Regulatory Excellence: The Role of Policy Learning and Reputation

David Vogel
University of California, Berkeley

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A critical characteristic of an excellent regulator is the ability to engage in policy learning. Policy learning has two key dimensions. First, policy learning requires that a regulator recognize the accomplishments and shortcomings of both the decisions made by other regulators as well as its own. Second, policy learning requires that the regulator demonstrate responsiveness to new information as it emerges. Engaging in policy learning is especially important for a regulator responsible for addressing health, safety, and environmental risks because risk management decisions are often based on provisional or contested scientific data. Such regulations may require making predictions or assumptions about the seriousness of the harms or dangers policymakers are seeking to ameliorate or prevent, which may or may not prove to be accurate.

The ability for a regulator to engage in policy learning may be impacted by two factors: the demands the public places on the regulator, and the agency's reputation. Reviewing the decisions of other agencies that were not subject to the same public pressures may give a regulator the opportunity to critically reassess and revisit its own decisions. Equally important, an agency's reputation can affect the willingness of officials from other agencies to learn from it. But the factors that shape an agency's reputation are complex. Not all regulatory policy failures undermine an agency's reputation, nor do all policy accomplishments necessarily enhance it. Much depends on how the public responds to or perceives the policy outcomes of an agency's decisions.

This essay explores three case studies of policy learning and reputation. Two case studies involve various dimensions of transatlantic regulatory policy learning – or the lack thereof – namely, comparisons of the regulation of ozone depleting chemicals and pharmaceutical products in the United States and Europe. The third case study examines the dynamics of regulatory reputation and learning within a single jurisdiction, focusing on the performance and impact of the agency responsible for regulating air pollution in California.

Regulating Ozone Depleting Chemicals in the United States and Europe

In 1974, two American scientists, Sherwood Rowland and Mario Molina, published a study suggesting that the release of chlorofluorocarbons (CFCs), a widely used chemical in both consumer products and industrial processes, might be depleting the ozone layer. This in turn would allow more ultraviolet light to penetrate the Earth, thus increasing the risk of skin cancer. Scientists on both sides of the Atlantic met Rowland and Molina's analysis with skepticism. At the time, there was no evidence that the ozone layer was actually thinning, or that, even if it was, that human activity was causing it. However, because the study was released at a time when public concerns about the environmental causes of cancer were politically salient, the U.S. Congress held several hearings to explore the policy implications of Rowland and Molina's research.

These hearings attracted considerable media attention. The American public quickly became persuaded that the use of CFCs in personal hygiene products such as aerosol hair sprays and deodorants posed credible and unacceptable environmental and health dangers. As Peter Morrisette noted, "The fear of skin cancer from the depletion of stratospheric ozone due to the use of CFCs as aerosol propellants in spray cans personalized the risk for many people."[1] Sales of aerosol products fell sharply. In 1975, a federal task force supported the CFC/ozone depletion theory and its links to skin cancer. It went on to make the precautionary recommendation that ozone-depleting emissions should be regulated unless new scientific evidence emerged to clearly refute the finding of the Rowland and Molina study. The following year the National Academy of Sciences confirmed the risk assessment of the task force, but also indicated that was unable to specify the urgency of the health and safety risks posed by CFCs.

In 1977, federal legislation granted the Environmental Protection Agency (EPA) the authority to regulate "any substance . . . which . . . may reasonably be anticipated to affect the stratosphere, especially ozone."[2] In March, 1978, three American regulatory agencies, namely EPA, the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) issued regulations banning all nonessential uses of CFC. These regulations affected nearly $3 billion worth of consumer products and ended half of all CFC domestic production in the United States.

European policymakers were of course aware of both the scientific findings and the public and policy responses to them in the United States. But they chose *not* to learn from them. Denmark was the only European Union (EU) member state to adopt a ban similar to that of the US. For its part, the European Council, after two years of delay, approved a compromise resolution which imposed restrictions on CFC production that were largely symbolic. In May, 1983, after a further review of scientific evidence, the EU concluded that no additional regulation was necessary.

Why were European policymakers unwilling to learn from the United States? Part of the explanation was the lack of comparable public pressure. While they had experienced a major drop in the US, sales of aerosol personal hygiene products remained stable in Europe. Indeed, those American firms that had stopped using CFC propellants in consumer products marketed in Europe saw their sales decline. But equally importantly, European officials did not trust American regulators, as the latter had developed a reputation in Europe for being too willing to issue "overhasty regulations" based on "scientifically disputed" evidence.[3]

This mistrust of American risk regulation was reflected, for example, in the comments of a British journalist who wrote in 1972: "We saw the Americans thrashing around from one pollution scare to the next. . . One moment it was cyclamates, mercury, the ozone, lead, cadmium – there they set seem set on working their way in a random manner through the whole periodic table."[4] A British social scientist observed in 1979, "American seem to have taken an excessively strict interpretation of risk, reducing 'reasonable risk,' to practically 'zero risk.'"[5] In part, this was true. The 1958 Delaney Clause to the Federal Food Drug and Cosmetic Act had established a policy of zero tolerance for any residue of carcinogenic pesticides or additive in processed food found to cause cancer, and it also established an extremely low threshold for designating a substance as a carcinogen. Neither had been adopted by any European country. European

officials had chosen to interpret the results of animal testing much more flexibly, and as a result many substances that were banned in the US remain permitted in Europe. When the CFC controversy emerged, it seemed influential to European policymakers that the American (excessively) low threshold standard was now being applied to risk regulations beyond food additives, including chemicals.

European officials believed that their insistence on a higher level of scientific proof or certainty than their counterparts in the US was more responsible since it reduced the likelihood that costly, unnecessary or unnecessarily stringent regulations would be adopted. In short, what they learned from the US approach to regulating health, safety, and environmental risks was what *not* to do. In this context, the Europeans clearly thought they were being excellent by not over-reacting to what they considered to be a speculative risk assessment. It was only after the dramatic 1985 announcement that a British scientific team had found a large hole in the ozone layer over Antarctica that European officials considered their standard of scientific risk proof to have been successfully met. As one scientist observed, "now we've got a hole in our atmosphere that you could see from Mars . . . it is harder to label [it] as just a computer hypothesis."[6] Accordingly, European officials were now willing to work with the United States to harmonize international risk regulations, which led to the signing of the Montreal Protocol in 1987 that imposed global restrictions on CFC depleting chemicals.

In this case, the reputations and credibility of American regulatory agencies were enhanced: their risk management decision-making – in particular their decision to impose significant restrictions on the basis of a plausible but not yet scientifically established risk – was vindicated: the ozone layer was in fact thinning, CFC emissions were its cause, and the depletion of the ozone layer had increased the incidence of skin cancer. But the precautionary American approach to the risks of ozone depletion only can be judged "excellent" in retrospect. Had future scientific research disproved the ozone depletion hypothesis, then the credibility and judgement of American regulatory officials would have been undermined and the more cautious European approach would have proven to be more responsible. This suggests an important lesson, namely that there are times when the excellence of a regulation – or the extent to which it has improved public welfare – might not be immediately apparent.

However, an important reason why American officials were able to make what turned out to be the "right" decision was due to public pressures: a highly risk averse American public considered the risks of CFCs to be both credible and unacceptable. Had the American public not supported, or demanded, this particular risk regulation, American policymakers may have been less willing to act against the use of CFCs in consumer products.

Significantly, the United States did not restrict other industrial or "essential" uses of CFCs such as for refrigeration and in air conditioners. The costs of doing so were considered excessive, in large measure because the US would have been acting alone. Since the Europeans had not imposed comparable regulations, a more sweeping ban would have placed American firms at a much greater comparative disadvantage. It would have forced firms operating in the United States to change their production methods, as contrasted with their products. From this perspective, Americans did "learn" from Europeans: initial US regulations were less stringent

than they might have been if European policymakers had initially taken the risks of ozone depletion more seriously.

While the risk assessments on which European regulatory officials initially relied proved to be mistaken, they did not suffer any loss of reputation for two reasons. First, their risk assessments *were* consistent with the preferences of the European public. Indeed their reputation might well have suffered had they decided to restrict the use of aerosol in personal hygiene products despite the insufficiency of the scientific evidence of a public health threat and in the face of strong public demand for these products. From this perspective, they could be seen as exhibiting an important dimension of regulatory excellence, namely protecting their legitimacy and reputation by making decisions that were responsive to or consistent with public preferences. Second, as soon as there was compelling evidence of the CFC ozone depletion theory, they did review and revise their risk assessment and entered into negotiations with the United States, which led to a new international agreement that phased out most uses of CFCs. Thus, European regulators were willing to "learn," but they required a higher scientific threshold of evidence before they were willing to act. Nonetheless, the fact that they were willing to revise their initial risk assessment when the scientific evidence became conclusive certainly exhibited an important dimension of regulatory excellence, namely the ability to learn from new information.

What makes this case somewhat ironic is that subsequently, the EU and the US "traded places." The US moved away from a precautionary approach to assessing and managing risks, instead increasingly demanding a high level of scientific "proof" before issuing new risk regulations in ways that were analogous to what European officials had earlier required with respect to CFCs. By contrast, over time the EU increasingly embraced the precautionary principle, which permitted regulatory action when "potentially dangerous effects" had been identified but "it was [still] impossible to determine which sufficient certainty the risk in question."[7] Had the risks of ozone-depleting chemicals emerged on the policy agendas on both sides of the Atlantic a decade later, it is entirely possible that the policy responses of the EU and the US would have been reversed.

It is, almost by definition, impossible to determine in advance when a precautionary approach is justified, since its appropriateness depends on the "certainty" of future scientific evidence. Initial risk regulations clearly can succumb to policy errors: they may either prove too stringent (false positives) and too lax (false negatives). Regardless of what their initial actions or inactions may be – decisions which, as this case suggests, are likely to be shaped by the public's risk perceptions – what is important is that regulators should be both able and willing to adjust them as new scientific information emerges. Thus, had new scientific evidence emerged to discredit the Rowland and Molina study, it would have been incumbent on American officials to revise and review the regulatory restrictions they had earlier imposed. In this case, it was the Europeans who were challenged to revise and review their earlier risk assessments, which they did.

Pharmaceutical Drug Regulation in the United States and Europe

The era of modern drug regulation can usefully be dated from the thalidomide disaster of the early 1960s. The approval and widespread use of this sedative by pregnant women in several European countries led to a dramatic increase in children born with birth defects, most notably in Germany where it was available without a prescription. Half of exposed children died by their first birthday. In the United States, Dr. Frances Kelsey at the Food and Drug Administration (FDA) had not yet approved the drug when its risks became public because she had concerns about its safety. However, a front-page story in the *Washington Post* highlighted the fact that it *might* have been approved - or in other words, the article claimed that there had been a near policy failure. This led to the widespread public concern that the US standards were too lax, and there was substantial political pressure for strengthening federal drug approval requirements.[8] Congress responded by enacting the 1962 Kefauver-Harris amendments to the Federal Food Drug and Cosmetic Act, which made American standards for drug approval "the most stringent in the world."[9]

Although the regulatory responses to the thalidomide disaster in Europe were more modest, the episode did prompt several European countries to reexamine the quality and independence of their regulatory institutions, as well as their policies and standards for drug development, approval, and surveillance. While European countries had been as likely to reject as to emulate the American model of drug regulation prior to the thalidomide disaster, afterwards, "nation by nation, introspection was quickly accompanied by extended gaze at the United States and the FDA, for it was widely perceived that American regulators had gotten matters 'correct' in the thalidomide affairs. . . [The FDA] became the 'gold standard' to which other nations referred in constructing new models and institutions."[10] Thus FDA's handling of Thalidomide clearly strengthened its global reputation and policy impact.

Nonetheless, the FDA's widely perceived near policy failure due to its previous drug approval standards had placed the public spotlight on the risks of approving unsafe drugs. Accordingly, agency officials now clearly understood that their approval of any drugs that turned out to have harmful side effects would result in substantial media, public, and congressional criticism. As legal scholar Frances Miller explains, "Precaution was the FDA's official watchdog in part because congressional oversight committees habitually announced hearings to rake the agency over the coals whenever the media accuses it of failing to protect the public from unsafe drugs and devices."[11] Consequently, both the costs of meeting FDA's strengthened pre-market testing requirements and the time required for a new drug to be approved increased substantially. During the 1960s, the development costs for a new chemical entity increased from $1.2 million to $11.5 million, while between the 1960s and 1980s average drug development times grew from 8.1 years to 14.2.[12]

By contrast, while regulatory institutions and some procedures were strengthened in Europe, the essential British and German approaches to drug approval did not fundamentally change. As a senior British regulatory official put it: "The role of regulators is in fact to achieve the release on to the market of those products which have had peer review which has chosen them to be satisfactory."[13] In 1986, the chairman of a British drug approval body described his work as "concerned strictly with scientific issues," pointedly adding that "drug regulatory

authorities should be immune from political or public pressure."[14] The latter two comments suggested that what some European regulatory officials *had* learned from the United States was the importance of *not* allowing public pressures to influence – and thus distort - the regulatory process.

Rather than strengthening their pre-market requirements, regulatory officials in Europe instead chose to enhance their ability to monitor the adverse health effects of previously approved drugs. In essence, while the United States sought to prevent harms to public health *before* they occurred by relying on experimental or scientific data, European officials placed greater emphasis on reducing harms to public health *after* they occurred by relying on actual evidence of harms to humans. Predictably, many more approved drugs were subsequently removed from the market in Britain than in the United States.[15]

However, the latter development did not undermine the reputation of European regulatory officials in their home countries nor did it persuade them of the superiority of the FDA's regulatory approach. On the contrary, British officials remained highly critical of the costly and time-consuming American standards for new drug approval. According to one official, it led to "inflexibility, rigidity, polarization and irrationality."[16]

As memories of the thalidomide crisis began to fade, the relative lack of availability of new drugs in the United States became increasingly salient. For critics of the FDA's "drug lag" – a term first coined in 1972 – it was now the Europeans whose more permissive drug approval standards appeared to be better at protecting public health. A report by the US Government Accounting Office tracked the introduction of fourteen significant new drugs. It found that thirteen were available for use in Europe before they were approved for use in the United States. A German study found that while the United States was, by a large margin, the leading producer of new drugs, it ranked ninth out of twelve countries in being the first to make new drugs available to its citizens.[17] In 1985, nearly half of US- discovered new chemical entities had yet to be introduced in the United States market, and more were being marketed in Germany than in the US.[18] That same year, it took more than thirty months for marketing approval to be granted in the United States as compared to six months in both Britain and France.[19]

The FDA now found itself increasingly criticized for denying Americans access to drugs that were already available in Europe. In 1980, Democratic Representative James Schuerer accused FDA of "contributing to needless suffering and death for thousands of Americans because it is denying them the life-enhancing and lifesavings drugs available elsewhere."[20] Two pharmacologists specifically cited the case of the drug nitzarepam, which was used to treat severe insomnia. It has been approved for use in Britain five years earlier than in the United States. They contended that thousands of American lives might have been saved during those five years, concluding "in view of the clear benefits demonstrable from some of the drugs introduced into Britain, it appears that the United States had lost more than it had gained from adopting a more conservative approach than did Britain in the post-thalidomide era."[21] Somewhat ironically, the agency's domestic critics now argued that the health and safety of Europeans had been enhanced precisely because European drug approval authorities had *not* emulated the FDA by tightening their drug approval requirements.

Yet these criticisms had little impact on the FDA's practices and priorities. Why was the agency unwilling to learn from the health impact of drug approval policies in Europe? Part of the reason was that the FDA had historically defined its strategy for fulfilling its core mission, namely protecting public health, in terms of preventing the public from being harmed by consuming unsafe drugs – a policy approach that had been reinforced by the public furor over thalidomide and the resultant 1962 legislation. This focus made it difficult for FDA to recognize that the public could also be harmed by drug approval standards and requirements that were *too* stringent. Put more formally, FDA's priority had been to avoid the risks of false negative policy errors; however, this made it insufficiently attentive to the risks of false positives, i.e., of taking too long to approve drugs that turned out to be both safe and effective.

Two other factors were also at work. One was the agency's longstanding role as the global leader or international standard-bearer in drug regulation. Its reputation as the "gold standard" had made the FDA disinterested in following - and possibly learning from - policy developments in other political jurisdictions, particularly from whose experience and expertise it considered inferior to its own drug approval authority.

The second factor was political. As the *Wall Street Journal* insightfully editorialized: "It is now clear that the FDA bureaucrats will never take any risks they can avoid. They have nothing to gain from approving an effective drug and everything to lose from making a mistake."[22] This view was echoed by a former FDA Commissioner, who recalled: "The message to the agency staff was very clear. Whenever a controversy over a drug is resolved by approval, the agency and the individual involved will likely be investigated. Whenever a drug is disapproved, no inquiry will be made."[23] This somewhat cynical assessment made sense. For those whose health and safety were harmed by approved drugs were easily identified; they and the public knew who they were. But those patients who suffered due to the unavailability of beneficial drugs were much more difficult to identify or politically mobilize, as they often did not know who they were.

It took the AIDS epidemic of the mid-1980s before the FDA became willing to review and revise standards for new drug approvals. AIDS was a fatal disease for which there were no approved drugs. Those who had contracted AIDS were unwilling to wait for new drugs to be thoroughly tested for safety and efficacy, since they might not be alive by the time the agency had completed its lengthy approval process. In 1987, the FDA approved a drug for the treatment of AIDS in only eighteen months. While this approval was faster than any drug in the FDA's history, it still failed to placate the highly mobilized activists in the AIDS community and their supporters, who accused the agency of "prolonging the roll call of death."[24]

Subsequently, the agency approved new rules designed to significantly reduce the time necessary to approve drugs designed to treat life-threatening illnesses. While taken in direct response to the AIDS crisis, these rules were also designed to speed up the commercial availability of drugs for other illnesses for which there was no effective treatments. Consequently, the median approval times for new drugs that fell within this classification declined from 26.7 months in 1993 to 19 months in 1994. [25]

Policy learning across the Atlantic –in this case from Europe to the United States – began to accelerate. In 1992, Congress approved legislation that required firms to submit a user fee to FDA for each new drug application. These fees would then go into a fund used to expedite the drug approval process. As part of the agreement that produced this legislation, the FDA promised to measurably reduce drug approval times, which it did: median approval time for all drugs fell to a little over a year.[26] Significantly, paying fees for drug approvals had long been the practice in several European countries. Subsequently, the FDA also began to authorize the use of third-party assessment for drug safety – a policy approach that it had resisted for several years, but which had also previously been adopted in Europe. Due to these and other policy changes, Europe and American drug approval standards have converged. The drug lag has essentially disappeared and a new drug is now as likely to first be approved in the United States as in Europe.

This case underlines both the importance of policy learning and the complex factors that can facilitate or impede it. To achieve regulatory excellence, regulators must be willing to learn – both by continually monitoring and reassessing their own policy impact as well as that of other regulatory authorities who face similar challenges. Regulatory policies cannot remain static or be based on what the agency has or has not achieved in the past. Rather, they must continually be reviewed and reassessed. In this context, it is important for regulators to recognize that more stringent regulations may not necessarily be more effective. Many important regulatory decisions involve trade-offs: reducing some risks may increase others. Thus what it takes to be an excellent regulator can change over time. Excellence may at times be associated with being extremely cautious, while at other times such caution can be viewed as flawed. An important dimension of regulatory excellence involves being responsive to changes in the public's policy preferences and risk assessments – as well as policy outcomes.

While all regulators should aspire to maintain excellence by learning and adapting, earning a reputation for regulatory excellence can produce mixed policy results. It might well make some regulatory officials in other agencies more likely to "learn" from the regulator with an excellent reputation, it may also make the agency with an excellent reputation less willing to learn itself from the experiences of other agencies and less likely to change when needed the policies and practices that led it to be known as excellent.

The California Air Resources Board

In 2006, the state of California enacted the Global Warming Solution Act. Described as "the most ambitious climate legislation enacted anywhere in North American and among the most aggressive policies in the world," this statute required the state to reduce its emissions of greenhouse gases (GHG) back to 1990 levels by 2020.[27] What was particularly striking about this legislation is that it was only ten pages long. The task of formulating the detailed and complex rules that would be needed to implement this broad goal was delegated to a state regulatory agency, the California Air Resources Board (CARB, or the Board). Why were the state's elected officials willing to vest so much authority in an administrative body established by the state legislature in 1967 to address the state's unusually poor air quality?

The most obvious explanation has been CARB's historical track record for accomplishing its primary regulatory responsibility, namely to improve air quality by reducing automobile emissions. By 2003, the main components of smog had been reduced by 99.3 percent for hydrocarbons, 96.2 percent for carbon monoxide, and 88.2 percent for nitrogen oxides.[28] This in turn led to substantial reductions in air pollution, most notably in southern California, where the air quality had historically been the worst in the United States. In this region, between 1973 and 1980 there were 644 violations of the federal one-hour ozone standard, while between 2003 and 2011, the standard was only violated twice.[29] While the region's population has doubled in size since 1970, the amount of smog in southern California declined by fifty percent. This was, literally, a highly visible regulatory policy accomplishment. The legal scholar Ann Carlson has written: "The sky is bluer and the air easier to breathe. The exhaust from tailpipe from new cars is invisible not black."[30] These impressive accomplishments had made CARB into "one of the most sophisticated and well-regarded environmental agencies in the world," one whose influence has extended far beyond the state's borders.[31]

It was its formidable policy accomplishments that had enabled the Board to win the confidence of the public and elected policymakers, and to be trusted with so much regulatory authority over the state's ambitious climate change regulatory policy initiatives.[32] According to Senator Fran Paley, an influential environmental legislator, "It seems hard to imagine that the Legislature would have vested power in CARB to devise an economic-wide program that will regulate all aspects of the state's economy unless it had tremendous confidence in CARB's regulatory capacity."[33] Indeed it is quite likely that without the regulatory reputation the Board had developed during the previous four decades, the legislature would have never approved the Global Warming Solution Act in the first place. For had the state's elected officials been unable to delegate such substantial regulatory authority to the CARB, they would have been forced to engage themselves in the politically challenging – and likely impossible – task of formulating and agreeing on a detailed plan for reducing carbon emissions. Moreover, it was the state's demonstrated success in reducing air pollution that gave policymakers the confidence that it also had the capacity to address the risks of global climate change.

CARB was able to develop early expertise over automotive emissions in California because of the federal government's 1967 decision to permit California – and only California – to develop its own regulatory standards beyond those set at the federal level. This enabled the CARB to function as an American laboratory for innovation on emission control technology and regulation. Indeed, the federal government has subsequently adopted virtually all of the state's innovative and more stringent emissions standards, typically with a lag of a few years. In 1977, the federal government recognized the importance of the CARB's regulatory leadership by permitting other states the option of adopting California's more stringent automotive emissions standards or the laxer ones issued by the federal government. Approximately one-quarter of the states have chosen to follow California's automotive emissions standards, which have also led to improved air quality in much of the United States. [34]

CARB has clearly benefited from the automotive industries' and the United Automobile Workers' relative lack of political influence within the state, as both would have strongly opposed many of the agency's policy initiatives. On the other hand, CARB has cultivated and benefited from a close relationship with independent manufacturers of pollution control

equipment. Many important innovations in the regulation of motor vehicle emissions were first developed by firms in California, including the two-way catalytic convertor and unleaded gasoline. The CARB's commitment to steadily strengthening emission standards has led to a cluster of firms located in the state that specialize in the development of new emissions controls technologies. These firms in turn have been important business backers of the CARB. Its close working relationship with the business community has enabled CARB to become a major leader in terms of identifying and implementing new approaches, technologies, and requirements for regulating air pollution from vehicles in the United States.

Two other factors have also played an important role in strengthening the CARB's impact, reputation, and effectiveness. One has to do with its sources of funding. Importantly, the CARB is not dependent on state appropriations for financial support. Rather, its funds come directly from the fees it imposes on the parties it regulates. This support structure has made it possible for the agency to steadily increase the size of its staff to cope with its growing set of increased regulatory responsibilities, and also to engage in long-term planning. It has also enabled the agency to hire and retain a well-paid staff of technically trained engineers, sophisticated lawyers, and policy experts. A second factor is its administrative structure. Its governing board, which is appointed by the Governor with Senate approval, consists of technical, scientific, and policy experts, as well as representatives from the state's largest regional air pollution control districts. This combination of expertise and political accountability has allowed the agency to develop leadership that is "both expert and politically sensitive."[35]

In sum, the CARB's unusually high reputation as an excellent regulatory agency stems from a variety of factors, including a few that are particularly significant in terms of thinking about regulatory excellence more generally. First, it is important that an agency have a clear policy objective, and that its ability to achieve this objective is publicly recognized and politically supported. In short, it must "deliver" measurable and valued public benefits. Second, an excellent agency must have substantial policy expertise, which in turns requires adequate and secure funding. Third, it needs to be situated within a political system in a way that balances political or public accountability with regulatory autonomy and independence. Fourth, it needs to cultivate a good working relationship with firms in the private sector who are likely to be the most important sources of technological innovations.

Finally, an excellent regulator needs to be in a position to experiment, in order to try policy innovations and assess their effectiveness. In this context, it is important to note that the regulatory autonomy given by the federal government to the state of California, and thus to the CARB, has been an important asset in the making of environmental policy in the United States. It has enabled the US to have *two* important air pollution control regulatory agencies, namely the EPA and the CARB, with the former able to benefit and learn from the track record of the latter. This case study thus provides important support for the diversity or decentralization of regulatory policymaking within a country and the critical opportunities this can provide for policy learning.

Regulatory Excellence as Regulatory Learning

The case of CARB also suggests that regulatory excellence may be a property not only of a single organization, but also of a system of regulating. In other words, what has helped make

the American system of auto emissions regulation excellent is that it contains a structure that allows for substantial opportunity for experimentation and thus domestic policy learning. In this context, California may now be in a position to offer important lessons to other states and possibly the federal government with respect to innovative policy approaches to address the risks of climate change. Clearly California continues to function as a regulatory laboratory: the rest of the United States can be expected to closely follow California's accomplishments – and possibly shortcomings – in order to assess which of the CARB's ambitious and wide ranging efforts to reduce greenhouse gas emissions are worth emulating.

This suggests that the future of climate change regulation in the United States will be significantly affected by CARB's track record. What lessons then, might CARB learn from the FDA if it is to maintain its reputation for excellence? One critical one would be to closely and carefully monitor the impact of its policy choices on both public opinion and the achievement of its policy goals. To maintain its reputation, the agency must avoid over-confidence. It must proceed carefully, and recognize that not all its policy choices will be wise or prudent. There is still much to learn about how greenhouse gas emissions can be most effectively and efficiently reduced, and as new economic and scientific date emerges, CARB must be willing to adjust its regulatory strategies.

It also must recognize that public acceptance of its legitimacy and authority cannot be taken for granted. The FDA found it difficult to listen to critics who argued that its too-stringent drug approval standards were undermining its core mission of protecting the public's health. The CARB must not make a similar mistake: it must learn to listen to and be responsive to public criticisms of its performance and adjust its policy choices accordingly. For example, if particular regulations issued by CARB were seen as hurting California's economy, or unduly interfering with the lifestyles of its residents, then its reputation might well become impaired and its policy effectiveness reduced. It must also be willing to learn from the other governments, both domestically and internationally, which have embarked on a wide range of climate change policies, some of which may differ from California's. Unlike the FDA, the CARB should not assume that its policies and programs represent the "gold standard" for efforts to address the risks of global climate change. An excellent agency is one that recognizes that it does not have a monopoly of expertise – and that enjoying a reputation for excellence in the past, or present, does not guarantee one in the future.

In contrast to ozone depletion there is a broad scientific consensus regarding the risks of climate change. Nonetheless, the ozone case study does emphasize the importance of treating all specific risk regulations as provisional: as new information about the sources and consequences of greenhouse gas emissions and the technologies for address them emerge – as they surely will – CARB may need to modify some of its regulations. An excellent regulatory agency can never be complacent: it must keep learning.

Excellent regulatory regimes engage in both exogenous and endogenous policy learning. In other words, such regimes learn from the experiences of others as well as from their own trials and errors. Furthermore, this learning process demands that the regulator be responsive to new information as it emerges. For health, safety, and environmental risk regulators, this learning process is particularly important, because such agencies often must make regulatory decisions

based upon equivocal or uncertain information. This itself implies that regulatory excellence may be provisional: it may often be difficult to initially assess which decision is the right one. At times it may even make sense for an agency to wait before it takes action, although at other times it may decide to act on the basis of limited information. In either case, it must be ever willing to change its actions in light of new information. What makes an agency excellent is less the quality of its initial decisions than its willingness and ability to respond to new information – information that may either confirm or challenge its initial policy choices.

The critical need for regulators to engage in continuous policy learning as new information becomes available either from their own experiences or those of other officials has been noted by influential students of public policy and administration such as Charles Sabel, Jonathan Zeitlin, and Peter May. [36] In particular, Sabel and Zeitlin's influential concept of experimentalist governance places particular emphasis on the critical role of policy feedback in enabling officials to assess, review, and revise their policy prescriptions, while May reminds policymakers that policy failures may represent important learning opportunities too.

Moreover, learning from the track records, decisions, and experiences of other agencies subject to different public pressures, functioning within different legal environments or relying on different scientific advice, represents an important source of policy learning and thus an important dimension of regulatory excellence. Such external sources can provide an agency with additional information to assess and evaluate its own processes and decisions. This does not mean that regulatory excellence can only be determined by reference to the decisions of other regulators. But it does suggest that since the challenges faced by any regulatory body are unlikely to be unique, monitoring the decisions made by regulatory officials in different political jurisdictions is critical: it can help regulators learn both what to do and what not to do.

Conclusion

What lessons for regulators emerge from the analysis of the case studies in this paper? Three major lessons can be drawn from these cases, contributing to our understanding of the dimensions of regulatory excellence.

First, excellent regulatory officials must place priority on maintaining public confidence in the mission, work, and decisions of their agencies. Regulatory officials are not (typically) elected. The very establishment of regulatory bureaucracies is intended to give officials a substantial degree of autonomy. They should not base every decision on public opinion polls nor seek to avoid public controversy at all costs. But at the same time, it is critical for them to recognize that they are embedded in democratic political systems and that therefore they need to be aware of and broadly responsive to public preferences, especially as these may shift. In the case of ozone depleting chemicals, both American and European authorities were able to retain their reputations precisely because each of their actions, even though they differed from one another, were broadly consistent with the risk perceptions of their respective publics. The same has been true of the CARB. That agency has been successful in large measure because Californians have strongly supported its policy goal of improving air quality. By contrast, while the FDA's initial focus on avoiding false negatives was clearly consistent with public preferences, as the focus and direction of public pressures on the agency began to change, it was

too slow to adjust. It did eventually do so, thus once again bringing into policies into better alignment with those of the broader American public. Taken together, the case studies show that if public preferences differ, as was true in the cases of both ozone depleting chemicals and transatlantic drug approval policies after 1962, different agencies (or the same agencies at different times) may reach very different decisions. But this does not necessarily diminish the value or excellence of the choices they made. If societies differ, then their regulators can and should act differently too – while still achieving excellence.

Second, excellent regulatory officials are never complacent: they must be continually open to and engaged in policy learning. Regulators are always faced with a wide range of policy options and often have to act in the face of scientific or technological uncertainty. Some may enjoy better reputations than others. Nonetheless, there is no substitute for policy learning both from one's own experiences and those of other agencies. In a sense, all regulatory policies and decisions are experiments: they are always provisional and they can also be improved. Much of the CARB's success can be attributed to its ability to engage in continuous policy learning about how mobile source pollutants can be more effectively and efficiently controlled. Likewise, the U.S. Environmental Protection Agency has been willing to learn from the CARB. European pollution control authorities were willing to significantly change their regulations for ozone depleting chemicals as new scientific data emerged, and, over time, the FDA demonstrated its regulatory excellence by exhibiting a willingness to learn from its counterparts in Europe.

Finally, regulatory excellence requires maintaining an appropriate relationship between regulatory agency officials and the business firms affected by their decisions. Here a balance must be struck. On one hand, it is critical that the agency avoid becoming the captive of business interests. But on the other hand, it also must be cognizant of the economic impact of its regulatory policies and be willing to learn from the knowledge and expertise of the private sector. CARB has been so successful precisely because it has been able to strike such a balance: it has both challenged the interests of the major automotive manufacturers, while at the same time it has worked closely with them and with other business innovators in pollution control technologies. Many of the accomplishments of California's climate change initiatives to date have been due to CARB's support of and its close working relationship with private sector firms with a financial stake in reducing greenhouse gas emissions, especially investors in clean technology. Too cozy a relationship with industry can undermine an agency's reputation and legitimacy, but at the same time, so can a relationship that is too adversarial. An excellent regulatory agency must recognize that its effectiveness can be enhanced if it is able to develop business allies and can demonstrate the ways in which its policies create economic as well as social value.

Notes

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David Vogel
University of California, Berkeley

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About the Author

David Vogel is Professor in the Haas School and Business and the Department of Political Science at the University of California, Berkeley. His research focuses on the comparative and international dimensions of consumer and environmental regulation, with a particular focus on Europe and the United States. His several books include *National Styles of Regulation: Environmental Policy in Great Britain and the United States, Trading Up: Consumer and Environmental Regulation in a Global* Economy, and *The Market for Virtue: The Potential and Limits of Corporate Social Responsibility.* He is also the coeditor of W*hat's The Beef? The Contested Governance of European Food Safety* and *Transatlantic Regulatory Cooperation: The Shifting Roles of the EU, the US and California. V*ogel's most recent book, *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* received the Lynton Keith Caldwell Prize for the best book on environmental politics and the best book award from the International Political Science Association's Research Committee on the Structure of Governance. He is currently working on a history of environmental policy innovation in California.