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## The Politics of Precaution, and the Reality

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In his new book, *The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States* (2012), David Vogel makes the claim that there has been a “transatlantic shift in regulatory stringency since 1990” (Vogel 2012: 5), from greater American precaution before 1990 to greater European precaution after 1990. He says that which side is “more risk averse” has reversed (p.2), and in some cases there has been “a literal ‘flip-flop,’ with the United States and the European Union (EU) switching places (p.5). He says this shift has been reflected in and enabled by the EU’s adoption of the precautionary principle (for example in the 1992 Maastricht Treaty), in the face of US criticisms (p.9). To demonstrate this shift, Vogel offers several salient case studies. He argues that this shift has been driven by three main factors: public opinion, preferences of government leaders, and criteria for policy evaluation.

By contrast, in *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (Wiener et al. 2011), we find no such large shift or reversal in relative transatlantic regulatory stringency and precaution. We find, instead, a complex pattern of regulation of multiple risks, with general parity between the US and Europe, punctuated by the selective application of precaution to specific risks on each side – sometimes manifesting greater European precaution since 1990, but sometimes greater US precaution since 1990, and no major aggregate shift. We find a pattern of particularity, not of broad principles. We find the causes of this complex pattern to derive more from the specific crises, public responses, actors and institutions involved in each risk and each regulation, rather than from wholesale national approaches to regulation. And rather than two discrete blocs moving in opposite directions, we find a process of borrowing, exchange and diffusion of policy ideas across these regulatory systems, yielding interconnectedness and hybridization.

There is actually much on which we agree. Both of our books are descriptive – comparative and historical – not mainly normative; they are not evaluating which regulations are better, nor whether the precautionary principle is warranted. Both of our books examine the actual regulation of health, safety and environmental risks in the US and EU over the last five decades. Both books measure the degree of relative precaution as a combination of timing (earliness in anticipation of an uncertain or emerging risk) and stringency: our book is explicit about this metric (see chapter 20), and Vogel appears to assess his cases along the same lines (he variously employs the terms stringency, risk aversion, and precaution).

In addition, we both agree that regulatory systems change over time. This may seem obvious, but it cuts against prominent popular and scholarly assumptions. Both of our books depart from the view that risk regulation is determined by fixed cultures of risk, such as the familiar but simplistic stereotypes of Americans as risk-taking technological optimists and of Europeans as risk-averse technological pessimists (these stereotypes are commonplace but are often more satirical than serious; see “The Rhetoric of Precaution,” chapter 1 in Wiener et al. 2011). Such a claim of fixed risk cultures is at odds with Vogel’s account of American regulation having been more risk-averse before 1990, and

with our finding of selective precautions for specific risks adopted on each side of the Atlantic. Both of our books also find that modern risk regulation is driven by modern politics, not predetermined by national “families of law” (Zweigert and Kötz 1998) or “legal origins” (La Porta et al., 2008). This move to a dynamic account is somewhat in contrast to David Vogel’s own prior work, in which he had argued that regulatory policies conform to distinct “national styles” (Vogel 1986); now he finds that Europe has switched to adopt much of what he had earlier called the American style (Vogel 2012: 289-90). Still, he continues to depict American and European risk regulation as coherent blocs that evolve as a whole.

### **Key differences**

Our books differ in our basic findings on the pattern of relative transatlantic precaution, and in our methods for reaching those findings. The most important difference is in the samples we selected to study.

#### *Case studies*

Vogel’s book has four case study chapters (on food and agriculture; air pollution; chemicals and hazardous substances; and consumer products). Our book has a dozen such chapters (on genetically modified [GM] foods; beef hormones and mad cow disease [bovine spongiform encephalopathy, or BSE]; tobacco; nuclear power; automobile air pollution; stratospheric ozone depletion and climate change; the marine environment; biodiversity; chemicals; medical safety; terrorism; information disclosure systems; and risk assessment systems). Each chapter of each book covers several specific regulations.

Vogel’s four chapters offer cases in which he finds greater EU precaution since 1990: beef hormones, GM foods, mad cow disease/BSE in animal feed, antibiotics in animal feed, climate change, chemicals, electronic wastes, and cosmetics. He also finds some cases of policy convergence (new drug approval, after earlier greater US precaution; and phthalates in children’s products, after initially greater EU precaution), and one counterexample of greater US precaution since 1990 (automobile air pollution).

Our book’s dozen chapters agree regarding several of these cases: we also find greater EU precaution since 1990 on beef hormones, GM foods, climate change, and chemicals; and convergence on new drug approval. But in contrast to Vogel, we find that on mad cow disease/BSE, regulatory policies were more precautionary since 1990 in the US than in the EU – both as to imports of British beef, and especially the risk of transmitting the human form, variant Creutzfeldt-Jacob Disease [vCJD], via blood donations. (The highly stringent US FDA blood donation policy, expressly labeled “precautionary,” was not discussed in Vogel’s book.) Our book does not include cases on electronic wastes or cosmetics. We briefly mention antibiotics in animal feed, where EU policies are more precautionary; phthalates, where EU policies were more precautionary after 1990 and then the US converged; and choking hazards in food, where US policies are more stringent. Meanwhile, our book also includes several other cases that show greater US

precaution since 1990: in addition to automobile air pollution and mad cow/BSE/vCJD, these include tobacco, nuclear power, fisheries, endangered species, and terrorism. If they could be weighted by severity, our cases seem to point even more strongly to greater US precaution, because fine particle air pollution and tobacco pose among the heaviest public health burdens, while nuclear or bio-terrorism poses among the largest looming threats (as however does climate change, where Europe has been more precautionary).

Vogel (2012) responds that our book “includes a number of policies that fall outside the scope” of his analysis (p.18). He continues: “I do not describe or attempt to explain risk regulations in general, or compare policy responses to very different kinds of risks. Rather, my focus is on a subset of risks, namely those that involve health, safety and environmental risks caused by business” (p.18). Among our cases that fall outside his “scope of analysis,” he says, are tobacco, choking hazards in food, terrorism, and medical care (p.18). He then pauses to recognize that the risk of terrorism has been regulated with more precaution by the US than by the EU in the last decade, in what he calls a “mirror image” of greater EU precaution on GM foods (pp.18-19). But Vogel excludes terrorism and the other cases just mentioned from his “scope of analysis,” summarizing: “my argument is not that the EU has become more risk-averse than the United States, but rather that it has become more risk-averse toward a broad range of health, safety and environmental risks caused by business activities” (pp.19-20).

No reason is given for this limited “scope of analysis” -- for not studying risk regulation overall. Why should “business” be the limiting factor? Vogel explains his restricted scope with the comment that “policies toward [his subset of risks] follow similar political dynamics that do not necessarily hold for public policies toward other kinds of risks ... [these approaches] *cannot* be extrapolated to ... other kinds of risks” (p.18). No evidence for this statement is presented. If true, it shows that his cases are not sufficient to generalize to overall regulatory trends. It even hints that Vogel chose his restricted scope to ensure that his case studies would turn out to prove the political dynamic sought to be proved.

Limiting the scope to risks “caused by business activity” could omit important risks that are relevant to the political explanations Vogel seeks to test, such as drinking water pollution (managed by municipalities), smoking tobacco, terrorism, traffic accidents, gun violence, obesity, and others (to the extent that these are deemed caused by individual choice). To study the role of crisis events (which Vogel calls “alarm bells” or “unfortunate events”) in spurring regulation, it would be useful to study the September 11 terrorist attacks (as they led to the creation of the Department of Homeland Security and the enactment of laws on aviation safety, financial tracking, and domestic surveillance; and arguably shifted public attention away from other risks to terrorism risks). To study the influence of business lobbies, it would be useful to look at the tobacco lobby; and at some regulations not governing business, in order to test how outcomes differ with and without the influence of business lobbies. And in many cases, risks arise from a combination of business and non-business activity (e.g. smoking tobacco, or terrorists on airplanes), making this scope inapplicable or arbitrary.

Even following Vogel's scope focused on "business," many of our book's additional cases fall within it: nuclear power (energy companies), tobacco (cigarette manufacturers), medical safety (hospitals and insurers), terrorism (aviation, shipping, banking, telecommunications, etc.), mad cow disease in blood (blood banks, hospitals), and choking hazards (food processors and toy manufacturers) -- all involve health, safety and environmental regulations of business activities, and greater US precaution. This expanded set of cases falling within Vogel's scope shows a more mixed pattern and not a large transatlantic shift. (Similarly, Vogel's claim that other countries are emulating EU standards is vulnerable to the same omission of other cases, regarding business or otherwise, that show a different pattern.)

Counting cases is insufficient, though, because neither set of cases is a representative sample of the full universe. Indeed that is the deeper difficulty with Vogel's claim: the cases he adduces are not a sufficient basis to infer the broad trend he asserts. His cases are not a representative unbiased sample -- of the larger universe of risk regulations overall, or even within his restricted "scope." Nonetheless, Vogel states: "I believe the cases I have chosen to discuss *are* representative of the politics and policies of risk regulation on both sides of the Atlantic between 1960 and 2010" (p.20). Yet he offers no reason for this belief. He does not describe any method for selecting his cases (beyond describing his "scope"). Case studies can be useful in revealing the policy process and generating hypotheses. But cases selected because they are salient (visible), easy to study (convenient), or deemed important or interesting by the author, are insufficient for generalizing to the state of the world -- they are not an unbiased sample from which to extrapolate (King et al., 1994). They are the cases under the lamppost, or already pointing to the author's hypothesis, or a manifestation of the availability heuristic. Kagan and Axelrad (2000: 18) candidly declared about their own book: "This volume of case studies, therefore, cannot support unqualified generalizations about any of the national legal systems as a whole or about the across-the-board impact of national styles of law and regulation." Vogel likewise concedes that his sample of cases is "selective" (p.20), and concedes that "they do not by themselves 'prove' a historical transatlantic shift in regulatory stringency with respect to consumer and environmental risks caused by business" (citing other works including our book) (p.20). By the same token, our larger set of cases pointing the opposite way does not prove a trend in the opposite direction -- though it does undermine Vogel's claim.

### *Quantitative analysis*

Recognizing the sample selection problem with case studies, in our book we also undertook a second complementary methodology: a large-N quantitative study of an unbiased sample (Swedlow et al., chapter 15 in Wiener et al. 2011). Compared to case studies, this approach is more shallow (neglecting details of law-in-action, implementation, and politics), but it also enables generalized inferences to be inferred from a representative sample. Through an extensive literature search, we identified all risks addressed during 1970-2004 (n=2,878), from which we drew a random sample of 100. We checked the random sample for representativeness across 18 types of risks.

Then we researched the regulation of each of these 100, and we scored each for relative precaution in each year.

We found no large shift in relative precaution – at most a 3% to 6% shift toward EU precaution, which implies no such shift in 94% to 97% of the set of risks; and we found that although a few risks in our sample moved toward greater EU or greater US precaution over the period, the most common trend among these risks was no change in relative precaution (Swedlow et al., chapter 15 in Wiener et al. 2011; see also Swedlow et al. 2009). Vogel quotes one sentence from this research (Swedlow et al. 2009: 251, quoted in Vogel 2012: 18), deeming it “broadly consistent with my analysis” (our text said “weakly consistent”), but he does not mention that the larger findings of our study show little to no support for a reversal or wholesale shift. Moreover, the time period of this large-N study was during the rise of EU competence over environmental regulation (e.g. the 1987 Single European Act, and the 1992 Maastricht Treaty adopting the precautionary principle), so looking only at the EU level might have indicated rising European precaution since about 1990 even if this was merely an artifact of the elevated level of competence (while the EU member states might have been highly precautionary before 1990); yet still we found no such rise. (Vogel’s reply suggests weighting our scores by the “magnitude of the harms”; as noted above, tobacco, air pollution, and other high-magnitude cases would likely indicate greater relative US precaution, though climate change leans the other way.)

### **Explanatory factors**

Much of Vogel’s book addresses his explanations for the asserted shift: public opinion, government leaders, and criteria for policy evaluation. Vogel tells an alluring story; it invokes the contemporary political rhetoric and the salient cases receiving attention from politicians and news media -- but not necessarily the actual policy making. People may accept Vogel’s political story because it fits their desired narrative: some want to believe in a more precautionary Europe because they favor precaution and want the US to compete with Europe to be the “leader”; others because they disfavor precaution and want the US to resist Europe’s statist moves. But as discussed above, the policymaking reality has not matched the political rhetoric. The two book titles are apt: Vogel’s book really is more about the *Politics*, while ours is more about the policy *Reality*.

The promise of Vogel’s explanatory factors is their ability to explain changes in the dependent variable, relative precaution. But if the reality is that relative precaution has *not* undergone a large shift, then Vogel’s three causal factors must not be as powerful as he claims. They could have been countered by other omitted variables (such as statutory instructions, judicial review, executive oversight, agency missions and culture, interest group pressures and coalitions, policy entrepreneurs, and crisis events) (Wiener & Richman 2010). And if the true pattern of precaution has been highly risk-specific, then attempts to contrast a US approach vs. an EU approach will be inadequate to explain varying policies regarding different risks (Wiener and Rogers 2002). Each of Vogel’s three explanations offers insights, but cannot account for the more complex pattern of

actual policies. A better view depicts risk regulation as an interconnected transnational web with particular explanations for particular policies.

### *Public opinion*

Vogel argues that the US public became satisfied with the level of risk regulation after about 1990, while Europeans wanted more (chapter 7; and p.286). Even if true, it is not clear why. Vogel says fewer “alarm bells” rang in the US than in Europe after 1990. Again, why? (random? past regulatory success? changing news media?). (Meanwhile, he also says that crisis events are not necessary or sufficient to spur risk regulation, p.40.) But Vogel omits important alarms yielding greater American demand for precaution, notably the September 11, 2001 terrorist attacks (see chapter 12 in Wiener et al. 2011).

The story about public opinion also needs to explain why responses to alarms are sometimes distant and inconsistent. Some alarm bells fostered regulation far from where the alarm occurred: for example, the thalidomide crisis in Europe in the 1960s was followed by greater US (not European) precaution (Vogel 2012: 200-201); and the mad cow crisis in Europe in the 1980s-90s was followed by greater US precaution (on imports of British beef, and especially on blood, see chapter 3 in Wiener et al. 2011). If the mad cow/BSE/vCJD crisis in Europe explains European public fear of GM foods, as Vogel suggests, why did this cross-application occur – and why were public perceptions of GM foods influenced in Europe but not in the US, while the US did react with greater precaution on vCJD in blood? (Moreover, the preceding blood crisis had been the HIV/AIDS contamination case in France, yet the US adopted more stringent measures on vCJD in blood than did France or the EU.)

### *Government leaders*

Vogel argues that Republican party power, partisan gridlock, and business lobbying have made it more difficult for the US Congress to adopt precautions (p.282-86). But US Presidents of both parties have advanced significant risk regulation. As Vogel recognizes in his chapter 4, the Bush (father), Clinton, Bush (son), and Obama administrations have all pushed ahead stringent regulations to reduce fine particulate matter air pollution (see also chapter 6 in Wiener et al. 2011). Further, US presidents pushed to regulate tobacco, over the industry’s opposition (President Clinton’s FDA sought authority to regulate tobacco, but lost in court; FDA received that authority when President Obama signed the Family Smoking Prevention and Tobacco Control Act in 2009 (see chapter 4 in Wiener et al. 2011). And the Bush (son) and Obama administrations have undertaken highly precautionary policies against threats of terrorism (id., chapter 12). These all illustrate greater US precaution since 1990.

It is true that the US has exhibited less precaution regarding climate change. The Clinton administration signed but never submitted the Kyoto Protocol for ratification (after the Senate voted unanimously not to ratify such a treaty); then the Bush (son) administration withdrew from the treaty. Nonetheless, some US states began to act, and the Obama EPA has begun issuing regulations on greenhouse gas emissions, reducing the

transatlantic divergence. And the reasons for US reluctance on climate policy seems specific to climate – e.g. the high cost of emissions abatement due to reliance on coal, low population density, long transport distances by car, and the end to new nuclear power plants after 1980 (ironically, an example of greater US precaution against nuclear power risks) – rather than due to a wholesale shift in relative precaution to Europe. Although potential “alarm bells” such as Hurricanes Katrina (2005) and Sandy (2012) have not yet spurred major climate legislation, US emissions are now declining due to the recession, shale gas replacing coal, and the new regulations.

### *Criteria for policy*

Vogel argues that the rise of cost-benefit analysis (CBA) in US regulatory oversight may explain the decline in US relative precaution since 1990. But there was no marked change in US policy criteria around 1990. CBA was applied to regulations by President Carter’s Executive Order (EO) 12044 (1978) and President Reagan’s EO 12291 (1981) (authorizing the Office of Information and Regulatory Affairs, OIRA, to review regulations). These were reaffirmed by President Clinton’s EO 12866 (1993) (still in force today).

Meanwhile, since 1990, CBA has risen in Europe. The 1992 Maastricht Treaty put CBA in the same Article as the precautionary principle (Art. 130r, now Art. 191 of the Treaty on the Functioning of the EU). The EU’s “Better Regulation” initiative was launched in 2001, with Impact Assessment (IA) Guidelines issued in 2005 and subsequently revised. In 2006, the EU established its Impact Assessment Board (IAB), as a counterpart to US OIRA. Vogel says that unlike OIRA, “the IAB has no veto power” (p.274). But in early 2010, President Barroso gave the IAB just that authority (European Commission 2010). The IAB has increased its rate of returning IAs from 9% in 2007 to more than 36% in each of 2010 and 2011 (European Commission 2012). In addition, European courts are increasingly backing up this role by requiring an IA to satisfy principles of EU law such as proportionality (Alemanno 2011).

The US commitment to CBA before 1990, and the evolution of Better Regulation and IA in Europe after 1990, undercut the claim that changing policy criteria spurred a shift toward greater relative European precaution after 1990. Instead, they illustrate the borrowing and diffusion of ideas across regulatory systems (Wiener 2006; chapter 20 in Wiener et al. 2011; Wiener 2013).

### **Further research**

Whether one agrees with him or not, David Vogel’s work teaches us to study carefully the evolution of risk regulatory systems. Further research could assess a longer time period, both past and future. Looking ahead, perhaps the EU’s political commitment to precaution will shape more actual policies over time -- or perhaps Better Regulation will moderate EU regulation. Further research could assess additional cases, such as nanotechnology, financial crises, oil spills, guns, cybersecurity, drinking water, cell

phones on airplanes, and others. It could assess not only policy adoption, but policy impacts. Ideally, future work could combine the strengths of both small-N in-depth case studies that identify hypotheses and institutional context, and large-N quantitative studies that test broad claims and help select cases for study (Levi-Faur 2004; Lieberman 2005, Swedlow et al. 2009). Further research could compare across types of institutions (e.g. administrative regulation, courts, private standards), and across member state policies within the EU and within the US. Sand (2000) and Zander (2010) each find significant variation in the degree of precaution applied to different risks by different EU member states, casting further doubt on claims of a coherent shift to greater EU-wide precaution. Beyond the transatlantic comparison, further research could compare regulation around the world. (On the global spectrum, the US and EU may look remarkably similar (Baldwin 2009).) And further research could trace the borrowing and diffusion of ideas across transnational networks (chapter 20 in Wiener et al. 2011; Slaughter 2009), both to study hybridization across regulatory systems and to test how learning occurs in a global policy laboratory.

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