of an autonomous regulatory body. In the five cases named above, major public crises preceded – and directly influenced – the establishment of a regulatory agency. In the cases of GMOs in the US and dangerous dogs in the UK, no major crisis occurred and no regulatory agency was created. In other words, a major crisis was required for the regime to move from infancy to childhood. This result, in addition to the previous finding regarding scientific evidence, occurred in both the US and UK cases, and was independent of sector, which reinforces the idea that the genealogical model is independent of national and sectoral boundaries.

There are some differences between the cases as well. No single case spends the same length of time at each stage as any other case; in addition, none of the cases spends a uniform amount of time at each of its own stages. In other words, temporal considerations appear to be connected to the idiosyncrasies of the particular case, or possibly to exogenous forces such as international pressures. Thus, while the genealogical model applies in general across all the countries and sectors studied, the peculiarities of individual cases (including political culture, traditions, and legal or constitutional frameworks) can influence the time it takes a particular regime to progress to a further stage.

And lastly, the youth stage in the US is particularly marked by the use of litigation to fortify an emerging regulatory regime. In the UK cases, litigation was conspicuously absent. This suggests that legal action may not be a critical part of the youth stage as previously hypothesized.

Conclusion

Being aware of general patterns and drivers of regulatory trajectories is especially important for those faced with the social and policy challenges posed by scientific

and technologically innovative activity – for example, at the time of writing, new developments such as nanotechnology or synthetic biology (Bowman and Hodge 2007; Torgersen 2009). The genealogical model of regulation proposed here can help researchers and policy-makers anticipate the early stage developments that are necessary to produce a lasting and stable regulatory regime.

This model is not without its flaws. While the model does suggest a relatively linear path for the development of regulatory regimes, it cannot predict the length of time that a regime might spend at each stage (although it does identify the elements and events that are necessary for the regime to proceed to the next stage). The cases investigated in this study demonstrate that the idiosyncrasies of particular sectors or national settings may dictate these temporal aspects of regulation, and that this may account for the opinions in the established literature that regulation occurs in unique circumstances that are devoid of general patterns. This suggests that there is room within the life-cycle model for country and sector specific variations. However, the extent of these variations should not be exaggerated or mistaken.

References

Ashford, N. A., Ayers, C. and Stone, R. F., 1985, Using regulation to change the market for innovation. *Harvard Environmental Law Review*, **9**(2), pp. 419–466.

Baldwin, R., Hood, C. and Rothstein, H., 2000, Assessing the Dangerous Dogs Act: When does a regulatory law fail? *Public Law* (Summer 2000), pp. 282–305.

Bamberger, K. A. and Mulligan, D. K., 2011, Privacy on the books and on the ground. *Stanford Law Review*, **63**(2), pp. 247–316.

Bardach, E., 1976, Policy termination as a political process. *Policy Sciences*, **7**(2), pp. 123–131.

Baxter, P. J., 1986, From Flixborough to Bhopal: Is legislation enough? *British Journal of Industrial Medicine*, **43**(1), pp. 1–5.

Beck, M. and Woolfson, C., 2000, The regulation of health and safety in Britain: From old Labour to new Labour. *Industrial Relations Journal*, **31**(1), pp. 35–49.

Bernauer, T., 2003. *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton, NJ: Princeton University Press).

Bernstein, M. H., 1955, *Regulating Business by Independent Commission* (Princeton: Princeton University Press).

Borraz, O., 2007a, Risk as public problems. *Journal of Risk Research*, **10**(7), pp. 941–957.

Borraz, O., 2007b, Governing standards: The rise of standardization processes in France and in the EU. *Governance*, **20**(1), pp. 57–84.

Bovens, M., 't Hart, P. and Peters, B. G., 2001, Analysing governance success and failure in six European states, in: M.Bovens, P.'t Hart and B. G. Peters (Eds) *Success and Failure in Public Governance: A Comparative Analysis* (Cheltenham, UK and Northampton, MA: Edward Elgar), pp. 12–29.

Bowman, D. M. and Hodge, G. A., 2007, Nanotechnology and public interest dialogue: Some international observations. *Bulletin of Science, Technology & Society*, **27**(2), pp. 118–132.

Brewster, N. A. T. and Goldsmith, P. D., 2007, Legal systems, institutional environment, and food safety. *Agricultural Economics*, **36**(1), pp. 23–38.

Burgess, A., 2002, Comparing national responses to perceived health risks from mobile phone masts. *Health, Risk & Society*, **4**(2), pp. 175–188.

Cairns, T. and Siegmund, E. G., 1981, PCBs. Regulatory history and analytical problems. *Analytical Chemistry*, **53**(11), pp. 1183A–1193A.

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

Cerny, P. G., 1999, Globalization and the erosion of democracy. *European Journal of Political Research*, **36**(1), pp. 1–26.

Chirinko, R. S. and Harper, E. P., Jr., 1993, Buckle up or slow down? New estimates of offsetting behavior and their implications for automobile safety regulation. *Journal of Policy Analysis and Management*, **12**(2), pp. 270–296.

Claybrook, J. and Bollier, D., 1985, The hidden benefits of regulation: Disclosing the auto safety payoff. *Yale Journal on Regulation*, **3**, pp. 87–131.

Collier, U., 1998. *Deregulation in the European Union: Environmental Perspectives* (London: Routledge).

Croucher, M., 2011, Are energy efficiency standards within the electricity sector a form of regulatory capture? *Energy Policy*, **39**(6), pp. 3602–3604.

Cuéllar, M.-F., 2005, Rethinking regulatory democracy. *Administrative Law Review*, **57**, pp. 411–500.

Dal Bo, E., 2006, Regulatory capture: A review. *Oxford Review of Economic Policy*, **22**(2), pp. 203–225.

DeLeon, P., 1983, Policy evaluation and program termination. *Policy Studies Review*, **2**(4), pp. 631–647.

Demsetz, H., 1968, Why regulate utilities? *Journal of Law and Economics*, **11**(1), pp. 55–65.

Derthick, M. and Quirk, P. J., 1985, *The Politics of Deregulation* (Washington, DC: Brookings Institute).

Eisner, M. A., 1994, Discovering patterns in regulatory history: Continuity, change and regulatory regimes. *Journal of Policy History*, **6**(2), pp. 157–187.

Fligstein, N., 1996, Markets and politics: A political-cultural approach to market institutions. *American Sociological Review*, **61**(4), pp. 656–673.

Florio, J., 1995, Federalism issues related to the probable emergence of the Toxic Substances Control Act. *Maryland Law Review*, **54**, pp. 1354–1372.

Garcia-Murillo, M., 2005, Regulatory responses to convergence; Experience from four countries. *Info – The Journal of Policy, Regulation and Strategy for Telecommunications*, **7**(1), pp. 20–40.

Gerodimos, Roman, 2004, The UK BSE crisis as a failure of government. *Public Administration*, **82**(4), pp. 911–929.

Hills, J. and Michalis, M., 2000, Restructuring regulation: Technological convergence and European telecommunications and broadcasting markets. *Review of International Political Economy*, **7**(3), pp. 434–464.

Holzinger, K., Knill, C. and Sommerer, T., 2008, Environmental policy convergence: The impact of international harmonization, transnational communication, and regulatory competition. *International Organization*, **62**(4), pp. 553–587.

Hood, C. and Rothstein, H., 2001, Risk regulation under pressure: Problem solving or blame shifting? *Administration & Society*, **33**(1), pp. 21–53.

Hood, C., Rothstein, H. and Spackman, M., with Rees, J. and Baldwin, R., 1999, Explaining risk regulation regimes: Exploring the "minimal feasible response" hypothesis. *Health, Risk & Society*, **1**(2), pp. 151–166.

Howlett, M. and Migone, A., 2012, Regulatory life cycles and comparative biotechnology regulation: Analyzing regulatory regimes in space and time, in: M. Howlettand, D. Laycock (Eds) *Regulating Next Generation Agri-Food Biotechnologies Lessons from European, North American and Asian Experiences* (London: Routledge), pp. 49–72.

Irwin, A., Smith, D. and Griffith, R., 1982, Risk analysis and public policy for major hazards. *Physics in Technology*, **13**, pp. 258–265.

James, P. and Walters, D., 2002, Worker representation in health and safety: Options for regulatory reform. *Industrial Relations Journal*, **33**(2), pp. 141–156.

Krasner, S. D., 1982, Structural causes and regime consequences: Regimes as intervening variables. *International Organization*, **36**(2), pp. 185–205.

Krebs, J., 2004, Establishing a single, independent food standards agency: The United Kingdom's experience. *Food and Drug Law Journal*, **59**, pp. 387–397.

Lang, T., Barling, D. and Caraher, M., 2001, Food, social policy and the environment: Towards a new model. *Social Policy and Administration*, **35**(5), pp. 538–558.

Lazer, D. and Mayer-Schonberger, V., 2002, Governing networks: Telecommunication deregulation in Europe and the United States. *Brooklyn Journal of International Law*, **3**, pp. 820–851.

Leiss, W., 2001, *In the Chamber of Risks: Understanding Risk Controversies* (McGill-Queen's University Press).

Leonardi, P. M., 2010, From road to lab to math: The co-evolution of technological, regulatory, and organizational innovations for automotive crash testing. *Social Studies of Science*, **40**(2), pp. 243–274.

Lewis, D. E., 2002, The politics of agency termination: Confronting the myth of agency immortality. *The Journal of Politics*, **64**(1), pp. 89–107.

Lilly, J. R. and Knepper, P., 1993, The corrections-commercial complex. *Crime and Delinquency*, **39**(2), pp. 150–166.
Lindblom, C. E., 1977, *Politics and Markets: The World's Political Economic Systems* (New York: Basic Books).
Lodge, M. and Hood, C., 2002, Pavlovian policy responses to media feeding frenzies? Dangerous dogs regulation in comparative perspective. *Journal of Contingencies and Crisis Management*, **10**(1), pp. 1–13.
Majone, G., 1999, Regulation in comparative perspective. *Journal of Comparative Policy Analysis: Research and Practice*, **1**(3), pp. 309–324.
Marden, E., 2003, Risk and regulation: US regulatory policy on genetically modified food and agriculture. *Boston College Law Review*, **44**, 733–787.
Mashaw, J. L. and Harfst, D. L., 1987, Regulation and legal culture: The case of motor vehicle safety. *Yale Journal on Regulation*, **4**, pp. 257–316.
May, P. J. and Winter, S. C., 1999, Regulatory enforcement and compliance: Examining Danish agro-environmental policy. *Journal of Policy Analysis and Management*, **18**, pp. 625–651.
McGarity, T. O., 2001, Politics by other means: Law, science, and policy in EPA's implementation of the Food Quality Protection Act. *Administrative Law Review*, **53, p**. 103–222.
McHughen, A. and Smyth, S., 2008, US regulatory system for genetically modified [genetically modified organism (GMO), rDNA or transgenic] crop cultivars. *Plant Biotechnology Journal*, **6**, pp. 2–12.
Millstone, E. and van Zwanenberg, P., 2002, The evolution of food safety policy-making institutions in the UK, EU and codex alimentarius. *Social Policy and Administration*, **36**(6), pp. 593–609.
Moran, M., 2001, The rise of the regulatory state in Britain. *Parliamentary Affairs*, **54**, pp. 19–34.
Otway, H. and Ravetz, J., 1984, On the regulation of technology: Examining the linear model. *Futures*, **16**(3), pp. 217–232.
Peltzman, S., 1975, The effects of automobile safety regulation. *Journal of Political Economy*, **83**(4), pp. 677–725.
Reagan, M. D., 1987, *Regulation: The Politics of Policy* (Boston: Little, Brown and Company).
Rosenbloom, D. H., 2007, Administrative law and regulation, in: J. Rabin, W. B. Hildreth and G. J. Miller (Eds) *Handbook of Public Administration* (London: CRC Taylor & Francis), pp. 635–696.
Ross, G., 2004, The public health implications of polychlorinated biphenyls (PCBs) in the environment. *Ecotoxicology and Environmental Safety*, **59**, pp. 275–291.
Rothstein, H., 2005, Escaping the regulatory net: Why regulatory reform can fail consumers. *Law and Policy*, **27**(4), pp. 520–548.
Sadee, C., Samuels, D. E. and O'Brien, T. P., 1977, The characteristics of the explosion of cyclohexane at the Nypro (UK) Flixborough plant on 1st June 1974. *Journal of Occupational Accidents*, **1**, pp. 203–235.
Schwartz, V. E. and Goldberg, P., 2005, A prescription for drug liability and regulation. *Oklahoma Law Review*, **58**(2), pp. 135–178.
Shapiro, S. A., 1990, Biotechnology and the design of regulation. *Ecology Law Quarterly*, **17**, 1–70.
Stigler, G. J., 1971, The theory of economic regulation. *Bell Journal of Economics and Management Science*, **3**(1), pp. 3–18.
Stigler, G. J., 1975, *The Citizen and the State: Essays on Regulation* (Chicago: University of Chicago Press).
Sunstein, C. R., 1991, Administrative substance. *Duke Law Journal*, **3**, pp. 607–646.
Temin, P., 1979, The origin of compulsory drug prescriptions. *Journal of Law and Economics*, **22**(1), pp. 91–105.
Temin, P., 1985, Government actions in times of crisis: Lessons from the history of drug regulation. *Journal of Social History*, **18**(3), pp. 433–438.
Torgersen, H., 2009, Synthetic biology in society: Learning from past experience? *Systems and Synthetic Biology*, **3**(1–4), pp. 9–17.
Trost, M. W., 1989, The regulation of polychlorinated biphenyls under the Toxic Substances Control Act. *Air Force Law Review*, **31**, pp. 117–135.
Whitford, A. B. and Tucker, J. A., 2012, Focal points in public policy: Evidence from voluntary regulation. *Review of Policy Research*, **29**(2), pp. 281–299.