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Market-Making and Regulation-Making: Crisis and Opportunity in Regulatory Regime Development

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Market-Making and Regulation-Making: Crisis and Opportunity in Regulatory Regime Development

Michael Howlett[1]

ABSTRACT*: Understanding the nature and origins of developing or immature regulatory regimes is of interest to students of market construction. The paper argues that this aspect of regulatory behaviour can be approached by applying the notion of regulatory life cycles developed over 55 years ago by Marver Bernstein to the area of new regulatory regimes. Drawing on the work of Leiss, Otway and Ravetz, and Hood and Rothstein and their colleagues, the paper develops a framework for analysing the activities of 'infant' or 'juvenile' regulatory regimes. The framework, based on clearer specification of the nature of the tasks, issues and techniques faced and followed, by regulators immediately after the birth of a regulatory agency or program, helps us to understand the range of possible variations in regulatory regimes, the factors driving their evolution and development, and the process through which they evolve towards maturity.*

Introduction: building markets and the role of regulatory agencies therein

Markets are network-like exchange arrangements of buyers and sellers that sometimes emerge in a quasi-naturalistic, autopoetic form (Ouchi 1980). At other times, however, they can be much more consciously designed and constructed entities (Hula 1988; Cantor et al 1992). Regardless of their origin, however, except for small-scale local arrangements, these kinds of market-type exchange networks require government assistance in order to survive and expand (Lindblom 1977; Fligstein 1996). This assistance ranges from the 'minimal' state involved in the protection of property rights favoured by classical political economists (Dobb 1973) to more sophisticated state leadership in the creation of property rights and their exchange – most notably in recent eras involving such high profile cases such as the development of various market-based emissions trading rights schemes (Mandell 2008; Voss 2007). Even "black" or illegal markets attain their status thanks to government prohibitions or price controls on some goods or services which serve to increase the returns accruing to their suppliers (Boulding 1947).

This means that markets and regulation are in no way antithetical categories of phenomena, *a priori*, but rather, as a range of social theorists from Adam Smith (2010) to Karl Polanyi (2001) have argued, go hand in hand; lest products are exchanged which sellers do not own, buyers fail to pay for goods and services they secure, or receive goods with characteristics they neither expect nor desire (Kahn 1970). This does not mean that all

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government regulation is by definition beneficial to business, or that all existing or historical economic regulation is helpful and required for markets to function effectively; only that some minimal level of property rights and goods and services regulation is necessary for markets to function at all and that, in many cases, the government's efforts which go into the creation and regulation of markets is much more extensive than often assumed or alleged (Cantor et al 1992).

Terms often used to describe government-market interactions such as government 'interference' in the economy or state 'intervention' are inherently misleading and have no historical, or present day, reality behind them (Freeman 1989). But that having been said, what is the 'proper', or optimal, role of the state in the economy, or to put it another way, of government regulation in the market? As the papers at this conference and in this project have noted, this question can be answered from two different perspectives: one, involving state action involved in the creation of markets or "*market making*", and the other, their actions following the initial moment of conception or "*regulation-making*".

Most of the papers prepared for this workshop, quite properly in a project on "Creating Markets in Asia", deal with the former situation – that is, "market-making" or the kinds of activities found where state actions *precede* the creation of market exchange arrangements. Such activity can take a number of forms. It includes those actions to secure the environment, or setting, in which exchange relations take place - involving such activities as the establishment of legal and policing systems, and an environment of peace and stability for production and consumption - but also more specific 'market-forcing' actions such as when public organisational forms are extended to new forms of economic exchange. Examples of the latter include when governments used public enterprises to create airline services for international mail delivery (Tupper 1979) or for the installation of communications and other kinds of infrastructure which would later be turned over to the "private sector" (Laux and Molot 1988); or when public university-based, or research council-based, research and development clusters are used to lead research work in emerging areas (such as solid state electronics and biotechnologies in the present era), which are later used found many private consumer or industrial product and service-based companies in these areas (Roessner 1988). They also extend, more commonly, to the use of extensive public sector procurement budgets, or the grant of service monopolies, or price guarantees to create markets for capital intensive technology-driven industries such as armaments or railway construction or, in the contemporary period, wind and other forms of non-carbon intensive energy production (Traves 1979; Rolfstam 2009; Badcock and Lenzen 2010).

These are all instances of policy designs for market creation which deserve closer scrutiny and inquiry in order to determine best practices in terms of institutions and rules which can be adopted from other countries' experiences to the Asian context (Howlett 2011). However this paper is not about market-making so much as it is about the second situation, or "*regulation-making*", whereby governments actions do not precede but rather *postdate* market creation, establishing new regulatory arrangements which are expected to allow already existing markets to grow and flourish. This is the realm of much traditional economic regulation in which states prohibit certain socio-economic practices and promote other ones in order to allow market actors to continue to profit from the sale of their goods and services (Salamon 2002).

Surprisingly, not a lot is known about key processes of regulation-making. Although a great deal has been written on economic regulation – usually from the standpoint of welfare economics which promotes the idea of justifying limited state 'intervention' in markets only to deal with very specific cases of 'market failures' (Kleiman and Teles 2006; Dollery and Wallis 1999) – most work takes the existence of relatively mature regulatory agencies for granted, and deals with the interaction between these relatively long-established regulatory agencies and the industries and activities they regulate (Clifton et al 2011).

But, understanding processes of regulatory development is crucial for new states and for those who wish to avoid mistakes made in the past which may have resulted in sub-optimal, either over- or under-regulation once the moment of regulatory creation has passed (Mashaw 1988). This paper examines a range of new writings on regulatory history in order to piece together a stages theory of regulatory evolution and the reasons regimes move from one stage to the next (see for example the excellent range of new historical writings on the subject such as Carpenter 2010, Law 2003; or Law and Libecap 2004). In doing so, it draws extensively upon, and refines, the early work by Marver Bernstein (1955) that first suggested the existence of a 'regulatory life cycle' and specifies a number of distinct stages that regulatory regimes pass through between 'birth' and 'death'. It suggests that 'regulation-making' moves in fits and starts as periodic crises provide opportunities for the expansion and institutionalisation of regulatory arrangements, but in a predictable set of steps as governments, generally, continually try to enact what Hood and his colleagues have termed "the minimum feasible" set of regulations in the context of changing sets of circumstances which periodically alters definitions about what is 'feasible' (Hood et al 1999).

Spatial and temporal variations in comparative regulatory regimes

The examination of regulatory regimes begins with the observation that the use of the coercive power of the state to achieve government goals through the control, or alteration, of societal (and governmental) behaviour is the essence of many common types of governing instruments, especially regulation (Hood 1986; Howlett 2011). There are numerous definitions of regulation, but a good general one defines it as 'a process or activity in which government requires or proscribes certain activities or behaviour 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). Thus, in this view, regulation is a prescription by the government, which must be complied with by the intended targets; and, failure to do so usually involves a penalty, sometimes financial but also often involving possible incarceration.

In general, all types of regulations involve the promulgation of more or less binding rules, which circumscribe or otherwise attempt to alter the behaviour of particular target groups (Kiviniemi 1986; Mitnick 1980:7). Rules take various forms and include such elements as standards, permits, prohibition, and executive orders. 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 specialised, quasi-judicial government agency (Rosenbloom 2007).

This type of regulation is very common in both social and economic spheres. In social areas it is used to encourage 'virtues' and discourage 'vices', however those are defined. Thus criminal law, for example, is a kind of regulatory activity, as are common laws and civil codes, which all countries have and which states develop and implement, usually relatively non-controversially (Cismaru and Lavack, 2007; May 2002). Direct government regulation of this kind can be very time-consuming and expensive, and several distinct forms of regulatory institutions have developed with semi-independent, quasi-judicial status in order to avoid or minimise these problems (Howlett 2011).

Economic regulation, which affects aspects of established markets for goods and service production, often utilises somewhat arms-length, but no less 'direct' forms of regulatory agencies such as the 'independent regulatory commission' (Cushman 1941; Majone 1997). These commissions and other kinds of administrative regulatory agencies and boards of various kinds are involved with the regulation, or control, of all aspects of market behaviour - production, distribution and consumption – although to different extents in different areas of economic activity, and with considerable variation in the range of activities undertaken – even in the same sector – across nations (Royer 2008; Weimer 2007).

There also exists a wide variety of organisational forms within the general type since, as Berg (2000) and Stern and Holder (1999) noted, in addition to questions related to their level of independence or autonomy, additional design criteria include the clarity of agency roles and objectives; their degree of accountability of governments or the public; their level and type of participation and transparency; and ultimately their predictability in terms of being bound by precedents either of their own making or through judicial review (Cushman 1941; Wu 2008. See also Berg, Memon and Skelton 2000).

Given the kinds of possible variations in agency configurations, it would not be surprising if each regulatory regime was somewhat idiosyncratic. And to a certain extent this is true and the factors, which go into their selection and creation, are complex (Jasanoff 1990; Brewster and Goldsmith 2007; Lodge 2011; Bollhoff 2002). Different countries can adopt similar or different types of regulation, or select different configurations of elements within different types, in their regulatory arrangements and this can easily result in different countries exhibiting distinct differences in regulatory style, process and content, either in general or on a sectoral basis. And different countries do often feature different propensities and tendencies to use particular types of regulatory tools or arrangements (Knill 1998).

However, different regulatory arrangements can also be thought of as existing as single instances, or variations, on the attributes of more general regulatory forms. Moreover, it has long been noted that national regimes, for example, tend to exhibit less difference than would be expected if each sectoral regime was completely idiosyncratic, leading to notions of 'regulatory styles' - in which specific regulatory arrangements are seen to exist as variations on a theme[1] - and of such ancillary notions as '*regulatory convergence*' - or the idea that regulatory regimes in different countries, although they may begin in a more idiosyncratic fashion, draw closer together and become more similar over time (Vick 2006; Holzinger, Knill and Sommerer 2008). That is, on a temporal level, different countries may proceed to regulation of different sectors and activities at different times and in different ways, but eventually emerge as 'lagged copies' of each other, in which some

countries emerge as regulatory leaders and others as laggards or emulators (Clifton et al 2011; Garcia-Murillo 2005; Hills and Michalis 2000; Shin 2006).

The mechanisms of such convergences, however, are not well known. Some accounts are deterministic, based on the idea that different governments face the same economic or technical problems and solutions and therefore tend to adopt the same tools for dealing with them (Drezner 2001). Others focus on the impact of other factors such as policy learning, international moves towards harmonisation and others which promote a common direction for regulatory evolution, even if regulations might have initially looked quite different at the outset (Drezner 2005; Holzinger and Knill 2005).

Understanding how such regimes evolve in different sectors remains a question of some interest to students and practitioners of economic regulation (Clifton et al 2011). As the discussion above suggests, there are two dimensions of this question that must be addressed in attempting to understand patterns of regulatory evolution. The first is spatial and revolves around exactly how the characteristics of regulatory regimes formulated at the sectoral level can be linked to more general domestic patterns (which, in turn, can often be linked to transnational or international developments). The second is temporal and addresses the question of how regulatory regimes change and evolve over time. Some apparently spatial variations may in fact originate in different stages of regime evolution, and determining if there is a 'standard' pattern of regulatory regime evolution is a subject of some interest to students of comparative regulation as well as to regulatory historians and contemporary practitioners and scholars (Rabin 1986). The discussion below addresses this temporal dimension in comparative regulatory studies focusing on works over the years, which have suggested the existence of a standardised regulatory life cycle or genealogy.

The idea of a regulatory genealogy

In his 1955 work, *Regulating Business by Independent Commission*, Marver Bernstein suggested that regulatory agencies tend to follow a set pattern of evolution or life cycle, one which roughly parallels a human life- with distinct stages of gestation, adolescence, maturity, decline and, ultimately, death (Bernstein 1955). Although he did not systematically develop this insight, the idea that there is a generic pattern of regulatory evolution, independent of nationality, sector or temporal period, has proven alluring and many students of regulation, de-regulation, and, more recently, re-regulation (Eisner 1994) have used similar concepts to analyse temporal patterns in the evolution of regulatory institutions and processes. Bernstein's idea of the likelihood of 'regulatory capture' during the mature phase of a regulatory agency, for example, has been oft-cited and underlay thinking by proponents of de-regulation like Alfred Kahn (1970) and George Stigler (1962 and 1975) concerning the potential for regulations to be shifted away from more ostensibly public interests at some point in their history; in Kahn's case justifying de-regulation of mature regimes, while in Stigler's issuing a caution against the creation of such rules and organisations in the first place (McCraw 1975 and 1982).

However, while some stages of the regulatory regime life cycle have been well explored, others have not been. The moment of regulatory birth, for example, has been examined in studies focusing on the question of *cui bono* - debating whose interests were served by the creation of a regulatory regime (Stigler 1971, 1975)[2] – as have the stages of

decline - in works focusing on policy termination (Bardach 1976; deLeon 1983; DeLeon 1978; Kirpatrick et al 1999; Lewis 2002) or de-regulation (Collier 1998; Derthick and Quirk 1985; Daugbjerg 1997; Eisner et al 1994; Lazer and Mayer-Schonberger 2002; Hammon and Knott 1998). The stage of maturity has also been examined by works focusing on issues such as regulatory capture and the role of the judiciary in regulatory review (McGarity 2001 and 1991; Shapiro and McGarity 1991; Hawkins and Thomas 1989; May and Winter 1999). However the immediate stages between what Bernstein termed "gestation" and what he called the youthful or "adolescent" stage of regulatory regime development, remain very much underexplored (Menard and Ghertman 2009; Ramesh and Howlett 2006).

After the "regulatory moment": origins of a framework and model

In general, the period between the gestation and adolescence of a regulatory regime can be expected to be one filled with much confusion, and experimentation, with less direct forms of regulation preceding the use of more direct, command and control, types. Once a regime is in place its fundamental elements may vary somewhat but overall post-adolescence it is expected to display some stability compared to earlier stages (McCraw 1986). This stability, as Bernstein recognised, is not unproblematic as conditions in the regulatory environment may be changing in such a way as to undermine the standards set by the regime. However, it is still to be expected that most regimes will exhibit significant path dependencies, highlighting the importance of events occurring in the initial, formative, period of the regulatory life cycle (Sydow and Schreyogg 2009; DeShazo and Freeman 2010).
Despite its role as a key stage in which the basic institutions and rules are developed, which will go on to form the basis for a sometimes very extended, typically decades-long, period of maturity. However, the initial stages of regulatory activity have not been the subject of many systematic studies. Fortunately some anecdotal work does exist on the very early stages of regulatory regime evolution in what Otway and Ravetz (1984) have referred to as the "Linear Model"of regulatory development, and these studies can be used to synthesise a basic model of the stages and sub-stages involved in early regulatory regime development (Hall 1978).

Drawing on their own experiences as regulators, Otway and Ravetz (1984) proposed a three stage model of the early stages of regulatory regime development, 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 it and finally to their implementation (see Figure 1). In this Linear Model, specific kinds of regulatory activity are associated with each phase in a standard-building process, from collecting data to monitoring hazard occurrence and, finally, to the preparation of codes, implementation of inspections, and enforcement.

This is a useful start. However, the model says little about the specific activities that take place in the critical middle "technical" stage of standard development. Leiss and others have argued this is a highly contested and often time-consuming stage and, in his own work Leiss (2001), argued that this stage could easily last 10-15 years.

Figure 1 – The linear model after Otway and Ravetz (1984)

Stage	Issue	Regulatory Activity

Scientific Phase	Recognise existence of hazard	Collect medical/ecological information
Technical Phase	Define practical limit values for hazard producers	Monitor process/facility for hazards
Administrative Phase	Implementation	Prepare operating and inspection codes, implement inspections, advice, sanctions, etc. Iterate as experience is gained.

Source: Otway and Ravetz (1984)

Leiss modeled his own version of these early stages by dividing Otway and Ravetz' second phase into two sub-stages (see Figure 2) falling between the 'recognition' of a potential threat and the later mature 'implementation' or "administrative" phase of regulatory agency creation. These early periods of activity were characterised by uncertainty regarding the extent of the threat posed by some phenomena - uncertainty which colours later efforts to prescribe preliminary product and behavioural standards in order to offset its potential risks.

Figure 2 – Stages of Risk Controversy after Leiss (2001)

Stage	**Characteristics**	**Problem**	**Regulatory Response**
Recognition	Development of threat perception	Public or governmental disquiet	Initial threat Definition and scoping
Early (10-15 years)	Incomplete hazard specification Poor Exposure Assessment Issue Characterisation	Scientific uncertainty Lack of clinical trials Stigmatisation	Downplay scope of hazard Let sleeping dogs lie Denial
Middle Stage (5-10 years)	Science underway Early epidemiology	Issue debates Internationalisation	Spin Venue Shifting
Mature Stage	Better science and	Stakeholder/Media	Bilateral

(decades)	epidemiology Issue capture	links Popular frame agreements	Negotiations Routinisation

Source: Leiss (2001)

Combining Bernstein-type genealogical labels with the additional stages identified by Leiss, Otway and Ravetz, generates the four-stage model found in Figure 3. As this figure shows, Leiss, Otway and Ravetz work can be thought of as filling in the missing gaps between Bernstein's "gestation" and "adolescent" stages of development: to continue the genealogical metaphor, adding the stages of "infancy" or "childhood" missing in Bernstein's original formulation.

Figure 3 – Stages of regulatory development after Bernstein (1955), Otaway and Ravetz (1984) and Leiss (2001)

Bernstein Stage (modified)	Otway and Ravetz Phase	Leiss Stage	Characteristics	Problem	Regulatory Response
Gestation	Scientific Phase	Recognition	Recognise existence of hazard, risk or threat	Public or governmental disquiet	Initial threat Definition and scoping
Infancy	Technical Phase	Early (10-15 years)	Incomplete hazard specification Poor Exposure Assessment Issue Characterisation	Scientific uncertainty Lack of clinical trials Stigmatisation	Downplay scope of hazard Let sleeping dogs lie Denial
Adolescence	Technical Phase	Middle Stage (5-10 years)	Science underway Early epidemiology	Issue debates Internationalisation	Spin Venue Shifting
Maturity	Administrative Phase	Mature Stage (decades)	Better science and epidemiology Issue capture	Stakeholder/Media links Popular frame Agreements	Bilateral negotiations Routinisation

Source: Bernstein, Otway and Ravetz (1984) and Leiss (2001)

This model improves on Bernstein's original formulation but continues to compress several distinct stages or sub-stages of regulatory evolution within the "infant" stage. Howlett and Migone (2010), based on work such as Borraz (2007a and 2007b), investigated the

development of nascent contemporary bio- and nano-technology regulatory regimes and identified several additional early phases in this early period. In their work they observed as many as four stages before an agency or rule regime entered into adolescence. Following the birth of the regime in a 'Pre-regulatory' stage of problem recognition, where a 'problem' emerges through accidents, state, or societal pressure bringing the new issue area onto the regulatory agenda (Fleischer 2010) and into what Otway and Ravetz termed the "Scientific" stage, Howlett and Migone identified a period of "Adaptive Experimentation" in which an attempt is made to adapt existing statutes and rules to current problems, using existing regulatory tools and agencies to attempt to cover off emerging issue areas. If this failed to address a problem, this period was followed by a period of "Standard-Seeking" when there is a desire to create new rules and standards but no clear knowledge of what they should be (Majone 2010; Borraz 2007) – a phase both Otway and Ravetz and Leiss described as a key part of their "Technical" stage. They thus inserted two additional stages into the Leiss-Otway-and-Ravetz model: separating out "early" and "late" childhood from "infancy".

Joining these three models together with Bernstein's idea of a regulatory life- cycle, generates a much more nuanced model of the regulatory life cycle than originally mooted by Bernstein: with nine stages in total over the course of a regulatory regime life cycle rather than just the four that Bernstein had originally identified. In this model (see Figure 4), it is expected that initial regulatory arrangements will undergo a large number of changes between "gestation" and "maturity" as the agency moves through periods of "infancy", "early childhood", "late childhood" and "adolescence", after which they will be more or less locked-in to the standards and processes developed in the pre-adult stages.

Figure 5 – Revised nine-stage model of the regulatory regime life cycle

Life Cycle Stage (After Bernstein)	**Liess/Otway and Ravetz/ Howlett and Migone Phase**	**Issues**	**Task**	**Administrative Techniques**
I. Gestation	*Pre-regulatory*	Emergence of 'problem' on the agenda as a threat, hazard or risk.	Dealing with accidents, state pressure, societal pressure brings the new issue area on the agenda.	Creation or designation of Primary Regulatory Agency.
II. Infancy	*Co-optive*	Attempt to adapt existing statutes and rules to current problems.	Efforts at issue suppression.	Delay use of existing regulatory tools and agencies to cover emerging issue areas.

III. **Early Childhood**	*Early Scientific Phase*	Successful issue re-framing/ stigmatisation	Poor knowledge base, heavily symbolic/ discursive struggles	Trying to get the problematisers (for e.g., industry or science as the case may be) to come up with the standards through various forms of 'voluntary' activity.
IV. **Late Childhood**	*Middle Technical Phase*	Desire to create new rules but no clear knowledge of what these rules/standards should be due to incomplete hazard characterisation and poor exposure assessment. Lobbying and back-room deal-making/lobbying Venue shopping	Standard-Seeking Large-scale research programs for hazard characterisation. Initial quantitative risk assessments.	Adaptive Experimentation using 'principles' rather than standards Emergence of a 'light' hierarchical hand or 'soft' regulation. If institutionalisation has not occurred in earlier phase then also deals with start-up issues such as institution staffing.
V. **Adolescence**	*Late Administrative Phase*	Completion of hazards assessment. Development of standards. Frozen issue frames. Issue ownership by specific groups.	Smaller-scale, maintenance research and legal/judicial activities.	Emergence of more 'direct' state regulation. Often this happens when scandals erupt, accidents occur or complaints arise about these, then the level of state authority and presence is ramped up.
VI. **Young** **Adulthood**	*Precedent Building*	Legal actions.	Court activities.	Rule adjustment.

VII. Maturation	*Routinisation*	Normalisation of the regulatory issues	Administrative activity	Emergence of specific agencies that 'own' the regulatory area
VIII. Decline	*Capture*	Regulatory capture. Emergence of clientelism	Maintaining a favorable environment for the regulatees.	Self-regulation
IX. **Death**	*Termination/* *Reform*	Modification/Death of the issue		De/Re-regulation

Sources: (Bernstein, 1955; Otway and Ravetz 1984; Leiss, 2001; Hood et al 1999a)

Of particular interest for this paper are the three distinct periods suggested to exist in the early stages of a regime after gestation and prior to adolescence. These are the essence of 'regulation-making' and discerning whether, and to what extent, this model accurately describes them is important for both students and practitioners interested in regulatory development. In what follows, this multi-staged model is examined in light of empirical evidence of the record of regulatory activity found in seven issue areas for which a large amount of secondary literature on the subject exists.

Testing the comparative genealogical approach to regulation-making

Examination of the evolution of numerous cases of regulatory development in different industrial and consumer sectors and countries lends credibility to the synthetic model developed above. The seven cases examined here are derived from the existing secondary literature on regulatory evolution and cover topics such as auto safety, PCBs, dangerous dogs, non-prescription drugs, cloning food animals and pesticides. These cases cover different sectors and time periods, and different countries or regions (five US and two EU cases). This allows, among other things, for the experiences of some new areas to be contrasted with older ones across a wide variety of regulatory environments. Moreover, since two of these cases – dangerous dogs and cloning food animals - never proceeded to the adolescent phase of development, they also cover off cases of both 'successful' and 'failed' regulatory regime development.

To anticipate, in all of the cases described here, regulation was found to proceed through the initial stages of the regulatory life cycle in a manner that closely follows the stages of the modified Bernstein life cycle model set out in Figure 5. Aberrations may be related to idiosyncrasies within a particular industry or sector, or to the actions of individuals involved in the regulatory process whose influence may have caused a deviation in the usual regulatory trajectory. Generally, however, the degree and methods of regulation in these examples progressed from "gestation" to "young adulthood" in the manner that the model would predict. This suggests, among other things, that considerable

spatial variation in emerging regulatory regimes may exist simply due to the timing of observations made of different regimes at different points in the evolution of a regime, and support the idea that a generalised regulatory cycle exists, as Bernstein originally argued.

Gestation

The "birth" stage of the regulatory life cycle occurs as soon as the regulatory problem emerges on the political agenda, or first becomes a salient issue within the public conscience, but before action is taken to mitigate the problem. In the US, for example, while personal automobiles had been mass-marketed for nearly 30 years previously, automobile safety did not become a relevant political issue until the years after the Second World War, when US cities began their gradual process of suburbanisation and personal automobile use expanded dramatically. At this point, the deficiencies in skill, or prudence of the driver, were seen as the real culprit and the car manufacturer was not considered responsible in any way (Mashaw and Harfst 1987). In other words, the problem of deaths and injuries attributable to automobile use had been identified, but US governments had not yet begun to investigate causes, or possible strategies, for legislative or regulatory action to attempt to solve the problem. Likewise in other sectors: in 1966, the first scientific reports on the dangers of polychlorinated biphenyls (PCBs) emerged, but no action was taken (Cairns and Siegmund 1981); in the 1960s, the health repercussions of some agricultural pesticides were first recognised (McGarity 2001), but no strategies had yet been formed to deal with them; and, the first discussions of research into the health hazards of genetically modified organisms (GMOs) were initiated by the National Institutes of Health between 1973 and 1976, but again, without discussion on a course of action (Fredrickson 1979). In all of these cases, at these points, a public health or safety problem, or a potential or actual threat, had been identified, but no public debate on what course of action to pursue (if any) ensued.

Infancy

At the "infancy" stage of the regulatory life cycle, a problem or threat is acknowledged, but political decision-makers remain reluctant to address the issue with any new legislation or regulation. Instead, they attempt to solve the problem using their existing legislative framework. For example, after more than 100 people were fatally poisoned by "Elixir Sulfanilamide" in 1937, the US federal government sued the manufacturer for mislabeling their product - rather than implementing a new regulatory regime to administer non-prescription drugs (Temin 1979). Also in the US, after the debate on the health risks of GMOs began in the 1970s, 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). In the European Union, after some theoretical research suggested that cloning animals for food production could result in public health risks, the EU parliament also attempted to adapt existing legislation to control food-supply animal clones (Weimer 2010).

Early childhood and late childhood

The "early childhood" stage is characterised by a government authority that is interested in collecting new data and sponsoring scientific research in a problem area, but is still reluctant to enact any radically different legislation or regulation. However, continuing problems and public and internal pressures at this time to resolve them results in a period of regulatory agenda-setting through stigmatisation and attempts to get the industry in question to participate in voluntary regulation measures ("early childhood"). This is often followed by ad-hoc attempts at firm sector-wide standards and extensive information gathering ("late childhood"). For example, regulation in the US automobile industry was in the "childhood" stages in the mid-60s, as safety concerns related to driving were reoriented from the driver to the manufacturer. In a good example of the "early childhood" stage, the need for manufactured vehicle safety standards was brought to the political agenda in part by the work of Connecticut senator Abraham Ribicoff and consumer advocate Ralph Nader, during which time the concept of regulating automobile manufacturing to produce safer vehicles became a politically salient idea. According to Mashaw and Harfst (1987: 258), "Sales of Nader's book [*Unsafe at Any Speed: The Designed-In Dangers of the American Automobile*] surged contemporaneously with congressional deliberations on the proposed legislation and helped generate a rationale for enactment that politicians seemed to find compelling". However, until 1966, manufacturing safety standards for US vehicles were purely voluntary (ibid.).

These stages of the regulatory trajectory are illustrated by other examples as well. Between 1972 and 1979, the US Food and Drug Administration conducted a significant amount of scientific research on the hazards and exposure levels of PCBs, and their regulatory efforts during this time included temporary recommendations rather than industry-wide regulation (Cairns and Siegmund 1981). In the EU in the 1990s, dog breeds that were seen as dangerously aggressive were banned on an ad-hoc basis in the midst of ongoing scientific research, but no independent regulatory body was commissioned in any EU country during this time (Lodge and Hood 2002). All of these examples feature ongoing, but incomplete, scientific research campaigns, and government action that is imprecise, ad-hoc, and aimed more at probing the public's awareness of the topic rather than enacting sweeping reforms.

Generally, some form of crisis must occur for the issue to pass across the new institutional threshold, an event which typically occurs in one of the childhood stages. In the case of automobile safety in the US, 50,000 annual deaths and 300,000 annual disabling injuries were enough to allow this to happen (Mashaw and Harfst 1987: 260). In the case of PCBs, a major poisoning incident in Japan and several smaller incidents in the US enabled the creation of an American regulatory regime (Cairns and Siegmund 1981). In the case of non-prescription medication, the Elixir Sulfanilamide fiasco, mentioned above, prompted the institution of a regulatory body towards the end of the childhood stage (Temin 1979).

However, just because an issue enters the regulatory life cycle, does not mean that it will necessarily pass through further stages. In the European Union, the absence of a health crisis related to animal cloning, for example, meant that regulation has stalled at the "infancy" stage, with no new regulatory agency being formed (Weimer 2010). Likewise, for GMOs in the United States (Shapiro 1990; Mostow 1992; see Bratspies 2002 for a more specific example) and for dangerous dogs regulation in the EU (Lodge and Hood 2002; Haupt 2006).

Adolescence

The "adolescent" stage is one described by Bernstein where regulatory standards begin to be developed in earnest by a newly formed regulatory institution. By this time, an agency of some kind has been formed, and proponents and opponents of regulation have been identified and their political positions solidified. The public debate, while perhaps not resolved, has had its issues clearly defined and arguments for, and against, regulation are from this point forward more or less frozen. Statutory and regulatory action is now being taken by government authorities, resistance to expansive interpretations of regulatory mandates is presented by lobby groups and industry representatives, and industry-wide regulation is beginning to take place. This is the regulatory stage that is easiest to document, because the presence of a young and activist independent regulatory commission means that actions from both proponents and opponents are clearly identified and recorded, as Bernstein (1955) noted.

There are many examples of this period of regulatory adolescence. In automobile safety in the US, this occurred between 1966 and 1968 after the formation of the National Highway Traffic Safety Administration (NHTSA) (Mashaw and Harfst 1987). In another example, the US Environmental Protection Agency (EPA), which had been given the authority to regulate PCBs in 1976, banned the use of PCBs in all food, drug and cosmetics processing and production applications in 1979 (Cairns and Siegmund 1981). In 1938, the US Food and Drug Administration was given the power to regulate non-prescription 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). In 1996, after two decades of scientific research on the health and environmental effects of pesticides, the US EPA was given extensive legal power to set up and enforce a regulatory regime for pesticides, including different tolerances for specific industries or specific target groups like children (McGarity 2001). In all of these cases, the creation of an independent regulatory commission in the childhood stage allowed a formal regulatory regime to come into existence and proceed to mandatory standard setting in the adolescent stage.

Young adulthood

Bernstein (1955) moved quickly from "adolescence" to "maturity". However, this again overly compressed the stages of the regulatory life cycle. Following the emergence of regulations in the "adolescent" phase, during the "young adulthood" stage of regulation, legal actions and court decisions set precedents that determine outcomes for the later stages of the regulatory life cycle. For instance, in the automobile safety case in 1968, after the National Highway Traffic Safety Administration (NHTSA) had ruled that front seat headrests should be mandatory on all new cars, a manufacturer of headrest add-ons sued the NHTSA 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). In addition, legal action as a way to define a regulatory regime can also originate from the government agency. In the 1940s, the US Food and Drug Administration attempted to prosecute pharmacies that were in violation of non-prescription drug regulation. One notable case

(*U.S. 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).

Figure 6 - Matrix of empirical examples as found in secondary sources, early stages of regulatory life cycle

Birth	**Infancy**	**Early Childhood**	**Late Childhood**	**Adolescence**	**Young Adulthood**
Emergence of problem.	Adaptation using existing laws and regulation.	Issue re-framing and stigmatisation; voluntary regulation.	Standard-seeking	Development of standards; frozen issues and positions	Legal precedents
US: Automobile safety, 1940-1950 (Mashaw and Harfst 1987)	US: Automobile safety, 1950-1960 (Mashaw and Harfst 1987)	US: Automobile safety, 1960-1966 (Mashaw and Harfst 1987)	IRC FORMED	US: Automobile safety, 1966-1968 (Mashaw and Harfst 1987)	US: Automobile safety, 1968-1975 (Mashaw and Harfst 1987)
US: PCBs, 1966-1968 (Cairns and Siegmund 1981)	US: PCBs, 1968-1972 (Cairns and Siegmund 1981)	US: PCBs, 1972-1976 (Cairns and Siegmund 1981)	US: PCBs, 1976-1979 (Cairns and Siegmund 1981) IRC FORMED	US: PCBs, 1979 (Cairns and Siegmund 1981)	
US: non-prescription drugs, 1930-1937 (Temin 1979)	US: non-prescription drugs, 1937-1938 (Temin 1979)	IRC FORMED			US: non-prescription drugs, 1948-1951 (Temin 1979)
EU: cloning animals for food production, 1997-2008 (Weimer 2010)	EU: cloning animals for food production, 2008-2010 (Weimer 2010)	no progress			
US: pesticides, 1960-1970 (McGarity 2001) -		IRC FORMED	US: pesticides, 1970-1996 (McGarity 2001)	US: pesticides, 1996-2000 (McGarity 2001)	Already happened (see left - McGarity 2001)
US: GMOs, 1973-1976 (Fredrickson 1979; Shapiro	US: GMOs, 1976-1984 (Shapiro 1990;	US: GMOs, 1984-1990 (Shapiro 1990; Mostow 1992)		No progress (see Bratspies 2002 for example)	

1990; Mostow 1992)	Mostow 1992)			
EU: dangerous dogs, 1990-1993 (Lodge and Hood 2002)			EU: dangerous dogs, 1993-2001 (Lodge and Hood 2002)	No progress (e.g., Germany: Haupt 2006)

After the "young adulthood" stage ends, and regulatory agency processes have been defined, regulatory regimes generally fall into a period of maturation, in which regulation is routinised and the legal authority of the independent regulatory commission is recognised and accepted by industry. But before they can reach that maturation period, they must pass through the early life cycle stages described here. The cases and their trajectories are summarised in Figure 6 above.

Drivers of regulatory regime transitions

Developing an accurate depiction of the typical pattern of regulatory regime development is an important first step in understanding the forces driving its evolution. It has been the argument of this paper that using models of regulatory life cycles in a comparative framework helps us to assess the pattern of development followed by regulation in different countries and sectors and helps develop such concepts such as regulatory convergence or the idea of regulatory styles.

Other authors have attempted to explore regional differences in regulation and understand the consequences of the nature of regulation in different countries in areas such as biotechnology (Isaac 2002, Bernauer 2003) and many others. Simple explanations like that of a global pressure towards similar regulation (Murphy and Levidow 2006) have proven inadequate, as Kinchy et al (2008) have demonstrated, and several variables have been invoked to explain regulatory differences and similarities in different countries and sectors of activity. These include factors such as differences in the nature of risk perception (Isaac 2002; Toke 2004) or in the institutional and participation elements affecting regulatory activity and regime formation (Jasanoff 2005). However, some of these purported differences may be more apparent than real, and may be examining regulatory regimes at different stages of development, reflecting not a spatial but rather a temporal source of diversity (Berk 1981; Graham 1993; Zelizer 2000 and 2009; Pierson 2005; Jordana and Levi Faur 2004; Majone 1997; McGarity 1986; Keller 1981, 1990 and 1994). An approach rooted in a more detailed study of regulatory trajectories, and the use of better models of the processes and stages of the evolution of regulatory regimes, is required to identify the actual pattern of regulatory regime evolution before the factors that drive regimes through the different stages of development can be correctly identified. In addition to helping identify the general process of regulatory regime evolution, employing such a genealogical model enables us to tackle some key questions like (1) what drives movements through this process; (2) under what circumstances it can stop at a particular stage and move no further; and, (3) why different areas move at different speeds.

As the above discussion has shown, with respect to the birth of a regulatory regime, a key driver of change is typically the emergence of some kind of real or perceived threat potentially and adversely affecting some element of the public, including market actors as well as social, or state ones (Fleischer 2005). That is, any kind of protective impulse present at the start of a regulatory trajectory requires some assessment of the nature and boundaries of the hazard involved and the development of standards clarifying permitted and unpermitted activity before it can emerge as a fully-fledged regulatory apparatus. And this is by no means an automatic process.

The 'search for standards' is a key component of regulatory regime infancy and it is fraught in many ways. Once a problem has been recognised and a decision taken to deal with it through regulation, the operational problem for nascent regulators remains to determine, in a justifiably defensible way, what standards they will use to assess regulatee conduct and with what effect (de Jager 1995; Shapiro 1965; Klayman 1983). This is especially problematic when disputes exist over the quality and caliber of data and information available to assess risks and hazards (Roberts 1984).

This can lead to temporary, ad hoc, or experimental efforts to deal with the problem using existing laws, statutes and resources, but requires a real crisis – usually the actual manifestation of the perceived threat – to move the regulatory impetus beyond infancy to early childhood and institutionalisation. Even once an agency is created, however, at least two further stages must be undergone before a mature regulatory regime emerges; stages in which regulatory powers are first defined and then tested in the courts before, if necessary, being refined or re-defined and routinised.

This can be a very long and drawn-out process but while these standards are being developed, regulators must still act to offset threats. During the infancy and childhood periods, as Leiss, Otway and Ravetz suggested, they do so in a state of constant uncertainty, both of the nature of the hazard and its exact causation and 'epidemiology'. There is a desire to create new rules to cover the innovation but without either legislatures or administrators having clear knowledge of what the rules/standards should be. The attempt to articulate rules in this condition of uncertainty very often leads to an early 'adaptive' phase, whereby attempts are made to stretch existing statutes and rules in order to cover the new problem. That is, existing regulations and already present organisational structures are utilised to attempt a 'normalising' response to the new item on the policy agenda. Various efforts to find the appropriate standard ensue, including funding research, using general 'principles' rather than specific standards, and trying to get the problematisers (e.g., industry or science as the case may be) to come up with a standard through various forms of 'voluntary' activity. When this adaptive stretching fails in the presence of a crisis, much conflict and uncertainty melts away, opening the ground for mandatory action (Marchant 2003; Geistfeld n.d.; Applegate 2002).

Even when standards start to emerge, however, regulation is often taken with a 'light' hierarchical hand using 'soft' regulatory instruments such as third-party certifications, more voluntary schemes and the like (Cashore et al 2002 and 2003).[3] If and when scandals continue to erupt, accidents occur or complaints arise about these, then the level of state authority and presence can be ramped up, leading to a final stage in which more 'direct' or 'hard' state regulation emerges. This regulation is then routinised and various schemes developed for its more efficient implementation (for example, HACCP in the food and drug areas. See Bernard 1998 and Demortain 1998).

Conclusion: key themes and findings

Experiences in the 1990s with de-regulation in fields such as airlines and railway transportation, utilities and other areas raised the analysis of the later stages of regulatory regime evolution - decline and death - and temporal issues in general, to the forefront of regulatory studies (Knott and Hammond 1988; Murillo, 2005; Vogel, 1996; Eisner 1994). Torres (2004) for example, argued that these events occurred as evolving technological and economic changes undermined the social and/or economic basis of the previous regulatory status quo, spurring state, economic and social actors to search for a new equilibrium. Just as the development of large-scale enterprises and corporate trusts undermined earlier regimes based on competitive small-scale market conditions, fed public discontent, and led to a regulatory compromise between capital and the state in many countries in the late 19th and early 20th century (Clifton et al 2011; Eisner 1993 and 1994), so similar movements led to reform efforts in the Asia Pacific and Latin America in the 1990s and after (Cheung, 2005; Hira, Huxtable and Leger, 2005; Vass and Bartle 2007).

Understanding the nature and origins of such regimes is especially of interest to students of regulation making and those involved in the development of markets more generally. While Bernstein did not address exactly how transitions between stages would occur, more recent observations of the evolution of other regulatory issue areas, such as chemical toxic regulations, genomics, nanotechnology and other areas have highlighted some of the characteristics of the early stages of the regulatory life cycle (Boucher, 2008; Seaton et al 2009) - just as experiences with de-regulation in areas such as transportation and utilities in the 1990s highlighted some of the relevant forces at work in the later stages of regulatory regime decline and death, or reform. Experiences with de-regulation in areas such as transportation and utilities regulation in the 1990s highlighted the significance of factors such as policy learning and bandwagon effects on policy reform (Ramesh and Howlett 2006); while a key element during the infant or juvenile stage of regulation revealed by the application of the model developed here are the problems nascent regulators have to deal with concerning uncertainty over potential hazards and the fear of over or under-regulation (Nichols and Zeckhauser 1988; Mashaw 1988; Aizenman 2009).

In the contemporary era it is especially important for those faced with the social and policy challenges posed by scientific and technologically innovative activity - such as, at the time of writing, new challenges and potential threats posed by new developments such as nanotechnology or synthetic biology (Bowman and Hodge 2007; Hodge, Bowman and Ludlow 2007; Furger et al 2007; Kuzma and Tanji 2010; Furger et al 2007; Kuzma et al 2008; Torgersen 2009; Kuzma, Majmaie and Larson 2008) and ongoing ones like controversies over the health and safety of mobile phones (Burgess 2002; Stilgoe 2007) - as well as a host of other issues linked to transitions in these countries to new forms of, for example, health, financial and social regulation, to be aware of the general pattern of regulatory evolution. Better understanding of general patterns of regulatory behaviour and evolution can help guide deliberation and action in regulation-making, especially, of course, in countries, such as many in Asia, where many regulatory institutions themselves are very new and regulatory regimes remain in the "adolescent" stage of development, or earlier.

Endnotes

[1] These propensities often have long historical roots and are circumscribed or encoded in various constitutional and institutional arrangements at the macro-political level - the idea of national administrative styles (Knill 1998; Howlett 2004).

[2] In addition to the Stigler "public vs private interest" debate, see Peltzman, (1976) and Skowronek (1981) and esp. Lodge and Hood 2002). For a critique of capture vs public interest explanations see McCraw (1975); Dal Bo (2006).

[3] While many standards are invoked by government command and control regulation, others can be developed in the private sphere, such as when manufacturing companies develop standards for products or where independent certification firms or associations guarantee that certain standards have been met in various kinds of private practices (Cashore 2002).

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