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Better Regulation in Europe

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Introduction

'Better Regulation' is sweeping Europe. Based on a White Paper on Governance[1] and an expert group report,[2] both issued in 2001, the European Commission under President Prodi adopted a suite of regulatory reform measures in 2002, including guidelines on impact assessment.[3] Following a Communication from the new Barroso Commission in March 2005,[4] these guidelines were revised in 2005[5] and updated again in 2006.[6] Impact Assessment (IA) is now required for all regulatory proposals on the Commission's Work Programme. In addition, the Commission is pressing for simplification of existing laws (through

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[1] European Commission, 'European Governance: A White Paper', COM(2001) 428.

[2] Mandelkern Group on Better Regulation, Final Report, November 2001.

[3] European Commission, Communication from the Commission on Impact Assessment, COM(2002) 276, 5 June 2002 (hereafter 'IA Guidelines 2002').

[4] European Commission, Communication from the Commission to the Council and the European Parliament, 'Better Regulation for Growth and Jobs in the European Union', COM(2005) 97, SEC(2005) 175, 16 March 2005.

[5] European Commission, Impact Assessment Guidelines, SEC(2005) 791, 15 June 2005 (hereafter 'IA Guidelines 2005').

[6] European Commission, Impact Assessment Guidelines, SEC(2005) 791, 15 June 2005, with 15 March 2006 update (hereafter 'IA Guidelines 2006').

consolidation, codification, and repeal), reduction of administrative costs ('cutting red tape'), and consultation with those affected by regulatory policies.

The member states of the European Union (EU) are likewise adopting programs of Better Regulation, some predating and spurring the Commission's efforts, and others in turn spurred by the Commission.[7] In 2004, a coalition of four of the rotating six-month Presidencies of the European Union (Ireland, Netherlands, Luxembourg, and Britain) issued a joint statement of their intention to pursue Better Regulation efforts during their upcoming Presidencies; this letter played an important role in spurring the European Commission to update and strengthen its IA Guidelines.[8] To note one prominent example of action by a member state, the UK has launched a Better Regulation Executive[9] and an external advisory Better Regulation Commission. In May 2005, UK Prime Minister Tony Blair delivered a speech on 'Risk and the State', emphasizing that risk regulation is absolutely necessary, but criticizing overregulation of small risks in the futile effort to reduce risks to zero (often as an overreaction to a recent crisis), thus impeding innovation and inducing perverse effects that 'do more damage than was done by the problem itself'. As a remedy, he advocated the program of 'Better Regulation' based on a 'rigorous risk-based approach' that will employ impact assessments and 'regulate only after reflection'.[10]

Will Better Regulation make a difference? Will it make things better? This study begins by examining the Better Regulation initiative as an exercise of legal borrowing, and by framing the question whether Better Regulation will really yield better results. After several transatlantic conflicts over regulatory topics such as the precautionary principle, genetically modified foods, and climate change, Europe and America now appear to be converging on the analytic basis for regulation. In a process of hybridization, European institutions are borrowing 'Better Regulation' reforms from both the US approach to regulatory review using benefit-cost analysis and from European member states' initiatives on administrative

[7] The Communication of 16 March 2005, COM(2005) 97, above, included a colourful chart of relative progress on Better Regulation among the member states. Highest marks went to Denmark, the UK, and Poland; lowest marks went to France, Portugal, and Cyprus. See below in the section on European Experience at n 88.

[8] See Joint Initiative on Regulatory Reform, a Letter from the EU Presidencies of Ireland, Netherlands, Luxembourg, and the UK, 26 January 2004, at <http://www.finance.gov.ie/documents/pressreleases/2004/janmcc12462. pdf>.

[9] See <http://www.betterregulation.gov.uk/> and < http://www.cabinetoffice.gov.uk/regulation/>.

[10] Prime Minister Tony Blair, 'Speech on Risk and the State', 26 May 2005, available at < http://www.number-10.gov.uk/output/Page7562.asp>.

costs and simplification; in turn the European Commission is helping to spread these reforms among the member states.

In the following sections, this study addresses in more detail the main components of Better Regulation—impact assessments and administrative simplification—and advocates the adoption of several institutional improvements. (Other aspects of regulatory reform in Europe, such as transparency, consultation, and subsidiarity, are mentioned here but are not the focus.) In many respects, the Better Regulation initiative promises salutary reforms, such as wider use of regulatory impact assessments and a reduction in unnecessary bureaucracy. In other respects, the European initiative speaks more of Procrustean deregulation than of better regulation. Meanwhile the European Commission still needs to establish the institutional infrastructure needed to succeed. I argue that the European program of Better Regulation is well-founded but could be even better if it adopted several strategies: enlarging the scope of impact assessment and benefit-cost analysis toward a broader, 'warmer', and more evenhanded application of these tools, with greater attention to multiple risks; moving beyond a narrow focus on cutting administrative costs or simplification for their own sake, toward criteria that address benefits as well as costs; centralizing expert oversight so that impact assessments actually influence decisions, both to say 'no' to bad ideas and 'yes' to good ideas; and undertaking *ex post* evaluation of policies for adaptive policy revision and for improvement of *ex ante* assessment methods. These reforms would help Better Regulation achieve its true objective: better, not just less or more. In turn, the US could study these European innovations and borrow from them where they prove successful.

Legal Borrowing

The Better Regulation initiative is a conscious exercise of legal borrowing. This borrowing has been both horizontal and vertical. Horizontal legal borrowing occurs when one co-equal legal system borrows from another, such as Europe borrowing from the US, or one European member state from another EU member state.[11] Vertical legal borrowing occurs when a supra-governmental regime borrows from its own constituent members, such as the EU-level institutions borrowing from EU member states.[12]

[11] The literature on horizontal legal borrowing (across states) is extensive; the classic is Alan Watson, *Legal Transplants: An Approach to Comparative Law* (2nd edn) (Athens, Ga: University of Georgia Press, 1993).

[12] A framework of legal borrowing that adds the vertical dimension (between states and federal and international bodies) is developed in Jonathan B Wiener, 'Something

The Better Regulation initiative in Europe borrows along both of these dimensions. It is an outgrowth of ideas percolating up from (vertically) and spreading across (horizontally) the EU member states; of the integration of EU institutions and the current EU platform of competitiveness, good governance, and sustainable development;[13] and also of deliberate (horizontal) borrowing from American law. It is thus a perfect example of legal 'hybridization', an evolutionary process involving the exchange and recombination of traits (here, legal ideas) from different species (here, legal systems) into new hybrid versions in response to changing needs.[14] As in biological evolution, legal hybrids do not always succeed. Mixing together legal concepts can be ineffective or incoherent.[15] As in biology, legal hybrids succeed when they possess novel combinations of traits that enable them to occupy new niches opened up by changing external demands. Better Regulation in Europe is a hybrid package of reforms attempting to respond to changing needs for regulatory management.

In its Impact Assessment Guidelines, the Commission tellingly quotes US President Woodrow Wilson: 'I not only use all the brains that I have, but all that I can borrow'.[16] The Commission's immediate point here is to espouse borrowing ideas from public input and interservice consultation to improve regulation, but the quotation simultaneously invokes the larger project of legal borrowing involved in the European initiative on Better Regulation, which emulates key concepts and tools of regulatory reform developed in the American administrative state over the past four decades.[17]

Borrowed for Something Blue: Legal Transplants in the Evolution of Global Environmental Law' (2001) 27 *Ecology LQ* 1295.

[13] A useful history of the connections of Better Regulation to these three elements of the EU platform is provided in Ragnar Lofstedt, 'The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis' (2004) 28 *J Risk & Uncert* 237–60.

[14] For further discussion on 'hybridization' of legal ideas and the counterpart concepts in evolutionary biology, see Jonathan B Wiener, 'Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems' (2003) 13 *Duke J Comparative & Int'l Law* 207, 254–61. An overview of evolutionary biology concepts applied to legal evolution is Simon Deakin, 'Evolution for Our Time: A Theory of Legal Memetics' (2002) 55 Current Legal Problems 1–42. See also sources cited in nn 29–31 below on legal borrowing and diffusion.

[15] See Wiener, n 14 above (noting failure of hybrids until new niches open); Willam Reppy, 'Eclecticism in Choice of Law: Hybrid Method or Mishmash?' (1983) 34 Mercer L Rev 645 (criticizing eclecticism as unpredictable and standardless, while endorsing careful construction and transparent selection of new hybrid methods). Moreover, diffusion itself can sometimes undermine incentives to innovate or can invite fads. See David Lazer, 'Regulatory Capitalism as a Networked Order', (March 2005) Annals of the American Academy 52–66.

[16] Quoted in IA Guidelines 2006, at 9.

[17] On the US history, see Richard Pildes and Cass R Sunstein, 'Reinventing the Regulatory State' (1995) 32 *U Chicago L Rev* 1; Elena Kagan, 'Presidential Administration' (2001) 114 *Harv L Rev* 2246.

What is now emerging is a global movement toward regulatory reform and Better Regulation, drawing significantly on American administrative law and oversight mechanisms.[18] The American sources of European Better Regulation are well recognized. For example, the head of Irish government recently observed:

> Better Regulation and EU-US perspectives are foremost in my mind these days. Better Regulation is a core theme of our EU Presidency and featured prominently at the recent Spring Economic Council . . . . There is a long tradition in American Public Administration of focussing on the quality and impact of regulation. Many of the policies, institutions and tools that support Better Regulation have their origins in the USA. For example, a lot of very significant anti-trust and consumer protection measures were put in place in the USA in the first decades of the 20th century. There is much that we have learned from the United States in relation to regulatory management and, through occasions like this, much that we can continue to learn . . . . We hope too that there will be shared learning. While we in the European Union are newer to the game, I hope that we have moved beyond our rookie season! The Union is making up ground quickly in respect of Better Regulation. This is as it should be. There is a deeper understanding within the European Institutions and Member States of the need for regulatory reform.[19]

This process is not one-way: American legal ideas are not the only ones being adopted in other countries. At the same time that the Better Regulation initiative is bringing the methods of impact assessment and regulatory review from the US to Europe, other legal concepts are also spreading from Europe and elsewhere to the US and beyond.[20] The precautionary principle is perhaps the best example of a European regulatory law export (adopted, for example, in US statutes and judicial decisions in the 1970s and by the city of San Francisco in 2003);

[18] See Benedict Kingsbury, Nico Krisch, and Richard B Stewart, 'The Emergence of Global Administrative Law', (summer/autumn 2005) 68 L & Contemp Probs 15; Richard B Stewart, 'Accountability and the Discontents of Globalization: US and EU Models for Regulatory Governance' (draft 2006); Robert W Hahn and Robert E Litan, 'Counting Regulatory Benefits and Costs: Lessons for the US and Europe' (2005) 8 J Int'l Econ Law 473–508; Robert W Hahn, *Reviving Regulatory Reform: A Global Perspective* (Washington, DC: AEI Press, 2001).

[19] Speech by the Taoiseach (head of government of Ireland), Mr Bertie Ahern, TD, at the IBEC Conference on EU-US Perspectives on Regulation, Dublin, 19 April 2004, available at <http://www.betterregulation.ie/index.asp?docID=57>.

[20] This mixed and multi-directional pattern stands in contrast to the claim that the globalization of law is a one-way process of imperious Americanization, eg Ugo Mattei, 'A Theory of Imperial Law: A Study on US Hegemony and the Latin Resistance' (2003) 10 Indiana J Global Legal Studies 383. Contrary to Mattei, European legal ideas are also being borrowed, including by America. And (as Mattei also recognizes) America is frequently a borrower of other countries' immigrants and ideas, so even the export of nominally 'American' legal ideas is often the reception, recombination, and re-export of others' ideas.

environmental contracts or covenants are another. The larger picture of globalization is one of shared hybridization across legal systems, that is, the mutual borrowing of many legal ideas across many countries and the creation of new hybrid legal concepts.[21] The Better Regulation initiative is itself a hybrid, combining the American tool of regulatory impact assessment (RIA) with European strands such as simplification and a standardized approach to measuring administrative costs.

Moreover, Better Regulation is not just an American idea. Considered as a form of structured reasoning to inform sound public policy and bureaucratic governance, as I describe below (recalling Benjamin Franklin's 'prudential algebra'), it is also a European idea: one need only think of Bentham, Hume, Smith, and Mill, and of Montaigne, Descartes, Rousseau, Voltaire, and Max Weber, to name a few. America did not invent the ideas of forecasting future risks, reasoned decision-making, and rigorously assessing public policy options, even if the US government has by now constructed a highly developed system for implementing these concepts. In recent years, British, Australian, and Italian scholars have made important contributions to Better Regulation.[22] And French scholars, across the political spectrum, have championed evidence-based reasoning for government policy; they include figures as diverse as Bertrand de Jouvenel[23] and Pierre Bourdieu.[24]

[21] On the spread of the precautionary principle and hybridization across legal systems, see Wiener, n 14 above.

[22] Eg N Gunningham and P Grabosky, *Smarter Regulation: Designing Environmental Policy* (Oxford: Oxford University Press, 1998); Christopher Hood, Henry Rothstein, and Robert Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford: Oxford University Press, 2001); Richard Macrory, 'Regulatory Justice: Sanctioning in a Post-Hampton World' (The Macrory Review of Penalties) (consultation document, March 2006); Claudio Radaelli, *What Does Regulatory Impact Assessment Mean in Europe*? AEI-Brookings Joint Center for Regulatory Studies, Related Publication 05–02, January 2005; Andrea Renda, *Impact Assessment in the EU* (Brussels: CEPS, 2006); Giandomenico Majone, *Regulating Europe* (London: Routledge, 1996).

[23] Bertrand de Jouvenel, *L'Art de la Conjecture* (Monaco: Editions du Rocher, 1964). This call for rigorous thinking about the future influenced Herman Kahn and Anthony J Wiener, *The Year 2000: A Framework for Speculation* (New York: Macmillan, 1967), which helped bring scenario-based forecasting and decision-making to the US government.

[24] Bourdieu is cited by Joseph Stiglitz, *Globalization and its Discontents* (London: Penguin, 2002), p x for the point that politicians need to engage in scientific debate based on facts and evidence before adopting public policies. Bourdieu was a leading French sociologist, 1930–2002, at L' Ecole des Hautes Etudes en sciences sociales (EHESS) and then at the Collège de France, a theorist of social fields and social capital, a leftist activist, and an opponent of liberal markets and globalization; he was the author of *Acts of Resistance: Against the Tyranny of the Market* (New York: New Press, 1999) and 'Utopia of Endless Exploitation: The Essence of Neoliberalism' *Le Monde Diplomatique*, December 1998, at <http://mondediplo.com/1998/12/08bourdieu> (denouncing market liberalism promoted by economists, and favoring public interest based on collective institutions and empirical verification of theory); he was also the subject of the documentary film *La*

It is worth noting that US Supreme Court Justice Stephen Breyer, in his book on what is now called Better Regulation, held up the French Conseil d'Etat as a model to transplant to the US.[25] And it was a French expert, Dieudonné Mandelkern, who led the multinational group whose report proposed the EU Better Regulation initiative in 2001.[26]

Legal borrowing of the concepts and nomenclature of 'better regulation' and 'regulatory impact assessment' does not necessarily mean convergence in the content of policies and procedures adopted to implement those ideas. As Claudio Radaelli has emphasized, the 'diffusion of a common RIA "bottle"' does not necessarily produce the same 'wine'.[27]

Nonetheless, it is striking that European regulatory policy is now expressly borrowing ideas from American law, even when transatlantic relations are relatively strained. It is even more striking that chief among these borrowed ideas is impact assessment as a check on regulation, or more precisely as a way to shape regulation. The contrast to the debate over the precautionary principle in the 1990s is stark: there Europe sought to export its aggressive platform over the objections of a reluctant US government, and to position Europe (at least rhetorically) as a distinct pro-environment alternative to American pro-market regulatory policy in the post-Cold War era.[28]

Sociologie est un Sport de Combat (2003). Said Bourdieu: 'Observation of reality puts us on our guard against the temptation to construct over-simple models' (from Bourdieu's work on the peasantry in Béarn; quoted in Douglas Johnson, ' Obituary: Pierre Bourdieu' the *Guardian* 28 January 2002, at <http://www.guardian.co.uk/obituaries/story/0,,640396,00.html>).

[25] Stephen G Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Cambridge, Mass: Harvard University Press, 1993), part III.

[26] Mandelkern Group Report, n 2 above.

[27] Claudio M Radaelli, 'Diffusion without Convergence: How Political Context Shapes the Adoption of Regulatory Impact Assessment', (October 2005) 12 *Journal of European Public Policy* 924–43.

[28] See Wiener, n 14 above (reporting the evolution of precaution in EU and US legal systems, and the claim that the EU had become more precautionary than the US by the 1990s). Studies in the 1980s typically found that the US used scientific and economic analysis more than did Europe, although the ultimate standards set were similar. Eg Sheila Jasanoff, *Risk Management and Political Culture* (New York: Russell Sage, 1986); David Vogel, *National Styles of Regulatin: Environmental Policy in Great Britain and the United States* (Ithaca, NY: Cornell University Press, 1986). Whether Europe *actually* adopted a more precautionary regulatory system than the US in the 1990s is, however, open to question. Several cases support that claim, including greater European precaution on hormones in beef, genetically modified foods, climate change, and toxic chemicals. On the other hand, several cases point the other way, including greater US precaution on mad cow disease (BSE) and vCJD in blood, particulate matter emissions from power plants and diesel vehicles, youth violence, and terrorism, see Wiener, n 14 above. But these cases are not a representative sample from which reliable generalizations can be drawn about trends in all risk regulation. We therefore studied a data set of all of the 2,878 risks identified in the US

What explains this rapprochement? First, it illustrates the view that legal borrowing is ubiquitous, occurring all the time in multiple directions.[29] Legal borrowing has played a strong role in the evolution and diffusion of environmental regulation in the past.[30] Borrowing has helped spread such legal concepts as environmental impact assessment, pollution discharge information disclosure registries, economic incentive instruments including emissions trading, and precaution. Scholars often write about these patterns of diffusion after they have occurred. Sometimes scholars also play a role in the process of transplantation as it occurs;[31] Better Regulation is one of those cases, as experts share ideas across the Atlantic through papers, conferences, and sabbaticals. A central point here is that the current borrowing of Better Regulation tools has not been much constrained by abstract ideological or rhetorical commitments, nor by supposed national styles or mentalities of law.[32]

and Europe over 1970–2004; we found no significant trend toward greater European precaution over the period. James K Hammitt, Jonathan B. Wiener, Brendon Swedlow, Denise Hall, and Zheng Zhou, 'Precautionary Regulation in Europe and the United States: A Quantitative Comparison' (October 2005) 25 *Risk Analysis* 1215–28.

[29] See Watson, n 11 above, 22; cf Jack L Walker. 'The Diffusion of Innovation Among the American States' (1969) 63 Am Poli Sci Rev 880–9 (within the US); Anne-Marie Slaughter, *A New World Order* (Princeton: Princeton University Press, 2004) (across international networks). There are parallel literatures on the diffusion of business and technological innovations, see Everett M Rogers, *Diffusion of Innovations* (5th edn) (New York: Free Press, 2003) (first pub 1963); on the diffusion of social innovations, see eg Torsten Hägerstrand, 'The Diffusion of Innovations' (1968) 4 *International Encyclopedia of Social Sciences* 194; A J Toynbee, (1961) 12 'A Study of History: Reconsiderations' 343 (describing as 'mimesis' the process of cross-cultural diffusion); and on the diffusion of political systems, see eg Kurt Weyland, 'Theories of Policy Diffusion', (2005) 57 *World Politics* 262–95; Zachary Elkins and Beth Simmons, 'On Waves, Clusters and Diffusion: A Conceptual Framework' (2004) *Annals of the American Academy* (AAPSS); Beth Simmons, Frank Dobbin, and Geoffrey Garrett, 'The International Diffusion of Liberalism', (Fall 2006) *International Organization*.

[30] See Peter H, Sand, *Transnational Environmental Law: Lessons in Global Change* (The Hague and Boston: Kluwer Law International, 1999) 241; Wiener, n 12 above; Per-olof Busch and Helge Jörgens, 'The International Sources of Policy Convergence: Explaining the Spread of Environmental Policy Innovations' (October 2005) 12 *Journal of European Public Policy* 860–84.

[31] Watson argues that much borrowing is carried out by elite jurists who borrow what they happen to know or come across in their travels, communications, and research (n 14 above, at 112–13). In a similar way, Peter Galison writes about the exchange of ideas across scientific disciplines occurring when experts participate in a 'trading zone' such as by collaborating on a common research tool. Peter Galison, *Image & Logic: A Material Culture of Microphysics* (Chicago: The University of Chicago Press, 1997).

[32] For the view that national styles or mentalities of law are highly influential, see Vogel, n 28 above; K Zweigert and H Kotz, *An Introduction to Comparative Law* (3rd edn, T Weir trans) (Oxford: Oxford University Press, 1998) (styles of legal systems are seen in their history, their 'predominant and characteristic mode of thought', their institutions, and their ideology, ibid 68); Pierre Legrand, 'European Legal Systems are Not Converging' (1996)

Contrasts between allegedly US and European approaches to law and regulation are overstated,[33] as intergroup contrasts often are.[34] Instead, the ongoing Better Regulation experience suggests that legal borrowing can readily occur across ostensibly different legal systems, as change agents of legal evolution (such as scholars or policy entrepreneurs within government) import legal concepts and as those legal concepts offer net benefits to the receiving society or its institutions.[35]

Second, economic and political globalization are increasing the opportunities for exchange of legal ideas. Trade, transnational and transgovernmental networks, epistemic communities of experts, and telecommunications (especially the internet) have made it more likely, even in just the last fifteen years, that legal concepts used in one country can be researched and cross-fertilized in another country. Even if national legal styles or mentalities governed in the past, increasing exchange across legal systems is leading those old ways to evolve toward more open, cosmopolitan attitudes, and a process of 'hybridization' in which mixtures of legal ideas create new hybrid modes that populate both sources.[36]

Third, 'it's the economy'. A major objective of Better Regulation is economic competitiveness.[37] The US adopted regulatory reform efforts in the 1970s and 1980s in part to combat inflation and recession. Europe turned to Better Regulation in the last five years to remedy its sluggish economy, which has been growing at about 2 percent per year of late, in contrast to roughly 3 to 4 percent per year in the US and nearly 10 percent per year in China. The Lisbon Strategy adopted in 2000 aims to make

45 ICLQ 52 (emphasizing distinctive national legal mentalities); Robert A Kagan, *Adversarial Legalism: The American Way of Law* (Cambridge, Mass: Harvard University Press, 2001). But see John Bell, *French Legal Cultures* (London: Cambridge University Press/Butterworths, 2001) (finding different legal cultures in the different institutions within France).

[33] Some have argued that Europe now follows the Precautionary Principle whereas the US does not, eg David Vogel, 'The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe', (2003) 33 British J Poli Sci 557–80, but our research finds little evidence of such a divergence. See Wiener, n 14 above (reviewing the debate); Hammitt *et al*, n 28 above (surveying a large array of risks and finding little or no trend toward greater European precaution).

[34] Cf Henri Tajfel, 'Experiments in Intergroup Discrimination' (1970) 223 *Scientific American* 96–102 (showing that people tend to exaggerate intergroup differences); Amartya Sen, *Identity and Violence: The Illusion of Destiny* (New York: WW Norton, 2006) (showing that group characterizations are misleading because they ignore enormous variation among individuals).

[35] For a model of legal borrowing supplied by change agents and potentially subject to benefit-cost analyses in the receiving jurisdiction (depending on the voting rules for adoption of law in the receiving institutions), see Wiener, n 12 above, at 1344–62.

[36] On hybridization of regulatory law, see Wiener, n 14 above, at 254–61.

[37] Better Regulation builds on the continuing program of regulatory reform of *economic* regulation—reform or deregulation of price controls, subsidies, and limits on

Europe the most productive economy in the world by 2010, while maintaining the European social model and fostering environmentally sustainable growth. The Better Regulation initiative is explicitly tied to the Lisbon Strategy. The Prodi Commission stressed good governance; the Barroso Commission stresses competitiveness.[38] Slow economic growth and high unemployment in Europe prompted the Lisbon Strategy to boost growth and jobs; the World Bank's 'Doing Business' reports added pressure on European governments to attract business via legal reform.[39] The four Presidencies' letter of January 2004 began with this opening paragraph:

> The European Commission's recent review of the European economy pointed out that regulatory reform is a key element in seeking to achieve the goals of the Lisbon strategy. The IMF has made it clear that improvements in the EU regulatory framework could deliver as much as a 7 per cent increase in GDP and a 3 per cent increase in productivity in the longer term.[40]

It almost goes without saying that one key purpose of regulatory reform is to reduce costs.[41] In the 1980s the US had a Task Force on Regulatory Relief, later called the Competitiveness Council; the EU now has a Competitiveness Council of Commissioners. The UK Better Regulation Executive was earlier called the Regulatory Impact Unit, and before that the Deregulation Unit in the 1990s. Reducing the costs of regulation is driven by both internal and external pressures. Because regulation

market access in regulated industries such as aviation, trucking, and banking. Despite the predictions of public choice theory that reform of economic regulation was unlikely to occur (because such regulation benefits concentrated industry interests who would lobby to maintain it), much reform and deregulation have in fact occurred. On the US experience focusing on telecommunications, see Robert Horwitz, *The Irony of Regulatory Reform* (Oxford: Oxford University Press, 1991); on the experience in the UK and Japan, see Steven Kent Vogel, *Freer Markets, More Rules: Regulatory Reform in Advanced Industrial Countries* (Ithaca, NY: Cornell University Press, 1998).

[38] In the Communication of 16 March 2005, COM(2005) 97, SEC(2005) 175, 'Better Regulation for Growth and Jobs in the European Union', the first objective identified is 'competitiveness', ibid 3.

[39] See n 176 below.

[40] See Joint Initiative on Regulatory Reform, n 8 above, at 1, citing European Commission, 'The EU Economy: 2003 Review', COM(2003) 729, and IMF, 'When Leaner isn't Meaner: Measuring Benefits and Spillovers of Greater Competition in Europe' 2003.

[41] Much of the debate addresses its efficacy in reducing costs. See Robert Baldwin, 'Is Better Regulation Better for Business?' (2004), at <http://www.lse.ac.uk/collections/pressAndInformationOffice/newsAndEvents/archives/2004/Is_BetterRegulation_betterForBusiness.htm> (criticizing inadequate regulatory relief meant to help industry); Corporate Environment Observer, 'Better Regulation: For Whom ?' (2004), at <http://www.corporateeurope.org/observer9/regulation.html> (criticizing regulatory relief undertaken at industry's behest).

imposes costs on the domestic economy, there is internal pressure for reform. Because some regulation favors domestic producers over foreign producers, yielding international trade disputes, there is external pressure for reform. (Meanwhile, of course, regulations also may have benefits, such as health and environmental protection, which could be lost if regulations were rescinded or diluted.)

Corroborating this point is the remarkable fact that Europe has also borrowed the regulatory tool of emissions trading from the US in order to implement the Kyoto Protocol. During the 1990s, European negotiators resisted and criticized US proposals for greenhouse gas emissions trading. Now, even while criticizing the US for its reluctance to join the Kyoto Protocol, Europe has adopted the very policy proposal that the US had been urging as the flagship instrument to achieve greenhouse gas emissions reductions.[42] The basic reason is no mystery: cost-effectiveness. When Europe ratified Kyoto and finally got down to implementing its targets, it became clear that emissions trading would be a cost-saving, highly effective method of reducing emissions.[43] Cost drove legal borrowing of emissions trading, despite a previously strong rhetorical opposition to this very legal tool and to its source—a rhetoric that one no longer hears in Europe.

Fourth, a related but somewhat different motivation for regulatory reform is to enable the Executive (the President, Prime Minister, or other head of government) to respond to the growth of the regulatory state. The Executive is held accountable by the public for both the costs of regulation (hence pressure to reduce regulation or its costliness), and for the harms of risks not prevented (hence pressure to regulate effectively). In the US, the Administrative Procedure Act of 1946 followed the New Deal expansion of administrative regulation, and Presidential Executive Orders on regulatory review in the 1970s, 1980s, and 1990s followed the

[42] See Wiener, n 12 above; Joseph Kruger and William Pizer, 'Greenhouse Gas Trading in Europe' (October 2004) *Environment* magazine, 8–23.

[43] One current concern is that states may distort the operation of the CO_2 allowance market, partly by allocating excess allowances to shield their industries, arguably leading to price volatility in the EU Emissions Trading System (ETS) in the spring of 2006 when this allocation pattern became apparent (and the market price dropped from 30 to 9 euros in one week). On the general problem, see Jonathan B Wiener, 'Global Environmental Regulation: Instrument Choice in Legal Context' (1999) 108 *Yale LJ* 677–800 , at Part V (warning that nation-states may interfere or 'meddle' with the operation of international allowance trading markets). Carol Rose observed that such 'meddling' is not always 'frivolous', because states may be protecting against local hotspots, see Carol Rose, 'Expanding The Choices for the Global Commons: Comparing Newfangled Tradable Allowance Schemes to Old-Fashioned Common Property Regimes', 10 *Duke Envtl L & Pol'y F* 45, 61 and n 69 (2000). But in CO_2 markets there are no serious hotspot concerns to justify state interference.

Great Society adoption of major health and environmental legislation. The President was compelled to deal with Congressional enactment of regulatory statutes (often delegating substantial power and discretion to regulatory agencies, and foisting on agencies the hard choices of reconciling competing objectives such as health versus cost); and to respond to judicial review of agency action (which is non-expert and not politically accountable, and may distort or ossify regulatory policy). Likewise in Europe, the Better Regulation initiative follows the increasing integration of EU institutions and the greater competency of the EU to regulate health and the environment after the Single European Act and the Maastricht, Amsterdam, and Nice treaties. Better Regulation is in part a move to find a common basis for regulation among the EU institutions (in particular the Commission, the Parliament, and the Council) and the member states, facilitating trade in the Single European Market and ensuring political accountability of government policy.[44] And Better Regulation responds to the need to re-establish the credibility and legitimacy of effective regulation in Europe after a series of public health crises such as mad cow disease (BSE), foot and mouth disease, and scares over dioxin in animal feed, benzene in Perrier, and genetically modified foods. In short, Better Regulation recognizes the need for sound management of the regulatory state, on both sides of the Atlantic.

Is Better Regulation Better?

Given that the EU is borrowing regulatory reform from the US, a normative evaluation of this exercise is in order. It would perhaps be typical for an American legal expert to espouse this flattering imitation, saying, yes, do as we have done, copy our system. But here I write to say: do as we have learned, not simply as we have done. Europe should not simply borrow directly from the US. Europe should innovate, not imitate. Moreover, regulatory reform in Europe must be adapted to suit European institutions. Through this process, Europe should experiment with institutional innovations that can make Better Regulation even better. Europe has an opportunity to do a better job at Better Regulation than the US has

[44] This is true even though the EU does not have the same type of executive branch as the US, headed by a President popularly elected for a term of four years. The EU has a college of Commissioners, appointed as a slate for a term of five years; the President of the Commission is its leader but is also a somewhat equal colleague and is not popularly elected. And the EU as a whole has a Presidency held in rotation by each member state for six months at a time. In these respects, the EU Executive function is weaker or more decentralized than the US Presidency. At the same time, the European Commission has a monopoly on the initiation of legislation, a power that the US President lacks.

done, or, at least, to try out new approaches that can be compared to the US system. If Europe demonstrates improvements in regulatory policy, those advances can and should be borrowed back by the US. Further, the adoption of Better Regulation in Europe can itself create a common language and platform for greater transatlantic communication and collaboration about regulatory policy.[45]

A key theme of this article is that where there are problems in regulatory reform and Better Regulation, such as the debate over benefit-cost analysis (BCA), there are valuable institutional remedies. Where there are controversies regarding the limitations or biases in analytic methods, the underlying sources of these problems are often institutional, not analytic, and can often be ameliorated by institutional reorientations. Thus Europe, and in turn the US, can make Better Regulation even better by investing in intelligent institutional structures and approaches.

'Better regulation' clearly expresses a more sympathetic view of regulation than does 'deregulation', or cost-cutting for greater competitiveness, or even than 'regulatory reform'. 'Reform' could imply improvement, but also pruning and paring, whereas 'better' casts a brighter light on creative approaches.[46] Critics of regulatory reform fear that it really means less regulation, that is, less protection, not better. Of course, cost reduction is desirable, as long as benefits are not reduced even more. European legal systems may need cost reduction and increased flexibility, for example in labor law. But 'better' regulation puts the focus on better results,

[45] One example is the series of US–High-Level Regulatory Cooperation Forum meetings now being held (the latest in January and May 2006).

[46] The Irish government defines 'Regulatory reform' as ' "changes that improve regulatory quality i.e. enhance the performance, cost-effectiveness or legal quality of regulations and related government formalities" [quoting OECD, *Regulatory Reform in Ireland* (2001), at 17]. . . . Examples of changes to the process of regulation include: impact analysis/assessment techniques; the use of alternatives to traditional regulation such as market mechanisms and economic incentives and "sunsetting" arrangements whereby regulations are formally reviewed at a future date to establish whether or not they are still valid or if they could be improved, reduced or even revoked'. By contrast, ' " Regulatory management, Better Regulation and Smarter Regulation" are the terms which are increasingly being used to convey the concept of an ongoing commitment to improving the processes of policy formulation, legislative drafting and enhancing the overall effectiveness and coherence of regulation. The idea of "Better Regulation" also helps to draw an important distinction between the wide reform agenda and deregulation. It is accepted that in some cases consumer, investor and the broader public interest may be better served by introducing new regulation and that in other cases it may be better served by removing regulation. No initial assumption is being made about either the existing quality or quantity of regulation or the need to deregulate. Instead, it is suggested that the goal of Better Regulation will not be achieved by simply seeking to minimise the volume of regulation but rather by using as simple and straightforward measures as possible to achieve policy objectives'. See <http://www.betterregulation.ie/index.asp?locID=20&docID=-1>.

outcomes, performance—not just on less regulation *per se* (nor more). The European initiative on Better Regulation has not gone into detail about what it means by 'better' results, apart from emphasizing accountability and competitiveness. At a first approximation, better results should mean improving societal well-being, that is, increasing societal net benefits, via less cost or more protection or, ideally, both.[47] 'Better' could in some cases imply 'less', but that depends on the calculus of better outcomes, not on a pre-analytic commitment to less regulation for its own sake. And sometimes 'less is more',[48] in the sense that better results can be achieved by more streamlined and lower-cost approaches, but again this is 'less' as a route to 'better' rather than less for its own sake. (Meanwhile, one can also question whether a much-touted program of Better Regulation is really making a difference, or whether it is just rhetoric and symbolic politics. Answering this question requires assessing the quality of impact assessments, the staff and resources being brought to bear, the structures and rules being adopted, and the actual influence on regulatory decisions. I discuss these issues further in the sections on Impact Assessment and Oversight below.)

The Better Regulation initiative could indeed yield better results. The use of impact assessment has the potential to improve regulatory policies and outcomes, increasing net benefits. Administrative cost reduction and simplification can reduce regulatory burdens and untangle needless bureaucratic rigidity. And the Better Regulation initiative, especially the use of IA, is moderating the earlier fervor for the precautionary principle;[49] indeed the European Commission has redefined the precautionary principle as requiring benefit-cost analysis.[50] Precaution can be worth-while to prevent uncertain and potentially irreversible risks, but it can also be excessive, incurring the costs of false positives, innovation foregone, and new countervailing risks (themselves uncertain and potentially

[47] This is plainly a first approximation. There is not space here to compare alternative conceptions of welfare, efficiency, Bentham, Kaldor-Hicks, Pareto, fairness, and other formulations. Suffice to say here that competitiveness is only one element of the overall social well-being that 'better' should entail; and that the European stewards of Better Regulation should develop a more thorough explanation of what they mean by 'better'. See below on 'warm analysis'.

[48] See UK Better Regulation Task Force report, *Regulation: Less is More* (March 2005).

[49] See Wiener, n 14 above, at 220–25; Lofstedt, n 13 above.

[50] See European Commission, Communication from the Commission on the Precautionary Principle, COM(2000) 1, Brussels, 2 February 2000 (available at <http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf>) (providing that precautionary regulation must satisfy proportionality and must be based on an analysis of benefits and costs).

irreversible).[51] Yet if the Better Regulation initiative focuses exclusively on competitiveness, that is, on reducing costs to industry, without considering social and environmental benefits, it risks yielding less regulation instead of better results. Moreover, increasing net benefits expands the social surplus that can be distributed to engage allies. To succeed and endure, the Better Regulation initiative needs to increase the net benefits of regulation.

In my experience, both in government and in academia, there is a huge swath of interests who favor less regulation regardless of its benefits, and a huge swath who favor more regulation regardless of its costs. In both cases, the alternative to analysis is sanctimony—supposing one knows the right answer without analyzing the consequences. In between these two potent and vocal campaigns is a narrow slice of those who genuinely want to compare the consequences (benefits and costs) of regulatory choices. It is very difficult for governments to maintain a steady commitment to comparing benefits and costs when great political pressure is brought to bear from one swath or the other.

In that light, I assess the Better Regulation initiative in terms of the major reform strategies it invokes, and their counterparts in US law. I address Impact Assessment (including both benefit-cost analysis (BCA) and risk assessment as an input to BCA), the problem of addressing multiple risks in concert, administrative costs, simplification, oversight, and *ex post* evaluation. For each of these issues, I offer suggestions on how to make Better Regulation even better, focusing on institutional innovations.

Impact Assessment

US Experience

In the United States, every President since the 1970s has formally required some form of regulatory impact assessment. President Nixon ordered a Quality of Life review, and President Ford ordered an inflationary impact review. President Carter issued Executive Order (EO) 12044 (23 March 1978), requiring economic analysis of regulations, and creating the Regulatory Analysis Review Group to provide interagency

[51] See Jonathan B Wiener, 'Precaution in a Multirisk World' Dennis J. Paustenbach (ed), in *Human and Ecological Risk Assessment: Theory and Practice* (New York: John Wiley, 2002) 1509–31.

oversight. In 1980, through the Paperwork Reduction Act,[52] the US Congress created the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB/OIRA). On 17 February 1981, less than a month after taking office, President Reagan signed EO 12291,[53] requiring regulations to yield benefits that 'outweigh' their costs, with a goal of maximizing net benefits, and directed OMB/OIRA to serve as the White House office with the authority to oversee regulatory impact analyses (RIAs).

On 30 September 1993, President Clinton issued EO 12866,[54] which confirmed the bipartisan commitment to RIA using benefit-cost analysis (BCA). EO 12866 replaced the word 'outweigh' with 'justify' (a less quantitative term, embracing a broader public judgment about the policy's merits). Section 1 of EO 12866 maintained the requirement to 'maximize net benefits', and in section 6 it expressly required full analysis of the range of types of costs and benefits, including economic, social, and environmental. EO 12866 also added emphasis on qualitative and distributional impacts, added an instruction to evaluate the countervailing health and environmental risks induced by regulation of a target risk (risk-risk tradeoffs), and added new procedures for transparency (including reporting by OIRA of outside contacts, inclusion of agency representatives at OIRA meetings held to discuss the agency's policies, and oversight of OIRA by a committee chaired by the Vice President).

Since the year 2001, the administration of current President Bush has retained the Clinton EO, reconfirming the bipartisan character of regulatory review. The Bush administration OIRA has issued more 'return' letters (saying 'no' to deficient regulations) than did the Clinton administration OIRA, but at the same time the Bush OIRA has also innovated the new device of 'prompt letters' (using BCA to say 'yes' to desirable regulations and urging agencies to adopt them; examples include requiring trans-fat content labels on food to reduce heart disease, and installing automatic electronic defibrillators in the workplace). OIRA has also issued new RIA Guidelines in Circular A-4,[55] calling for more use of

[52] Codified at 44 USC 3501 ff. Despite the name of this law, the US approach (mandated by the series of Presidential EOs) focuses on BCA—full assessment of both benefits and costs—rather than on trying to reduce paperwork costs (administrative costs) alone.

[53] 46 Fed Reg 13193 (published 19 February 1981).

[54] Executive Order 12866, 'Regulatory Planning and Review', 58 Fed Reg 51735 (4 October 1993), available at <http://www.whitehouse.gov/omb/inforeg/eo12866. pdf>. As a senior staff person in the President's Council of Economic Advisers (CEA) at the time, I assisted in the drafting of EO 12866.

[55] OMB/OIRA, Circular A-4, 'Regulatory Analysis', 17 September 2003, available at < http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

cost-effectiveness analysis (C-EA), lower discount rates (3% as well as 7%, and potentially even lower than 3% for long-term intergenerational effects), risk-risk tradeoff analysis, and probabilistic scenarios of impacts exceeding $1 billion. Further, OIRA has issued guidelines as required by the Information Quality Act, a bulletin on peer review, and a proposed Bulletin on Risk Assessment. President Bush transferred oversight of OIRA from the office of the Vice President to the office of the White House Chief of Staff.[56] And OIRA now posts all significant documents on its website, <http://www.whitehouse.gov/omb/inforeg/regpol.html>.

In short, there is a bipartisan consensus among US Presidents of both political parties over the last four decades to require agencies to produce RIAs and to use BCA for risk management. One prominent author has heralded the era of the 'cost-benefit state'.[57] Another says that monetized BCA has become 'the norm for government policy'.[58] It should also be noted that BCA in the US addresses all types of costs and benefits—including economic, social, and environmental—and thus is comparable to the 'Integrated Impact Assessment' conducted in the EU.[59]

But BCA is still not applied to all regulatory policies in the US. Federal agencies in the US appear to quantify some benefits or costs of regulatory proposals most of the time, but to quantify and monetize both benefits and costs only about half the time.[60] One reason for this incomplete use of BCA may be that federal statutes vary in whether they require, permit, or prohibit reliance on BCA in agency regulatory decision-making. Congress often requires agencies to use BCA, as in the Consumer Product Safety Act (CPSA 1972) (consumer products), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 1975) (pesticides), Toxics Substances Control Act (TSCA, section 6 (1977) (toxic substances), and Unfunded Mandates Reform Act (UMRA, 1995) ('unfunded mandates'

[56] EO 13258 (2002), at <http://www.whitehouse.gov/omb/inforeg/eo13258.pdf>. This shift in roles was apparently requested by Vice President Cheney, who preferred to focus on other issues. In some administrations, there can be a difference of perspectives and even competition between the President and Vice President, so the transfer of oversight from the Vice President to the White House Chief of Staff may bring regulatory review more closely in line with the President's policy agenda. This would continue a trend toward Presidential direction of regulatory matters that was already under way in the earlier Carter, Reagan, Bush, and Clinton administrations, see Elena Kagan, 'Presidential Administration', (2001) 114 Harv L Rev 2246.

[57] Cass R Sunstein, *The Cost-Benefit State: The Future of Regulatory Protection* (Chicago: American Bar Association, 2002).

[58] W Kip Viscusi, 'Monetizing the Benefits of Risk and Environmental Regulation' (2006) 33 *Fordham Urban Law Journal* 1033–44.

[59] IA Guidelines 2006, Annex 13, make clear that BCA in the EU also includes economic, environmental, and social impacts.

[60] Hahn and Muething, (2003) 55 *Admin L Rev* 608–42.

on states, businesses). Sometimes Congress permits BCA without requiring its use in decision-making, for example, in the Occupational Safety and Health Act (OSHAct 3(8), 1972) (as to workplace hazards other than toxics), Clean Water Act (CWA, section 304, 1972) (water pollution technology standards), and Safe Drinking Water Act (SDWA, 1996 amendments) (drinking water contaminants). But some Congressional statutes prohibit agencies' use of BCA in regulation, such as the Clean Air Act (CAA, section 109, 1970) (national ambient air quality standards), OSHAct section 6(b)(5) (1972) (workplace toxics), Endangered Species Act (ESA, section 7, 1973) (endangered species), Resource Conservation and Recovery Act (RCRA, section 3004m, 1984) (hazardous waste treatment standards), and Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, section 121, 1986) (hazardous waste cleanup standards). The Presidential EOs requiring BCA do not countermand a Congressional prohibition on using BCA to set standards, but they can require the agency to conduct a BCA as an informative analytic matter even if the agency is prohibited by the statute from relying on the BCA in setting a standard. Thus, the incomplete application of BCA suggests that OMB/OIRA has limited resources to supervise agency conduct, that some impacts are difficult to quantify or monetize, and that spreading the culture of impact assessment across the agencies is still a work in progress.

Moreover, BCA is not required for several other aspects of US regulation. It is not required for Congressional legislation, although the Unfunded Mandates Reform Act (UMRA, 1995) encourages it. Nor is it required for international treaties involving regulatory commitments.[61] Nor is BCA adequately employed in evaluating federal spending decisions, including both new spending and cutbacks,[62] nor in evaluating public works such as water resource projects (despite the history of BCA being developed to evaluate dams since the 1930s),[63] nor in evaluating

[61] Agency regulations adopted pursuant to an international treaty would presumably be subject to EO 12866, but by the time such a regulation reaches OIRA the international treaty has already been negotiated and ratified and the regulation is therefore difficult to revise. To address this problem, the US State Department has recently proposed requiring agencies to consult with OMB/OIRA earlier, on the regulatory impacts of pending new international agreements. 71 Fed Reg 28831 (18 May 2006). The State Department already requires agencies to consult with OMB before making new budgetary commitments in international agreements. See 22 CFR § 181.4(e).

[62] See Robert W Hahn, 'The Cost-Benefit of Budget Cutting', AEI-Brookings Policy Matters 06–12 (May 2006).

[63] The federal Reclamation Act of 1902 required economic analysis of projects, and the federal Flood Control Act of 1936 required projects to demonstrate that 'the benefits to

national forest logging (despite section 6(k) of the 1976 National Forest Management Act (NFMA), requiring economic suitability for timber cutting). Nor is BCA required for major federal actions (such as projects or policy decisions) under the environmental impact statement (EIS) provision of the National Environmental Policy Act (NEPA), despite an early effort to incorporate BCA into the EIS as a way to strengthen environmental protection.[64] Nor is BCA adequately employed in evaluating trade measures, despite the requirement in Section 201 of the Trade Act of 1974 that trade safeguards must 'provide greater economic and social benefits than costs'.[65] Nor is BCA yet employed to evaluate counterterrorism operations (despite the early history of BCA and systems analysis being brought to the US military by Defense Secretary

whomsoever they may accrue are in excess of the estimated costs', 33 USC § 701a. Although federal water agencies such as the Bureau of Reclamation, US Department of the Interior, evaluate some project benefits and costs, they typically have not conducted a full BCA including environmental impacts. See Alan V Kneese, 'Whatever Happened to Benefit-Cost Analysis?' (2000) 116 Water Resources Updates 58–61, at <http://www.ucowr.siu.edu/updates/116/index.html>. Economists have long argued for correcting this omission and thereby protecting the environment by making *greater* use of BCA, including environmental impacts. See Maynard M Hufschmidt, 'Benefit-Cost Analysis: 1933–85' (2000) 116 Water Resources Update 42–9, at <http://www.ucowr.siu.edu/updates/116/index. html> (noting studies in 1950, 1958, and 1962 espousing this view, and changes proposed by the Carter administration to expand BCA to ensure environmental protection in water projects). Economist and BCA advocate Kip Viscusi wrote an early paper for the pro-environment Ralph Nader group making this point: federal water agencies' BCA was unduly narrow and should be expanded to account for environmental impacts. See Richard L Berkman and W Kip Viscusi, *Damming The West: Ralph Nader's Study Group Report on the Bureau of Reclamation* (New York: Grossman Publishers, 1973). Viscusi continues to advocate BCA for both public works projects and regulations, see W Kip Viscusi, 'Monetizing the Benefits of Risk and Environmental Regulation', AEI-Brookings Joint Center Working Paper 06–09 (April 2006).

[64] See Judge Skelley Wright's opinion in *Calvert Cliffs Coordinating Committee v AEC*, 449 F 2d 1109 (DC Cir 1971) (finding that the EIS provision in NEPA section 102(2)(C) requires BCA of federal projects, in order to take into account their previously neglected environmental costs), *cert denied*, 404 US 942 (1972). The US Supreme Court subsequently held that NEPA requires only a 'purely procedural' exercise of informed decision-making—a so-called 'stop and think' exercise—with no substantive criteria for such decisions. See *Stryker's Bay Neighborhood Council Inc v Karlen*, 444 US 223 (1980). NEPA has been held by the courts not to apply to international trade agreements like NAFTA, see *Public Citizen v United States Trade Representative*, 5 F 3d 549 (DC Cir 1993), nor to federal spending laws, *Andrus v Sierra Club*, 442 US 347 (1979). In addition, various exemptions to NEPA have been adopted, including statutory exemptions for EPA actions under the Clean Air Act, 15 USC § 793(c)(1), and many actions under the Clean Water Act, 33 USC § 1371(c)(1); and judicial exemptions for EPA actions under environmental laws deemed to require the 'functional equivalent' of the EIS process. See Jonathan M Cosco, 'NEPA for the Gander: NEPA's Application to Critical Habitat Designations and Other "Benevolent" Federal Action' (1998) 8 *Duke Envtl L & Pol'y F* 345.

[65] 19 USC 2251(a).

Robert McNamara's 'Whiz Kids' in the 1960s), and it is only beginning to be applied (with difficulty) to the new wave of homeland security regulations.[66]

European Experience

In the European Union, Impact Assessment of new regulations is now required in almost all countries and at the EU level, and BCA is increasingly employed. There is a long history of the use of environmental impact assessment used to inform decision-makers (as under NEPA in the US), with some versions requiring actual financial compensation for the environmental harms of projects,[67] and thus a kind of BCA imposed on projects through tort law or the law of expropriation (takings) of neighbors' property.

BCA applied to modern regulatory decisions is also increasingly required in Europe. Most generally, the Proportionality Principle, a general principle of European law,[68] has been held to imply some version of BCA. In the *Pfizer* case, the court observed (paras 410–11):

The Court considers that a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management . . . . the

[66] See Jessica Stern and Jonathan B Wiener, 'Precaution Against Terrorism' (2006) 9 *J Risk Research* 393–447 and also in Paul Bracken, Ian Bremmer, and David Gordon (eds), *Managing Strategic Surprise* (Cambridge: Cambridge University Press, forthcoming 2007). Analysis of counterterrorism policies (both domestic homeland security and external intelligence and military operations) is particularly urgent, because effective counterterrorism is essential, but counterproductive policies can do serious damage to national security as well as to human life. See ibid (arguing that little serious *ex ante* analysis was done of the Iraq invasion, with the result that serious countervailing risks were neglected, including collateral civilian deaths, blowback, bog-down, distraction, and theft; and advocating subjecting counterterrorism policies to a joint OIRA-NSC oversight process using analytic tools of BCA and risk-risk tradeoff analysis); Linda Bilmes and Joseph E Stiglitz, 'The Economic Costs of the Iraq War' (2006) National Bureau of Economic Research (NBER) Working Paper 12054, available at <www.z.gsb.columbia.edu/faculty/jstiglitz/newworks.cfm> (arguing that the costs of the Iraq War were greatly underestimated *ex ante*, and calling for BCA of future such interventions). See generally Barbara Tuchman, *The March of Folly* (New York: Knopf, 1984) (on the counterproductive results of military campaigns undertaken without adequate analysis of likely outcomes). Yet these policies are difficult to analyze because information may be classified, because terrorists are strategic agents who respond to preventive measures hence requiring dynamic game theory models, and because some consequences may be hard to quantify (eg loss of privacy and freedom).

[67] See Jane Holder, *Environmental Assessment: The Regulation of Decision Making* (Oxford: Oxford University Press, 2005) (focusing on the history in the UK), including her discussion of the compensation requirement under the writ *ad quod damnum* in the thirteenth century.

[68] Nicholas Emiliou, *The Principle of Proportionality in European Law: A Comparative Study* (London: Kluwer Law International, 1996).

principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued . . . .[69]

The Communication on the Precautionary Principle of February 2000 requires precautionary regulations to be *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), *subject to review* in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment. In effect, the Communication reclaims the PP as part of decision analysis.[70]

Adopted late in 2000, the Nice Treaty of the EU (building on the Amsterdam and Maastricht treaties) provides in Article 174(3) that European environmental policy must be based on an assessment of 'the potential benefits and costs of action or lack of action'. Unlike in the US, it does not appear that any European Union laws prohibit the use of BCA, although such prohibitions may exist in member states' laws.

[69] Case T-13/99, *Pfizer Animal Health SA v Council*, 2002 WL 31337 (European Court of First Instance, 11 September 2002). But the court remarked in para. 456: 'The Court observes that the importance of the objective pursued by the contested regulation, i.e. the protection of human health, may justify adverse consequences, and even substantial adverse consequences, for certain traders . . . The protection of public health, which the contested regulation is intended to guarantee, must take precedence over economic considerations.'

[70] Several scholars have developed approaches to melding the PP with consequentialist decision analysis. See eg Ralph L Keeney and Detlof von Winterfeldt, 'Appraising the Precautionary Principle—A Decision Analysis Perspective' (2001) 4 *J Risk Research* 191; John D Graham, 'Decision-Analytic Refinements of the Precautionary Principle' (2001) 4 *J Risk Research* 127; Olivier Godard, Claude Henry, Patrick Lagadec, and Erwann Michel-Kerian, *Traité des Nouveaux Risques* (Paris: Gallimard, 2002); Richard B Stewart, 'Environmental Regulatory Decisionmaking under Uncertainty' (2002) 20 *Research in Law and Economics* 71–152; Michael Dekay, Mitchell Small, Paul Fischbeck, Scott Farrow, Alison Cullen, J B Kadane, Lester Lave, Granger Morgan, and K Takemura, 'Risk-Based Decision Analysis in Support of Precautionary Policies' (2002) 5 *J Risk Research* 391; Scott Farrow, 'Using Risk-Assessment, Benefit-Cost Analysis, and Real Options to Implement a Precautionary Principle' (2004) 24 *Risk Analysis* 727; Christian Gollier and Nicolas Treich, 'Decision Making under Uncertainty: The Economics of the Precautionary Principle' (2003) 27 *J Risk & Uncertainty* 77; Pauline Barrieu and Bernard Sinclair-Dégagné, 'On Precautionary Policies' (forthcoming 2006) Management Science.

The new EU 'Better Regulation' initiative has launched Impact Assessment Guidelines (2002, revised 2005, updated 2006) requiring a form of BCA.[71] The IA Guidelines require identification of the problem, consideration of alternative policy options (including no action), and assessment of the 'positive and negative' economic, social, and environmental impacts (including direct and indirect impacts) of each policy option.[72] The Guidelines use the terminology of 'positive and negative impacts' to include both a fully quantified and monetized BCA, and a partially quantified/partially qualitative 'multi-criteria analysis', as well as a cost-effectiveness analysis where relevant.[73]

Several EU member states have adopted strong Better Regulation programs with RIA procedures.[76] For example:

- The UK has conducted several reviews of its risk regulation system,[77] created the Better Regulation Executive[78] in the Cabinet Office, and the external advisory Better Regulation Commission. The government announced a Better Regulation Action Plan,[79] and developed comprehensive guidelines on risk management which instruct government bodies to seek transparency and proportionality through the use of risk assessment, analysis of market failures, valuation (of monetary and non-monetary impacts, including attention to public concerns), impact assessment including benefit-cost analysis of alternative policy options, and monitoring of policy implementation.[80]
- Ireland has created a regulatory reform office in the Department of the Taoiseach, and a Statutory Law Revision and Consolidation Unit in the Office of the Attorney General.[81] Ireland began these efforts through a Coordinating Group of Secretaries in 1995, which issued a report on Delivering Better Government in 1996.[82] These efforts were organized under the Strategic Management Initiative and its Working Group on Regulatory Reform. The government issued a report on Reducing Red Tape in 1999,[83] and a report on Regulating Better in 2004,[84] committing to rigorous use of Regulatory Impact Analysis.

[76] For more on RIAs in a variety of countries, see OECD, *RIA Inventory* (Paris: OECD, 2003).

[77] These include the Hampton review on Reducing Administrative Burdens (2005) at <http://www.hm-treasury.gov.uk/budget/budget_05/press_notices/bud_bud05_presshampton.cfm>, the Macrory review on Regulatory Penalties (interim consultation document, May 2006) at <http://www.cabinetoffice.gov.uk/regulation/reviewing_regulation/penalties/index.asp>, and the Davidson review on implementation of EU legislation (forthcoming 2006), as well as the Better Regulation Task Force (now Commission) report on *Regulation—Less is More* (March 2005) at <http://www.brc.gov.uk/publications/lessismoreentry.asp>. For further details and links to each document see <http://www.cabinetoffice.gov.uk/regulation/>.

[78] See <http://www.cabinetoffice.gov.uk/regulation/>.

[79] See <http://www.hm-treasury.gov.uk./newsroom_and_speeches/press/2005/press_50_05.cfm>.

[80] See HM Treasury, *The Green Book* (2003); HM Treasury, 'Managing Risks to the Public: Appraisal Guidance' (June 2005). For an overview of these efforts, see UK House of Lords, Economic Affairs Committee, *Government Policy on the Management of Risk* (June 2006), at <http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeconaf/183/183i.pdf>.

[81] See <http://www.betterregulation.ie/>.

[82] Available at <http://www.betterregulation.ie/attached_files/upload/static/1151.pdf>.

[83] Available at <http://www.betterregulation.ie/index.asp?docID=37>.

[84] Department of the Taoiseach, *Regulating Better: A Government White Paper Setting out Six Principles of Better Regulation* (January 2004), available at <http://www.betterregulation.ie/upload/Regulating_Better_html/index.html>.

In June 2005 it decided to require RIA across all departments, and in October 2005 the government issued RIA Guidelines.[85]

- The Netherlands has adopted a strong program of Administrative Cost reduction, including pioneering the Standard Cost Model which is now being borrowed by many other countries,[86] and setting a goal of 25 percent reduction of administrative burden.[87] But it remains to be seen whether the Netherlands will undertake a broader program of Better Regulation using Impact Assessment and BCA.
- France, although it did not begin to adopt Better Regulation measures until more recently, has now created a Better Regulation office at the Ministry of Finance, Economy and Industry (transferring functions there from the Réforme de l'Etat previously in the Prime Minister's office, in order to combine regulatory oversight with budgetary oversight). France has also launched a Better Regulation program in the Conseil d'Etat. And France has proposed a new law requiring impact assessment of all new legislation.
- Germany, under its new coalition government headed by Chancellor Angela Merkel, has made better regulation a high priority. Under the rubric 'Scaling Back Bureaucracy', the Merkel government has appointed a minister to lead the program, adopted the Standard Cost Model as well as RIA Guidelines, and begun an assessment of administrative burdens with a view to adopting a political goal to reduce such burdens in the near future.

In its 16 March 2005 Communication on Better Regulation, the European Commission attached a chart summarizing progress on Better Regulation and Impact Assessment (see below, pp. 472–3).[88] Events are moving quickly in this field, so this chart may already be out of date. Still, the chart is noteworthy for its very clear effort to shame laggard countries into adopting Impact Assessment procedures. Denmark, Poland, and the

[85] See RIA Guidelines: 'How to Conduct a Regulatory Impact Analysis', and 'Regulatory Impact Analysis: Lessons from the Pilot Exercise', both available at <http://www.betterregulation.ie/eng/index.asp?docID=80>.

[86] The Standard Cost Model Network, a consortium of countries using this approach, is at <www.administrative-burdens.com>.

[87] See Bert Doorn and Christiaan Prins, 'A Dutch Treat: The Netherlands Presidency and Regulatory Reform', *Challenge Europe*, Issue 13—What Future for Europe's Economic and Social Model? (30 January 2005), at <http://www.theepc.be/en/ce.asp?TYP=CE&LV=177&see=y&t=42&PG=CE/EN/detail&l=2&AI=417>.

[88] Adapted from European Commission, Communication from the Commission to the Council and the European Parliament, 'Better Regulation for Growth and Jobs in the

UK scored the highest (10 points out of a possible 11); France, Portugal, and Cyprus scored zero. But as noted above, already France has taken important actions since this chart was published.

Of course, even where countries have adopted IA systems, they may be implementing such reviews in different ways. For example, Radaelli finds that IA is aimed at improving substantive policy consequences in the US, at managing the bureaucracy in the UK, at transparency in the Netherlands, and at formal adherence to rules in countries like France and Germany.[89] But IA arguably serves all of these objectives in each of these countries; certainly it does in the US. And IA is also an evolving program, so that the substantive consequentialism of US regulatory review and the transparency of Dutch administrative cost measurement may well be adopted in other countries over time.

A Brief Evaluation

It is by now fairly clear that the choice to use IA and BCA is not a partisan matter. IA is a tool for better decision-making employed on both the center-left and the center-right, and it is a mechanism of interbranch relations—to enable Presidential management of the regulatory state (both in the US and in the European Union). It has become the mainstream consensus approach, albeit with critics on each flank. In the United States, IA using economic analysis such as BCA has been espoused by a wide array of actors across the political spectrum, including not only Republican Presidents Nixon, Ford, Reagan, and both Bushes, but also Democratic Presidents Carter and Clinton, Judge Skelley Wright (in the *Calvert Cliffs* case cited above), US Supreme Court Justice Stephen Breyer[90] (appointed to the Court by President Clinton), and law professors Cass Sunstein[91] and Buzz Thompson,[92] among many others, as well

European Union', COM(2005) 97, SEC(2005) 175, 16 March 2005, n 4 above, at 17 (footnote omitted). The footnote in the table (omitted here) references the chart to 'Commission Staff Working Paper: Report on the Implementation of the European Charter for Small Enterprises in the Member States of the European Union—SEC(2005) 167, 8.2.2005, p. 36', but the chart addresses Impact Assessment procedures in general and only the last two columns address impacts on small businesses.

[89] See Radaelli, n 27 above. [90] Breyer, n 25 above.

[91] Cass R Sunstein, *Risk and Reason* (New York: Cambridge University Press, 2002); Sunstein, n 57 above. Sunstein is also the author of *Radicals in Robes: Why Extreme Right-Wing Courts are Wrong for America* (New York: Basic Books, 2005).

[92] Barton Thompson, Jr, 'People or Prairie Chickens: The Uncertain Search for Optimal Biodiversity', (1999) 51 *Stanford Law Review* 1127.

Overview of measures in the area of Better Regulation and impact assessment*

	Better regulation programme	Specific RIA policy	Obligatory RIA	Alternative instruments considered	Guidelines on RIA	Coordinating body for RIA	Consultation part of RIA	Formal consultation procedures	Direct stakeholder consultation	Tests of impact on small enterprises	Exemptions for SMEs	*Total Y+ (Y)*
Belgium	(Y)	N.A.	(Y)	N.A.	(Y)	(Y)	N	(Y)	(Y)	(Y)	N	*7*
Czech Republic	Y	N.A.	N	Y	N.A.	N.A.	N.A.	N.A.	N.A.	(Y)	N	*3*
Denmark	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	*10*
Germany	Y	N.A.	N.A.	N.A.	Y	Y	Y	Y	N.A.	N.A.	N.A.	*5*
Estonia	N	N	Y	Y	Y	N.A.	N.A.	N	N	N.A.	Y	*4*
Greece	(Y)	(Y)	N	N	N	N	Y	N	N	N	N.A.	*3*
Spain	Y	(Y)	Y	Y	(Y)	(Y)	N	N	N	N	N.A.	*6*
France	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	*0*
Ireland	Y	N	N	(Y)	(Y)	N	(Y)	(Y)	N	N	N	*5*
Italy	(Y)	Y	N	(Y)	Y	(Y)	(Y)	N	Y	(Y)	N	*8*
Cyprus	N	N	N	N	N	N	N	N	N	N	N.A.	*0*
Latvia	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	*9*
Lithuania	N.A.	Y	Y	Y	Y	N.A.	N.A.	N.A.	N	N.A.	N.A.	*4*
Luxembourg	Y	N.A.	Y	Y	N.A.	Y	Y	Y	N	N	Y	*7*

as many economists of diverse political persuasions,[93] including Alan Blinder[94] and Joseph Stiglitz.[95] In Europe, Better Regulation via IA is espoused by a chorus of political leaders across the political spectrum, including Tony Blair, Gordon Brown, Bertie Ahern, Romano Prodi, Jose Manuel Barroso, Gunther Verheugen, and others; and it has been adopted by both the European Commission and the EU member states.

At the same time, IA of regulations, especially IA using BCA, has been criticized as anti-environmental, chiefly on the grounds that it tends to delay regulations and to overstate costs and understate health and environmental benefits (such as human life, ecological vitality, and aesthetics) which are difficult to measure.[96] Similarly, environmental IA under NEPA has been criticized—notably by industry and the military—for delaying new projects. (As I point out below, another distinct problem with BCA occurs when it focuses narrowly on a target risk and on industry compliance costs, to the neglect of countervailing risks and ancillary benefits.)

Advocates of BCA answer that if BCA is done well, it will measure all important impacts. They are optimistic about the ability of economic methods to develop quantified and monetized measures even of amenities

[93] Eg Kenneth Arrow, Maureen Cropper, George Eads, Robert Hahn, Lester Lave, Roger Noll, Paul Portney, Milt Russell, Richard Schmalensee, Kerry Smith, and Robert Stavins, 'Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?', (1996) 272 *Science* 221–2 (advocating the use of BCA as a tool to help inform regulatory policy decisions).

[94] See Alan Blinder, *Hard Heads, Soft Hearts: Tough-Minded Economics for a Just Society* (Reading, Mass: Addison-Wesley, 1988). Prof Blinder was a member of the Council of Economic Advisers (CEA) appointed by President Clinton.

[95] Joseph Stiglitz was first a member and later Chair of CEA under President Clinton, and winner of the Nobel Prize. While a critic of *laissez-faire* globalization (see Stiglitz, n 24 above), Prof Stiglitz has espoused BCA with improvements to reflect advances in economic understanding, as reflected in his support and role in the drafting of President Clinton's EO 12866, and in his scholarship such as Joseph E Stiglitz, *Economics of the Public Sector* (3rd edn) (New York: WW Norton, 2000); Joseph E Stiglitz, 'The Rate of Discount for Cost-Benefit Analysis and the Theory of the Second Best', in R Lind (ed), *Discounting for Time and Risk in Energy Policy* (Washington, DC: RFF Press, 1982) 151–204. And he has recently written: 'The most important things in life—like life itself—are priceless. But that does not mean that issues involving the preservation of life (or a way of life), like defense, should not be subjected to cool, hard economic analysis'. Joseph E Stiglitz, 'Analysis on True Cost-Benefit of Iraq "Project" Virtually Absent', Daily Yomiuri Online, 4 March 2006, at <http://www.yomiuri.co.jp/dy/columns/syndicate/20060313dy02.htm>. See also Bilmes and Stiglitz, n 66 above (advocating BCA).

[96] See David Driesen, 'Is Cost-Benefit Analysis Neutral?' (2006) 77 *U Colo L Rev* 335; Frank Ackerman, Lisa Heinzerling, and Rachel Massey, 'Applying Cost-Benefit to Past Decisions: Was Environmental Protection ever a Good Idea?' (2005) 57 *Admin L Rev* 155. Other critiques attack the ethics of monetizing health and environmental benefits, see Frank Ackerman and Lisa Heinzerling, *Priceless: Knowing the Price of Everything and the Value of Nothing* (New York: The New Press 2004). Rebuttals to these critiques include Viscusi, n 58 above; and Robert W Hahn, *In Defense of the Economic Analysis of Regulation* (Washington, DC: American Enterprise Institute Press, 2005).

not traded in markets.[97] And they point to the transparency gains of forcing decisions to be based on a rigorous analysis made available to the public.

An additional point is that, if costs to industry will inevitably be pressed by industry lobbyists (with or without BCA), then failing to quantify health and environmental benefits (by eschewing BCA) will actually lead to underprotection of those social values. If interest group politics favors concentrated industry groups over diffuse environmental beneficiaries, then BCA is more important to clarify the benefits than the costs. If risk reduction or other benefits are not quantified and compared via BCA, those benefits will be neglected in a political calculus that inevitably focuses on cost. To be sure, much costly environmental legislation has been enacted without quantification of benefits (or costs), but those laws may represent interest group deals more than a maximization of public net benefits.

And, fundamentally, advocates respond: if government does not use some version of comparing benefits and costs, then on what alternative basis will it make decisions? Critics of BCA often fail to explain an alternative method for making decisions.[98] Not comparing benefits and costs may simply lead to decisions which are less transparent, less subject to debate and correction, and more arbitrary and biased than is BCA, that is, to decisions which are driven by overreaction to crisis events,[99] underreaction to routine, systemic, or unseen concerns,[100] and raw political

[97] Eg Viscusi says: 'any regulatory benefit from a risk regulation or environmental regulation that should be legitimately recognized in the policy analysis process potentially can be quantified in monetary terms'. Viscusi, n 58 above.

[98] Some advocate setting standards 'as low as feasible', but a feasibility test would be insensitive to benefits, would regulate more profitable industries more tightly than less profitable industries (sending perverse signals and potentially conflicting with environmental justice concerns by protecting poorer communities less than richer communities), and would be less protective than BCA where BCA would warrant shutting down a noxious industry but the 'feasible' constraint would keep the industry in business.

[99] See Robert V Percival, 'Environmental Legislation and the Problem of Collective Action', (1998) 9 *Duke Envtl L & Pol'y F* 9; Thomas Birkland, *After Disaster: Agenda Setting, Public Policy, and Focusing Events* (Washington, DC: Georgetown University Press, 1997); Thomas Birkland, *Lessons of Disaster: Policy Change after Catastrophic Events* (Washington, DC: Georgetown University Press, 2006).

[100] See Cass R Sunstein, 'Cognition and Cost-Benefit Analysis' (2000)29 *Journal of Legal Studies*, reprinted in Mathew Adler and Eric Posner (eds), *Cost-Benefit Analysis* (Chicago: University of Chicago Press, 2001); Richard Posner, *Catastrophe: Risk and Response* (New York: Oxford University Press, 2004) (arguing that the public and government give inadequate attention to low-probability high-consequence risks of extreme events, but that on BCA criteria such risks should be addressed more aggressively); Jonathan B Wiener, Book review of Richard Posner, *Catastrophe: Risk and Response* (2004) and Jared Diamond, *Collapse: How Societies Choose to Fail or Succeed* (2005), in (2005) 24 *Journal of Policy Analysis & Management* 885–9; Cass R Sunstein, 'On the Divergent American Reactions to Terrorism and Climate Change', AEI-Brookings Joint Center for Regulatory Studies, Working Paper 06–13 (May 2006).

power (especially of concentrated industry groups) rather than analysis. The alternative to analysis may often be sanctimony—acting without analyzing, on the supposition that we 'know' the right answer—hastily choosing regulation or deregulation, green technologies or counterterror tactics, depending on who is in power.

In advising the European Commission on these questions, the Mandelkern Group Report rejected claims of bias:

> Some see RIAs as an excuse to impose a business-focused, deregulatory agenda on policy makers. For a RIA done well, this is absolutely not the case. Rather, as stated elsewhere, the RIA simply sets out the information in a clear and concise way to inform—not control—the political decision. This point needs to be stressed as appropriate and real efforts need to be made to ensure that both benefits and costs are included in the assessment.
>
> Another possible problem is the political pressure to do something—anything—now, irrespective of a proper assessment (sometimes known in its most extreme form as a 'knee-jerk reaction') . . . . development of a good RIA system is likely to reduce the incidence of this reaction as the need for good assessment becomes commonly understood and supported . . . .
>
> A further situation can be where the main political decision has already been taken (perhaps in a government programme or party manifesto). In these cases there can be a reluctance to undertake assessment of the implementation options available. However, almost always details remain to be resolved where an assessment can play an important role in informing, in a very explicit manner, those taking the decisions on the details about the trade-offs that they are making. Finally, there is often the perception that doing RIA takes too much time and delays the policy development process to an unacceptable degree. However, when RIA is an integrated part of the process, any delays in the earlier stages are minimised and often outweighed by time and cost savings later in the process where the greater defensibility of the policy solutions and the increased buy-in by stakeholders are important.[101]

There is not the space here to sort out this entire debate. After briefly assessing the pros and cons of IA in this subsection, I suggest in the next subsection that Europe, committed as it already is to using IA in Better Regulation, should experiment with a set of institutional innovations which will test whether the criticisms can be overcome and whether IA can thus be made to perform even better than it has so far.

The criticisms of IA (especially using BCA) seem to me to be worth taking seriously, but not fatal to a sensible application of weighing the pros and cons of important decisions. There is no better alternative way of

[101] Mandelkern Group Report (2001) at 25.

making policy, and it has become the mainstream consensus approach. The criticisms should therefore motivate better policy analysis, not its rejection. The concerns about omission of important impacts, including countervailing risks and ancillary benefits, are crucial; as I suggest below, they warrant a broader more embracing form of BCA. The concern about delay is quite important, but delay is amenable to a weighing of its own pros and cons. The benefit of delay is that additional analysis can improve decisions (and defer policy burdens); the cost is that delay can forfeit the value of earlier policy adoption (eg earlier protection of victims, or earlier authorization of a useful invention). Weighing these conflicting effects is the task of Value of Information/Cost of Information (VOI/COI) techniques, one component of BCA. This idea is reflected in the European IA Guidelines' doctrine of 'proportionate analysis', and roughly in the difference between initial IA and Extended IA in Europe, as well as initial Environmental Assessments versus full Environmental Impact Statements under US NEPA law, and insignificant versus significant regulatory actions under OMB review. Note that the cost of delay cuts both ways: who bears its costs depends on the default rule in force while the analysis is pending. Regulatory impact assessment (RIA) may delay regulation of private actors, while environmental impact assessment (EIA) may delay projects sought by private actors. The delays posed by RIA themselves can cut both ways, depending on who bears the cost of the delay: if the law requires IA before adopting a regulation that would restrict a risky product or facility (as for many pollution controls), then delay favors industry and the cost is borne by victims; but if the law requires IA before licensing of a new product or site (as for new drugs or pesticides or energy facilities), then delay favors victims and the cost is borne by industry and consumers. The question is institutional rather than analytic. Moreover, as the Mandelkern group points out, a careful IA can resolve and avoid problems that would yield delay later on, so it can achieve less delay overall. In short, delay turns out to be a problem that calls for better BCA, not avoiding BCA.

Meanwhile, retrospective analyses of a variety of policies do not bear out the concern that BCA is biased toward overstating costs and understating benefits. *Ex post* evaluations of a growing set of cases (though not yet a representative sample) have found that *both* benefits and costs appear to have been overstated in *ex ante* RIAs.[102] Certainly specific cases

[102] See OMB, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (Washington, DC: US Office of Management and Budget, 2005), ch III, 41–9; Winston Harrington, Richard D. Morgenstern, and Peter Nelson, 'On the Accuracy of Regulatory Cost Estimates' (2000) 19 *Journal of Policy Analysis and Management* 297–332.

can be cited of BCA recommending less stringent regulation, but perhaps those recommendations were warranted. In several other key cases, RIA and BCA have been used to identify and promulgate some of the most important advances in more stringent environmental and health protection. These include the phaseout of CFCs, the phasedown of lead (Pb) in gasoline (petrol), and the restrictions on particulate matter emissions from power plants and diesel engines.[103] Indeed these are three policies on which the US, using BCA, adopted policies that were substantially more precautionary (earlier and more stringent) than Europe.[104] Critics contend that in the past BCA has more often been used to reduce than to increase the stringency of new regulations.[105] As I argue below, even if this is true, it is as much or more a result of the institutional posture of BCA as of the analytic methodology of BCA, and both of these can be ameliorated in the European program of Better Regulation.

Why might costs and benefits be over- or understated in *ex ante* BCA? Costs may be overstated *ex ante* if industry opposes regulation citing high cost estimates, and then once a rule is imposed, industry finds less costly means of complying than it thought or said it could (though at some expense of managerial time); and if the extent of implementation of the policy is predicted *ex ante* to be greater than it actually turns out to be. On the other hand, costs could be understated *ex ante* if they focus on a subset of costs such as industry compliance costs and neglect wider or longer-term effects such as foregone innovation.

Benefits may be understated *ex ante* if risk assessments focus on one risk at a time and omit multiple simultaneous exposures; if they neglect low-probability extreme events; if they neglect sensitive subpopulations; or if they omit ancillary benefits from unintended reductions in other risks.

[103] Ackerman *et al*, n 96 above , review the Lead Phasedown and argue that it does not show the success of BCA in supporting a more stringent policy on lead (Pb) in gasoline because the BCA came late in the story (in the 1980s), after several decades of the use of lead in gasoline (since the 1920s) and after a prior regulation to reduce lead in gasoline had been adopted in the 1970s without reliance on BCA. By contrast, Driesen, n 96 above, at 364, states that 'this case does seem to offer reasonably good evidence of CBA motivating an increase in stringency'. In addition, the conclusion to be drawn from the Ackerman *et al* critique is not that BCA did not support a more aggressive phaseout of lead in gasoline (it did), but that BCA should have been undertaken decades earlier. Ackerman *et al* say that BCA could not have been conducted earlier because the data on health effects of lead were lacking, yet they cite evidence of the longstanding scientific appreciation of the adverse health effects of lead exposure; and they neglect the endogenous character of benefits data: if BCA had been required or undertaken, evidence to quantify the benefits would have been sought and collected. The reduction in lead emissions due to the first regulation in the 1970s was not the only way to generate exposure and dose-response data, as Ackerman *et al* assert; variations across locations, and changes in exposure over prior decades, could also have been studied.

[104] See Wiener, n 14 above.

[105] See Driesen, n 96 above.

And benefits may be understated *ex ante* if monetized BCA omits or underestimates impacts that are difficult to measure in monetary terms. On the other hand, benefits may be overstated *ex ante* if the implementation of the policy is predicted to be greater than actually turns out to occur; if countervailing risks created by the policy are omitted; if the methods of valuation used to monetize environmental benefits (such as contingent valuation surveys regarding non-market assets such as ecosystems) tend to overstate benefits or if the risk assessments which underlie the calculation of policy benefits use conservative default assumptions and methods that tend to overstate risks and hence benefits (due to such factors as overstated linear no-threshold dose-response extrapolations, use of most sensitive test species, identifying any observed effect as adverse, making animal-to-human extrapolations without accounting for mechanistic differences ('modes of action'), using 'maximum exposed individual' exposure assumptions, and using large safety factors for extrapolation to human subpopulations).

The result is that risk assessment exhibits simultaneous excessive attention to some (small) risks, and inattention to other (larger) risks. To address many of these problems, US EPA has adopted new cancer risk assessment guidelines,[106] which require greater use of evidence before resorting to conservative default assumptions, greater attention to modes of action, and more attention to children and other susceptible subgroups. And US OMB/OIRA has issued a proposed Bulletin on Risk Assessment in January 2006,[107] seeking to ensure greater transparency and realism, use of central estimates, and consistent criteria for identifying adverse effects. In addition, although few statutes specify the criteria for scientific risk assessment,[108] courts have begun to apply general statutory edicts to use the 'best available science' to require agencies to conduct high-quality risk assessments.[109]

[106] US Environmental Protection Agency (2005), Guidelines for Carcinogen Risk Assessment, EP/630/P-03/0001F <www.epa.gov/cancerguidelines>.

[107] US OMB, Proposed Bulletin on Risk Assessment, 9 January 2006, available at <www.whitehouse.gov/omb/inforeg/infopoltech.html#iq>. This initiative is endorsed in concept by Nicholas Bagley and Richard L Revesz, 'Centralized Oversight of the Regulatory State', AEI-Brookings Joint Center for Regulatory Studies, Related publication 06–12 (April 2006), at 44–53 (forthcoming in (2006) 106 *Columbia L Rev*, Section IV.A).

[108] See Kelsey Stansell, Mark Marvelli, and Jonathan B Wiener, ' "Adverse Effects" And Similar Terms In U.S. Law', Report for the Dose Response Specialty Group of the Society for Risk Analysis (SRA) (July 2005), available at <www.sra.org/drsg/docs/Adverse_Effects_Report.pdf>.

[109] Eg *Chlorine Chemistry Council v EPA*, 206 F 3d 1286 (DC Cir 2000) (vacating goal for maximum level of chloroform because agency set goal based on linear low-dose extrapolation when it had just found that a threshold model was superior). See also Leather Industries v EPA, 40 F 3d 392 (DC Cir 1994) (remanding standard for selenium content in sewage sludge because the exposure assumption—children eating sludge on highway median strips—was not credible).

To make Better Regulation effective, European institutions need to address these questions of risk assessment as well. So far, the approach of European institutions to risk assessment has been ad hoc or ill-defined. In the EU, the move toward quantitative risk assessment has been more recent than in the US (where it accelerated in the 1980s following the US Supreme Court's *Benzene* decision[110] and the 1983 publication of the National Academy of Sciences 'Redbook'.[111]) EU use of risk assessment has been driven in part by WTO decisions under the Agreement on Sanitary and Phytosanitary Standards (SPS), which requires a scientific risk assessment to support international trade restrictions.[112] The European Commission has espoused scientific risk assessment as a predicate to any invocation of the precautionary principle,[113] and the European Court of Justice held, in a case on mad cow disease (BSE) quite reminiscent of *Benzene*, that member state governments may not invoke precaution to regulate risks that the Commission has deemed insignificant.[114] Still, major risk regulations within the EU sometimes proceed without risk assessments, as in the recent *Pfizer* and *Alpharma* cases regarding antibiotics in animal feed,[115] in which the Court of First Instance held that a ban could be adopted without a risk assessment and even when the relevant scientific advisory committee had recommended against a ban or had not been consulted at all (despite a requirement for such consultation). The court ruled in the *Pfizer* case, paras 139 and 142–44:

> . . . a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality . . . . [But] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified . . . a

[110] *Industrial Union Dept, AFL-CIO v American Petroleum Institute*, 448 US 607 (1980).

[111] NAS/NRC, *Risk Assessment in the Federal Government: Managing the Process* (Washington, DC: National Academies Press, 1983).

[112] See Steve Charnovitz, 'The Supervision of Health and Biosafety Regulation by World Trade Rules' (2000) 13 *Tulane Envtl LJ* 271.

[113] Commission of the European Communities, Communication from the Commission on the Precautionary Principle, COM(2000) 1, Brussels, 2 February, 2000, available at <http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf>.

[114] Case 1/00, *Commission of the European Communities v French Republic* (Failure of a Member State to fulfill its obligations—Refusal to end the ban on British beef and veal), 2001 ECR I-09989 (European Court of Justice, 2001).

[115] Case T-13/99, *Pfizer Animal Health SA v Council*, 2002 WL 31337 (European Court of First Instance, 11 September 2002); Case T-70/99, *Alpharma Inc v Council*, 2002 WL 31338 (European Court of First Instance, 11 September 2002).

preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully demonstrated by conclusive scientific evidence,' appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.

This statement is confusing. The court appears to misunderstand the purpose of a risk assessment, which is never to provide 'conclusive scientific evidence' (which does not exist) but rather to provide a forecast of (inevitably uncertain) future risks. The court holds that a 'purely hypothetical' risk or 'mere conjecture' is inadequate, but that a risk assessment is not required, and it remains unclear what the court means by its alternative of 'adequately backed up by the scientific data'—an invitation to further litigation. The Better Regulation initiative should resolve these confusions by requiring risk assessment (as called for in the European Commission's February 2000 Communication on the Precautionary Principle), setting criteria for risk assessments, and explaining that risk assessment is a method to forecast uncertain future scenarios.

Nor is incomplete information a reason to reject BCA. Information about future events is never complete or certain. Given uncertainty, some form of BCA seems superior to the alternative methods of decision-making. A raw political (non-analytic) choice of goals would be arbitrary or distorted by rent-seeking politics; even if well-intentioned, it may simply neglect important costs and benefits (especially to those who lack effective political voice) and thereby yield policy errors.[116] The Mandelkern Group advised that it is certainly sometimes the case that there is a

paucity of good quality data on benefits and costs, including the difficulty of estimating the value of non-marketed goods (e.g. environmental degradation or damage to human health). Whilst this will indeed affect the overall quality of the assessment—which can only be as good as the inputted data—it is not a sufficient argument for not carrying out any assessment at all. Use of error estimation and ranges (rather than single figures) for benefits and costs can help, as can the input from consultation with stakeholders and intelligent use of available data, consultants and academic expertise. Seeking input from a wide range of stakeholders can help avoid the kind of bias otherwise possible from vested interests.[117]

Likewise, the US Council on Environmental Quality (CEQ) guidelines for environmental IA under NEPA address uncertainty by requiring the

[116] See John D Graham and Jonathan B Wiener, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Cambridge, Mass: Harvard University Press, 1995) (arguing that failure to analyze full impacts of policy choices often results in selective neglect of impacts on constituencies lacking effective political voice; thus, good impact assessment can advance both efficiency and equity).

[117] Mandelkern Group Report (2001), at 24.

agency to obtain additional information at reasonable cost, to describe the remaining uncertainties, and to make an express judgment about the importance of such questions for the impacts being assessed.[118] As noted above, in its IA Guidelines in 2005, the European Commission addressed this issue through the doctrine of 'proportionate analysis', requiring services of the Commission to invest in additional information where the benefits of doing so (in improved decisions) justify the costs.[119]

Institutional Innovations

Given its commitment to IA as the key tool for Better Regulation, Europe now faces the debate over the pros and cons of BCA, and, at the same time, an opportunity to make progress through institutional innovations. Many of the real problems with IA and BCA are institutional, not analytic. Economics is not fundamentally opposed to ecology: both words derive from the Greek *oikos* for household, and they should be able to cohabit graciously. The concern that the tools of IA and BCA are biased against environmental protection arises largely because of the institutional postures in which the tools are applied: too coldly, to 'just say no', and too narrowly. Making progress on these institutional biases by using BCA more 'warmly', using it to say 'yes' as well as no, and using it more widely, would make Better Regulation even better.

IA and BCA are tools, not rules. They are mechanisms to inform decision-making, not the decision itself. The decision itself is and must be an exercise of judgment by a public official. Policy must be based on and express that judgment, rather than be dictated by a cold numerical

[118] 40 CFR 1502.22 (promulgated at 51 Fed Reg 15625, 25 April 1986) ('(a) If the incomplete information relevant to reasonably foreseeable significant adverse impacts is essential to a reasoned choice among alternatives and the overall costs of obtaining it are not exorbitant, the agency shall include the information in the environmental impact statement. (b) If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement: (1) A statement that such information is incomplete or unavailable; (2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment; (3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment, and (4) the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, "reasonably foreseeable" includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.').

[119] IA Guidelines 2006, Part II, s 5, at 8.

calculus. At the same time, that public policy judgment will often be better made when it is informed by a careful structured comparison of consequences, whether that is termed an analysis of 'benefits and costs' or 'positive and negative impacts'. Simply choosing policy goals on unstated or raw political criteria would be arbitrary, invite partisan volatility, and lack transparency. At least some version of BCA offers a transparent opportunity to evaluate and debate the reasons given. The key should be this function of considering alternatives and consequences and giving reasons for decisions, rather than quantification *per se*.

Here I suggest several institutional innovations that Europe could pursue to make Better Regulation even better.

'Warm Analysis'

Given its determination to use IA and BCA, Europe should employ what I will call 'Warm Analysis'. Along a spectrum from 'hot' to 'cold', one can locate policy based on moral outrage at the hot end (imagine the crowd or the politician who reacts intensely, often to a recent crisis or scandal, expressing moralistic norms of sin, blame, and punishment, and giving little or no attention to, or even opposing, analysis of wider consequences), and one can locate policy based on strict monetized BCA at the end of cool or cold analysis (imagine the accountant wearing a green eye shade who counts statistics, manages only what is measured, and maximizes wealth dispassionately).[120] 'Warm analysis' would occupy the center of this spectrum, embodying serious analysis of the full variety of impacts and tradeoffs, some quantitative and some qualitative, with compassion for both those who incur risks and those who incur abatement costs. As I will argue here, warm analysis can be understood as the application of BCA to BCA—or optimal optimization—recognizing

[120] See Christopher H Schroeder, 'Cool Analysis Versus Moral Outrage in the Development of Federal Environmental Criminal Law', (1993) 35 *William and Mary Law Review* 251, 253–8. Schroeder limits 'cool analysis' to self-interested utility maximization in which risks are calculated as the 'thin' expected value of probability and harm. Two aspects that Schroeder puts under the heading of 'moral outrage'—the inclusion in an individual's utility function of effects on others and on society as a whole, and the recognition of 'thick' qualitative attributes of risk—do not seem to me to fit the notion of moral outrage, and would fit better under what I am calling 'warm analysis'. By contrast, moral outrage at the hot end of the spectrum is characterized by an intense and moralist or absolutist response focused on sin, blame, and prohibition, lacking (or even opposed to) analysis of consequences, tradeoffs, and proportionality. Schroeder describes the moral outrage felt by environmentalists who see pollution as a sin and compliance as an obligation; consider also the moral outrage felt after a terrorist attack and the call for a 'crusade' of 'shock and awe' to strike back. See Stern and Wiener, n 66 above.

that information and analysis are themselves costly (chiefly in delay) and that omitting important effects is itself a costly error of analysis. Sensible application of BCA requires applying it not only to regulatory policies but also to the analytic review process itself. Hot moral outrage neglects important impacts and tradeoffs, and is vulnerable to heuristic errors; cold analysis applies monetized BCA to policies but neglects the costs of delay and of omitting important but unquantified impacts. Warm analysis is thus more embracing than either hot or cold approaches, while remaining truer to the core principle of BCA.

The crucial task for good public policy is to think through decisions. It is therefore to engage in a structured consideration of the major alternatives and consequences, in order to inform sound judgment through reason. The crucial task is not just an accounting exercise, nor strict economic optimization, though economic tools can be helpful. That is the key reason that in EO 12866 we chose to use the term 'justify' in place of 'outweigh', and to expressly allow consideration of non-quantified impacts (while encouraging quantification). 'Warm analysis' compares pros and cons in a structured decision framework but without limiting the comparison to strictly quantified and monetized impacts.

This approach is the 'prudential algebra' recommended by Benjamin Franklin in 1772:

> In the Affair of so much Importance to you, wherein you ask my Advice, I cannot for want of sufficient Premises, advise you *what* to determine, but if you please I will tell you *how*. When those difficult Cases occur, they are difficult, chiefly because while we have them under Consideration, all the Reasons *pro* and *con* are not present to the Mind at the same time; but sometimes one Set present themselves, and at other times another, the first being out of Sight . . . . To get over this, my Way is, to divide half a Sheet of Paper by a Line into two Columns; writing over the one Pro, and over the other Con. Then during three or four Days Consideration, I put down under the different heads short Hints of the different Motives, that at different Times occur to me, *for* or *against* the Measure. When I have thus got them all together in one View, I endeavour to estimate their respective Weights . . . and thus proceeding I find at length where the Ballance lies . . . And, tho' the Weight of Reasons cannot be taken with the Precision of Algebraic Quantities, yet, when e28 0 TD-pc(Considur)9.7(, seompimactls and compaem-

Franklin describes a careful structured approach to ensuring that all the important consequences are 'on screen',[122] quantifying their weights as much as possible but not insisting on algebraic precision, and coming to a considered judgment about the best course of action. He emphasizes that errors—'rash Steps'—are principally due to omitting important reasons and not to quantifying each reason too little or too much. Similarly, John Maynard Keynes remarked that 'it is better to be roughly right than precisely wrong'.[123] Cass Sunstein has advocated BCA as a cognitive approach to informed decision-making rather than as a strictly numerical calculus of optimization,[124] and Amartya Sen has advocated broadening the types of impacts and valuations incorporated into BCA.[125] As quoted above, the Mandelkern Group urged the use of ranges rather than point estimates, to account for uncertainties in the forecasts of benefits and costs—an insight borne out in the *ex post* studies of BCAs.

Warm Analysis is not a rejection of BCA using quantified, monetized values. Indeed, BCA itself justifies the Warm Analysis approach. With limited resources to analyze decisions, there is some tradeoff between accuracy (getting the decision right) and precision (calculating exact numbers), which suggests that on standard BCA criteria, it would often do more to improve policy decisions to get the full set of consequences before the decision-maker (so that 'the whole lies before me', in Franklin's words) than it would to invest in precisely quantifying only a few of those consequences while neglecting others or unduly delaying the decision. This is akin to the question of how much analysis is optimal: more analysis yields fewer policy errors, but also incurs costs in money and time (delay), so one must compare the Value of Information (VOI) versus the Cost of Information (COI). Such a BCA of BCA, or meta-BCA, shows that it is better to assess the full consequences than to quantify precisely just a few. A Cold Analysis that quantifies some impacts but omits other recognized important impacts (or takes too long) is in effect assigning a weight of zero to those omitted impacts, which is a greater error than including them in a qualitative or partly quantified way.[126] If the cost

[122] See Howard Margolis, *Dealing with Risk* (Chicago: University of Chicago, Press 1996).

[123] Quoted in Alan Greenspan, Chairman of the Federal Reserve Board, 'Bias in the Consumer Price Index', Testimony before the Committee on the Budget, US House of Representatives, 4 March 1997, at <http://www.federalreserve.gov/Boarddocs/testimony/1997/19970304.htm>.

[124] See Sunstein, n 100 above.

[125] See Amartya Sen, 'The Discipline of Cost-Benefit Analysis', (2000) 29 *J Legal Stud* 931–52 (favoring BCA if it uses a broader set of values instead of only market valuations).

[126] Thus either inadequate comparison of benefits and costs (as espoused by critics of BCA) or excessive quantification of a few benefits and costs (as undertaken in some BCAs)

(including delay) of precisely quantifying all the impacts is lower than its benefits, then full quantification is warranted. And this meta-BCA suggests that, over time, as we find ways to quantify and monetize more impacts—to reduce the COI or increase the VOI—more exacting analysis would be warranted. Our methods of quantification and valuation are endogenous and should respond to the use of BCA, as qualified by meta-BCA, to become 'Warm Analysis' by improving our ability to make diverse impacts more understandable.[127]

While the academic debate over BCA often pits advocates of Cool Analysis against sharp critics who reject statistics and monetization without clearly identifying a preferred alternative decision-making method (implying a preference for populist moral outrage), the practical reality is that the approach to Warm Analysis that I am describing is already available, even required, under the major legal requirements for BCA. In the US, EO 12866 expressly requires analysis of both qualitative and quantitative factors, and calls on agencies to show that benefits 'justify' (not 'outweigh') the costs. OMB/OIRA Circular A-4 requires attention to unquantified as well as quantified impacts. CEQ guidelines on environmental IA require assessment of impacts despite incomplete information. In the EU, the IA Guidelines require analysis of 'all positive and negative impacts', with the

would threaten what Franklin called a 'rash step'. In a similar vein, the late Allen Kneese—an economist and advocate of using BCA in environmental policy—worried that overly precise BCAs may 'let method outrun content'. Kneese, n 63 above, at 60. Likewise, the joint statement by eleven noted economists advocating BCA was careful to say that BCA has an important role to play in helping inform regulatory decision-making, although it should not be the sole basis for such decision-making, that agencies 'should not be bound by strict benefit-cost tests', and that agencies should take into account uncertainties, ranges of estimates, unquantified impacts, and distributional impacts. See Arrow *et al*, n 93 above.

[127] I do not propose to leave everything 'blurry', as one critic of BCA has urged, see Lisa Heinzerling, 'Regulatory Costs of Mythic Proportions', (1999) 107 *Yale LJ* 1981, 2069. My point is that a comprehensive Warm Analysis offers greater clarity than either a Cold Analysis that omits important factors, or a non-BCA approach that omits important factors. Nor do I agree that a careful structured analysis of pros and cons lacking full quantification would be 'vacuous' (see Sunstein, n 100 above) or 'vapid' (see Driesen, n 96 above). The key point is to get the decision-maker to consider the full portfolio of important choices and consequences, see Margolis, n 122 above, Graham and Wiener, n 116 above. This approach avoids the 'false promise of determinacy' that critics fear in strictly quantified BCA, see Amy Sinden, 'Cass Sunstein's Cost-Benefit Lite: Economics for Liberals', (2004) 29 *Colum J Envtl L* 191, 194. At the same time, I am optimistic about the ability to improve methods of analysis over time to quantify more kinds of impacts (especially through investment in research and staff capacity, through greater demand for such analysis via initiatives such as Better Regulation, and through *ex post* evaluations to improve *ex ante* methods, as discussed below). For another effort to find a 'middle way between all or nothing analytically' that bears similarities to my version of 'warm analysis'—yet authored by a critic of quantitative analysis—see Richard Parker, 'The Empirical Roots of the Regulatory Reform Movement: A Critical Appraisal', (2006) 58 *Admin L Rev* 359, 394–5.

possibility of using formal BCA or C-EA where warranted.[128] (They do not, however, set a goal of 'maximizing net benefits', as the US orders do; the EU should consider adding this objective in its next updated IA Guidelines.) And the EU IA Guidelines call for 'Proportionate Analysis', to choose the degree of analysis warranted by the problem.[129]

A particular question, to which little space can be devoted here, is—given a decision to monetize valuations of impacts—what monetary estimates should be used for the values of health, life, and environmental impacts? Willingness-to-pay (or to accept) is a useful but imperfect proxy for utility, limited by ability to pay and variations in marginal utility of income, by market imperfections in mobility and information, and by heuristic misperceptions of risk.[130] There is a lively controversy over whether and how to adjust monetized values of the value of a life to account for the expected years of life lost when risks occur at different ages, or to account for different levels of income and associated demand for risk protection. Using a single value of a statistical life (VSL) for all premature deaths seems insensitive to the timing of the death occurring early or late in life, as well as insensitive to other attributes of the risk that people find more or less undesirable.[131] But devi Twehedulutes e.vB

different VSL or value of a statistical life-year (VSLY) for different risks, populations, and ages is criticized as unfair and even as inconsistent with willingness to pay.[132] Here, I simply point out that the US and Europe are already using monetized VSL fi

uses discount rates of 7 and 3 percent (or even lower for long-term intergenerational effects), while the EU Guidelines require a discount rate of 4 percent.[136] These and other differences could serve as the point of departure for a wider comparative review of US and EU approaches to monetizing in BCA and to Cool versus Warm Analysis in general.

Using BCA to say 'Yes' as well as 'No'

The second institutional innovation Europe should pursue is to use RIA and BCA evenhandedly, not only to say 'No' to the Bad (ie reject or 'return' regulation proposed by agencies), but also to say 'Yes' to the Good (ie 'prompt' new regulation). This is especially apt in the EU, where the European Commission initiates legislation, so it could use BCA to identify the best new policies to pursue—even more directly than can the White House in the US system, because the US Presidency is so often reacting to Congressional legislation and to agencies' implementing regulations. But it is also highly important in the US, where RIA and BCA have traditionally been positioned as a one-way 'No' check by the Presidency on the tide of lawmaking by the Congress and concomitant regulating by the agencies. It is this institutional posture, more than any analytic bias, that puts BCA in the position cited by critics[137] of being used more often to restrain regulation than to promote it. That posture erodes the credibility of BCA; a more evenhanded posture is needed that uses BCA to maximize net benefits by *both* adding and subtracting regulations as warranted. There are good reasons to think that, even as some proposed regulations would yield benefits that do not justify their costs and should be revised or rejected, there are other regulations that agencies are not proposing that would increase net benefits—such as health and environmental regulations that would yield broadly diffuse benefits but concentrated costs.[138] To fill this institutional gap, in the last five years, OMB/OIRA has adopted the pathbreaking innovation of 'prompt letters' to urge agencies to consider adopting new regulations that look attractive on BCA criteria. Such evenhanded application of BCA would increase net benefits, while incidentally shoring up the credibility of BCA. The US should develop a more routine approach to identifying

[136] IA Guidelines 2006, Annex 12 (adding in footnote 45 that 'This rate broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s'.).

[137] Eg Driesen, n 96 above; Bagley and Revesz, n 107 above.

[138] This is indeed a standard prediction of public choice theory. See William N Eskridge, Jr, 'Politics without Romance: Implications of Public Choice Theory for Statutory Interpretation' (1988) 74 *Va L Rev* 275.

promising subjects for prompt letters, such as by issuing an annual request for proposed prompt letters (as a counterpart to OIRA's annual request for burden-reducing proposals), by assigning one or more OIRA staff to identify and develop prompt letters, and by including prompt letters more explicitly in the next revision of the Executive Order.[139] Europe, too, should also develop this kind of an evenhanded approach to IA and BCA.

Wider Application

Third, IA and BCA should be applied more widely, not just to health and environmental rules but also to other important policies, such as trade measures, forest management, projects such as dams and highways, and homeland security and counterterrorism. As discussed in detail above, BCA was initially applied to many of these topics, but no longer is, or is not adequately conducted. Broadening its application would, in many of these domains, position BCA institutionally on the side of health and environmental protection—and as a more powerful tool than environmental groups have often had in these arenas to date. Combined with the continued application of BCA to regulations, this broadened role for BCA would help achieve the more neutral posture to which it aspires, while also bringing more sensible policy results in each domain.[140]

BCA should be used not only to limit costs, but also to increase net benefits. That is the explicit instruction of EO 12866. Thus, if BCA indicates that a regulation should be made more stringent than proposed, that finding should be on the same footing as a BCA in another case indicating that less stringent regulation would be preferable. BCA should correct both over- and under-regulation. And BCA should be applied to deregulation as well as to new regulation.[141] There is no reason to assume in the abstract that every deregulatory move will reduce costs more than benefits; that question should be subject to BCA.

Applying BCA to legislation would be more straightforward in the EU (where the European Commission initiates legislation and is also committed to IA), than in the US (where Congress initiates legislation but is not committed to IA—unless the Congress itself would take seriously the proposals to establish a BCA process and review office, such as

[139] See Bagley and Revesz, n 107 above.

[140] See Robert W Hahn and Cass R Sunstein, 'A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis', (2002) 150 *U Pa L Rev* 1489, 1499 (advocating broader use of BCA to render it a more neutral tool).

[141] See OMB Circular A-4, n 55 above, at 1 (covering both regulation and deregulation).

in the General Accountability Office or the Congressional Budget Office, and listen to the analyses produced by that office).

Optimal Analysis

Fourth, the meta-BCA idea should be incorporated in an institutional mechanism. Where BCA remains highly contested, its application should be based on its own pros and cons (judged by the implementing agency, subject to executive branch review), rather than mandated or prohibited by law. In US law, EO 12866 and Circular A-4 already give some discretion to agencies to tailor the type of BCA or C-EA to the regulatory matter in question. Going further, Congress could enact a 'superauthorization' to authorize (but not mandate) agencies to use BCA or C-EA or other analytic techniques where optimal, notwithstanding prohibitions (or requirements) in existing individual laws.[142] In EU law, the European Commission should develop a regular system to animate its 'proportionate analysis' criterion through routine, considered selection of the optimal type and degree of analysis for each major policy initiative.

Multiple Risks

As it constructs its program of Impact Assessment, the EU can tackle a difficult but inescapable problem that risk regulators have not yet fully addressed: the phenomenon of multiple risks. Government agencies and scientists typically assess the risk of one chemical or technology at a time.[143] For the most part, agencies regulate one risk at a time.[144] Many individual risks have thereby been reduced. But increasing recognition of the interconnectedness among multiple risks poses new demands, including the need to forecast the joint effects of simultaneous exposure to multiple risks, and to analyze the full portfolio effects, including ancillary benefits (AB) and countervailing risks (CR), of any effort to reduce a target risk.

One reason for the single-risk approach is that the cost of information (COI) increases as the problem becomes more complex. Another is institutional fragmentation—dividing up problems into smaller pieces to be addressed by different government bodies—which is the logical result

[142] See Jonathan B Wiener, Testimony on Regulatory Reform Legislation before the Committee on Governmental Affairs, US Senate, 1995.

[143] International Life Sciences Institute (ILSI), *A Framework for Cumulative Risk Assessment*, ILSI Risk Science Institute Workshop Report 5 (1999), available at <http://rsi.ilsi.org/file/rsiframrpt.pdf> (visited 10 September 2003) ('Traditionally, these risk assessments have been conducted on individual chemicals medium by medium; however, humans are exposed to multiple chemicals by multiple routes concurrently in daily life').

[144] See J Clarence Davies and Jan Mazurek, Pollution Control in the United States: Evaluating the System (Washington, DC: RFF Press, 1999).

of special interest politics, legislators' credit-claiming, and specialization in governance. Such specialization can be desirable, and some degree of specialization is inevitable because a monolithic government entity could not handle all issues at once (and would raise other concerns about concentration of power). But fragmentation can also yield problems when issues are interconnected. Fragmentation into specialized agencies with narrow missions exacerbates the inattention to risk-risk tradeoffs, by causing spillover effects into the domains of other agencies (eg the EPA asbestos ban yielding weaker brake linings and hence increased highway accidents, or EPA limits on air toxics emissions yielding increased exposures to workers inside factories). Even within an agency's own domain, these tradeoffs can occur (eg NHTSA requiring higher fuel efficiency levels without assessing vehicle safety, or requiring airbags without assessing injuries to children; or the Iraq war plans addressing cost—albeit underestimated—but omitting the countervailing risks of collateral damage, blowback, theft, degraded combat readiness, and distraction from other threats). Actions by one government entity can impose spillover effects on others—'regulatory externalities'. Some version of coordination or integration is therefore needed.

The real world is one of interconnection and complexity, in which people and ecosystems are exposed to multiple risks at the same time. Naturalist John Muir famously remarked in 1869 that 'when we try to pick out anything by itself, we find it hitched to everything else in the universe'.[145] The modern science of ecotoxicology is moving to formalize that insight in models of simultaneous 'multiple stressors'.[146] Modern legal scholars see the same thing: 'It only takes a moment's reflection to see that multiple-risk situations are quite common'.[147] 'Most of today's environmental law violates basic principles of ecology. Nature teaches the connectedness of all activities, but most current-generation law regulates separate pollutants with little consideration of ecosystems as a whole.'[148]

[145] John Muir, *My First Summer in the Sierra* (San Francisco: Sierra Club Books, 1988), 110 (journal entry for 27 July 1869).

[146] See Nico M Van Straalen, 'Ecotoxicology Becomes Stress Ecology' (1 September 2003) *Envtl Sci & Tech* 325A; JA Foran and SA Ferenc (eds), *Multiple Stressors in Ecological Risk and Impact Assessment* (Pensacola, Fla: Society of Environmental Toxicology and Chemistry (SETAC) Press, 1999); SA Ferenc and JA Foran (eds), *Multiple Stressors in Ecological Risk and Impact Assessment: Approach to Risk Estimation* (Pensacola, Fla: SETAC Press, 2000).

[147] Mark Grady, Book Review, 'Discontinuities and Information Burdens', reviewing William Landes and Richard Posner, *The Economic Structure of Tort Law* (1987), 56 *Geo Wash L Rev* 658, 664 (1988).

[148] E Donald Elliot, 'Toward Ecological Law and Policy', in Marion R Chertow and Daniel C Esty, (eds)., *Thinking Ecologically* (New Haven: Yale University Press, 1997).

The multirisk world poses challenges for risk assessment. First, risk assessors should develop the means to forecast the joint effects of simultaneous exposure to multiple risks. The joint effect may be synergistic (supralinear), linear (additive), or offsetting (subtractive), but the key point is that it is the joint effect rather than the sum of the individual effects that must be forecast. Second, increasing interconnections may accelerate the transmission of risks (such as disease or terrorism) across countries and continents, through increasingly dense networks among ecological, trade, travel, and telecommunications systems (including the internet). Risk assessment needs to account for these propagation vectors. Third, rather than simply forecasting single variables (such as exposure to a chemical), risk assessors need to develop multiple scenarios incorporating the mix of multiple variables affecting risk, weighted by probability judgments and sensitivity analyses.[149] US OMB Circular A-4 (September 2003) now requires a formal probabilistic portfolio of scenarios for policies with impacts exceeding $1 billion.

The multirisk world also challenges risk management. In theory, BCA embraces all effects. But in practice, BCA is often limited to looking only at the reduction in the target risk (TR) versus the increase in industry compliance cost. The problem is that risk-risk tradeoffs—the phenomenon that efforts to reduce a target risk may induce new countervailing risks[150]—are thereby ignored. The focus on TR omits countervailing and ancillary effects. And the focus on industry compliance cost favors options in which the cost of shifting from a restricted product or activity to a new substitute is low; but these substitutes can pose their own countervailing risks.

The solution is a full portfolio analysis (to 'treat the whole patient' rather than focusing on one risk or symptom at a time) that applies BCA more broadly, to maximize overall risk reduction (including countervailing risks (CR) and ancillary benefits (AB), as well as target risk (TR) reductions) less overall social costs (c, including administrative costs, compliance costs, and foregone innovation).[151] Thus risk-risk tradeoff

[149] Kahn and Wiener, n 23 above; de Jouvenel, n 23 above; Stephen Schneider, 'Can We Estimate the likelihood of Climatic Changes at 2100? An Editorial Comment', (2002) 52 *Climatic Change* 441–51 (criticizing single-scenario forecasts and calling for probability-weighted portfolios of scenarios).

[150] See Graham and Wiener, n 116 above.

[151] A short version is: max($\Delta TR - \Delta CR + \Delta AB - C$). See Jonathan B Wiener, 'Managing the Iatrogenic Risks of Risk Management', (1998) 9 *Risk: Health Safety Environment* 39–82. Equal attention to ancillary benefits (as well as countervailing risks) is urged by Samuel J Rascoff and Richard L Revesz, 'The Biases of Risk Tradeoff Analysis: Towards Parity in Regulatory Policy' (2002) 69 *U Chi L Rev* 1763. I agree, as we stated expressly in Grahan and Wiener above n 116, at 2, 37, 232. Indeed several of the examples of ABs offered by Rascoff and Revesz are the same examples we cited in ibid. No normative bias was intended; the goal should be an evaluation of the full portfolio of consequences.

analysis needs to be made an explicit part of BCA (or conducted on its own where BCA is prohibited or otherwise not used). Even opponents of BCA agree that these risk-risk tradeoffs deserve analysis.[152]

EO 12866 expressly requires consideration of adverse health and environmental impacts in section 6. OMB/OIRA's Circular A-4 (2003) contains narrative instructions to perform risk-risk tradeoff analysis, although the table it attaches as a scorecard to guide agency calculations does not contain a line on which risk-risk impacts (countervailing or ancillary effects) are to be entered.[153]

The EU IA Guidelines simply say: 'Identify (direct and indirect) environmental, economic and social impacts and how they occur'.[154] They should pay closer attention to countervailing risks and ancillary benefits, because these factors are so often neglected in the IA process.

The phenomenon of multiple risks underscores the need for Integrated Impacts Assessment—not different IA requirements segmented into particular topics. In the US the RIA is an integrated IA, but there are also specialized IAs on environment, federalism, takings, small business, children, and others. OMB Circular A-4 encourages agencies to combine these into one document. In the EU there is one Integrated IA on economic, social, and environmental impacts (but there is also talk of creating a special IA on

[152] Thomas O McGarity, 'A Cost-Benefit State' (1998) 50 *Admin L Rev* 7, 40–2 ('There is a grain of truth in the proposition that single-minded regulation of some health and safety risks can increase others. For example, when the Consumer Product Safety Commission promulgated a flammability standard for children's sleepwear, some manufacturers responded by treating the sleepwear with the chemical TRIS, which was later found to be carcinogenic. Health and safety agencies should take care not to create more risks than they eliminate. To the extent feasible, agencies should address ancillary risks that flow in a direct causal sequence from the conduct required or induced by their regulations. [Internal footnote: All of the risk-risk tradeoffs described in the case studies of the recent book, *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment*, are of this variety]. Agencies should also coordinate regulatory initiatives with other agencies to ensure that one agency's regulation does not unduly increase risks within another agency's domain.')

[153] Other approaches do not achieve this full portfolio analysis. For example, 'income-risk' ('health-health') analysis translates costs into risk units by estimating the amount of household income reduction (due to regulatory cost) associated with a death (due to reduced household expenditures on health). This in effect 'riskizes' costs, instead of the standard practice of 'monetizing' health risks, to achieve a common numeraire; but it does not address the risk-risk phenomena of CR or AB, which are additional effects apart from regulatory costs. 'Precaution' typically looks only at ΔTR and ignores CR and C (although the European Commission's Communication calls for attention to C). A focus on 'Administrative Costs' ('red tape') is only a subset of C, and reducing Administrative Costs could increase social costs, for example if a good BCA would necessitate some administrative costs, or if requiring industry to do more paperwork for information disclosure would save lives.

[154] IA Guidelines 2006, at 26.

competitiveness). The Commission's Communication of 16 March 2005 (at 13) remarks:

> Impact Assessment system was introduced to integrate and replace all previous single-sector assessments, as un-integrated analyses had been found to have little effect on the quality of policy-making. It requires the Commission to systematically assess, on an equal basis, the likely economic (including competitiveness), environmental and social implications of its proposals and to highlight the potential trade-offs. This new impact assessment system aims at helping the Commission to improve the quality and transparency of its proposals and to identify balanced solutions consistent with Community policy objectives.

Beyond risk-risk analysis in policy development, there should be networks of notification across agencies of cross-domain side effects. In the US, EPA now notifies OSHA when air toxics regulations may induce employers to stop exterior emissions by sealing the factory, thereby trapping toxics inside the workplace. But this was agreed only after OSHA complained, and there is still no government-wide process for such notifications across all agencies. The EU has a process of 'Interservice Consultation',[155] but it is not yet clear whether it will address the problem of cross-domain regulatory externality, or act as a more general invitation to comment on others' proposals.

At the legislative level, a key move is toward methods of Integrated Pollution Control.[156] In the 1990s, the United Kingdom made significant efforts to adopt IPC, in its 1990 and 1995 Environmental Protection Acts and its creation of an integrated pollution control agency.[157] The EU and other countries have considered borrowing the IPC.[158] In the US, this

[155] IA Guidelines, updated 15 March 2006, Part II, s 7, at 9–12.

[156] Lakshman Guruswamy, 'The Case for Integrated Pollution Control' (Autumn 1991) 54 *Law & Contemp Probs* 41; Nigel Haigh and Irene Erwin (eds), *Integrated Pollution Control* (Washington, DC: The Conservation Foundation and the Institute for European Environmental Policy, 1990).

[157] Richard Macrory, 'Integrated Prevention and Pollution Control: The UK Experience' in C Backes and G Betlem (eds), *Integrated Pollution Prevention and Control* (The Hague: Kluwer International, 1991) 53–64; Albert Weale, 'Environmental Regulation and Administrative Reform in Britain' in Giandomenico Majone (ed). *Regulating Europe* (London: Rountledge, 1996) 106; Michael Purdue, 'Integrated Pollution Control in the Environmental Protection Act 1990: A Coming of Age of Environmental Law?' (1991) 54 *Mod L Rev* 534; Neil Carter and Philip Lowe, 'The Establishment of a Cross-Sector Environment Agency' in T Gray (ed), *UK Environmental Policy in the 1990s* (New York: St Martin's Press,1995) 38.

[158] See Chris Backes and Gerrit Betlem (eds), *Integrated Pollution Prevention and Control: The EC Directive from a Comparative Legal and Economic Perspective* (The Hague: Kluwer Law International, 1999); Johannes Zöttl, 'Towards Integrated Protection of the Environment in Germany?' (2000) 12 *J Envtl L* 281.

may require statutory changes to enable, for example, EPA's program offices for air, water, and waste to develop joint multimedia regulations, or several agencies to collaborate. Ultimately, the numerous narrowly targeted statutes could be combined into a Comprehensive Environment (or Risk) Act that integrates regulatory standards and instruments while ensuring attention to multiple risks.

The EU concept of 'Interservice Steering Groups' is also promising.[159] Similarly, the US White House often fosters interagency collaboration. Interagency teams assembled to deal with shared or spillover problems connect the matrix by linking horizontally across the set of vertically isolated government silos.

More aggressively, one could pursue structural integration. This could include merger of related agencies, to internalize cross-domain regulatory externalities. For example, in the United States, EPA (Environmental Protection Agency) and OSHA (Occupational Safety and Health Administration) might be merged, or those two might be combined into a new Risk Department along with others such as the CPSC (Consumer Product Safety Commission), NHTSA (National Highway Traffic Safety Administration), the aviation safety branch of FAA (Federal Aviation Authority) (now partly of TSA, the Transportation Security Administration), and the food safety branch of the FDA. Land and resource management agencies such as the Forest Service, National Park Service, BLM (Bureau of Land Management), FWS (Fish and Wildlife Service), and NMFS (National Marine Fisheries Service) could also be merged into an integrated resource conservation agency. In the EU, one can imagine combining DG (Directorates General) such as DG Environment and DG SANCO (Health and Consumer Affairs). But all these mergers would only be worthwhile if they improved decision-making on complex multirisk problems. They would yield little if the statutory authority to regulate were not also revised, or if the cultures of the pre-existing units remained so balkanized that they continued to regulate without regard for their effects on each other. Merged agencies may continue to operate with fragmented internal structures (as EPA's different program offices are fragmented despite the integrationist agenda for

[159] IA Guidelines, updated 15 March 2006, Part II, s 6, at 9 ('An Inter-Service Steering Group is compulsory for all items of a cross-cutting nature. The Roadmap asks DGs to provide valid justification in those instances when no Inter-Service Steering Group is envisaged. These groups are there to provide specialised inputs and to bring a wider perspective to the process. Involving other DGs from the early stages will also make it easier to reach agreement during the Inter-Service Consultation').

founding EPA). The recent merger of several US agencies into the new Department of Homeland Security offers an opportunity to study and learn from a mega-merger of risk regulatory agencies. In addition to the concern that mergers may mean greater centralization of power, there is also the concern that more centralized management could be more rigid even as a multirisk world demands more agile and creative policymaking. All things considered, merger of agencies seems not as urgent as inculcating a multirisk approach in each agency.

Finally, the White House and the European Commission could each create a Primary Risk Manager to help coordinate risk regulation across the government.[160] Like a primary care physician who monitors the whole patient but refers more serious ailments to specialists, the primary risk manager would dispatch specific problems to expert agencies while supervising and monitoring the whole. The primary risk manager could help coordinate responses to multiple simultaneous risks, and ensure attention to ancillary effects that cross agency jurisdictions. It could also ensure within-agency consideration of ancillary effects.

One point here is that Better Regulation of multiple interconnected risks can imply the need for more, not less regulation—for more comprehensive regulation to avoid perverse shifts (induced regulatory externalities). That is, when narrow regulation creates countervailing risks, rather than regulate the target risk less, the optimal strategy may be to adopt more embracing regulation that internalizes both the market externality (target risk) and the regulatory externality (countervailing risk). Such comprehensive approaches can also be less costly than the sum of separate regulations for each risk. For example, if regulating CO_2 alone induces perverse shifts to emissions of methane (CH_4) that increase net global warming, the optimal solution might be to regulate both in a comprehensive multigas approach—both more protective and less costly.[161]

Administrative Simplification

The leading phalanx of Better Regulation in European member states is currently the campaign to reduce administrative costs and adopt simplification measures. For example, the Netherlands developed the standard

[160] Graham and Wiener, n 116 above ch 11.

[161] See Jonathan B Wiener, 'Protecting the Global Environment' in ibid, ch 10; Richard B Stewart and Jonathan B Wiener, *Reconstructing Climate Policy* (Washington, DC: AEI Press, 2003).

cost model to measure administrative costs, the UK is cutting red tape, the Merkel government in Germany is scaling back bureaucracy, and France hosted a June 2006 conference on administrative simplification. The EU has programs on administrative cost reduction and simplification. The OECD has developed a red tape scoreboard and is conducting a pilot exercise in the road freight transport sector.

Administrative costs are the costs of furnishing information and of processing government functions. Reducing administrative costs can be pursued both *ex ante* (in review of proposed new regulations and information requirements) and *ex post* (to reduce the costs of existing programs). 'Simplification' entails combining, codifying, or repealing old laws, in order to make them easier to understand, to reduce the complexity of bureaucratic steps the public must navigate, and to remove obsolete provisions.

Administrative cost reduction and simplification can be highly desirable, especially in legal systems encumbered with outdated and uncodified rules and a labyrinth of bureaucracy. But administrative cost reduction and simplification pursued narrowly could be counterproductive. They need to be evaluated in terms of their full social costs and benefits.

Administrative Costs

Reducing administrative costs can be one important way to remove barriers to business activities, facilitate new business startups, and diminish the hassles and intrusions faced by individuals. In Europe, the standard cost model (SCM) is being applied to measure and reduce paperwork burdens and time consumption due to information demands imposed on businesses and individuals by regulation. The Netherlands pioneered the SCM in 2002, and there is now an SCM Network involving at least nine EU member states.[162] Further, European governments are setting political targets, such as a 20 or 25 percent reduction in administrative costs from a base level estimated by the SCM inventory.[163] European member states face both national (member state) and EU administrative

[162] See the SCM Network website at <http://www.administrative-burdens.com/>. A brief discussion of progress to date is in European Commission, Communication from the Commission on an EU common methodology for assessing administrative costs imposed by legislation, SEC(2005)1329, COM(2005) 518 final (Brussels, 21 October 2005), at 4.

[163] See examples at the SCM Network website, n 162 above. For example, on 27 April 2006, Austria set a target of reducing administrative costs by 25 percent by 2010 using the SCM, see <http://www.administrative-burdens.com/default.asp?page=1&article=69>.

requirements, but reducing the latter may increase the former.[164] The European Commission has developed a common methodology for measuring administrative burden[165] and is undertaking a pilot project to measure administrative costs in industry sectors (initially construction, with others to be added next year) across Europe. In May 2006, European Commission Vice President Günter Verheugen announced the EU's own 25 percent target to reduce administrative costs, to be achieved in partnership with the member states' own cost reduction programs.[166]

In the US, the Paperwork Reduction Acts of 1980 and 1995, and OMB Circular A-130,[167] established the objective and methods of cutting administrative costs. OMB measures the time spent by businesses

[164] The Commission pointed out: 'Administrative obligations should therefore not be presented as mere "red tape", a term normally reserved for needlessly time-consuming, excessively complicated or useless procedures. Nor should EU administrative obligations be presented as a mere cost factor, as it often replaces 25 different national legislations and thus decreases operating costs at EU level'. European Commission, Communication from the Commission on an EU common methodology for assessing administrative costs imposed by legislation, SEC(2005)1329, COM(2005) 518 final (Brussels, 21 October 2005), at 2 (footnote omitted).

[165] See IA Guidelines 2006, Annex 10 (on administrative cost measurement); European Commission, Communication from the Commission on an EU common methodology for assessing administrative costs imposed by legislation, SEC(2005)1329, COM(2005) 518 final (Brussels, 21 October 2005).

[166] He said: 'I believe that we should give particular attention to the administrative costs of regulation since these costs can be cut without affecting the objectives of the legislation itself. They are the proverbial "low hanging fruit" of our Better Regulation agenda. And they are the major irritants European citizens and businesses are confronted with in their daily lives. Crucially, work done by several Member States, notably the Netherlands, suggests that both these costs and the potential for reducing them are very significant. If these estimates are correct, Europe is spending more than 2.5% of its GDP—or some 275 billion euros every year—on reporting requirements and other administrative obligations linked to our regulatory system. Moreover, these costs fall disproportionally on small and medium sized enterprises—the job engine of the European economy. This is patently absurd at a time that we are putting competitiveness at the heart of our policy agenda. I am, therefore, of the opinion that we should look at cutting these costs by 25% and I will take a proposal to the Commission suggesting how this objective can be achieved. To lay the foundations for this proposal, I have instructed my services to launch the necessary studies, which will provide a baseline against which we can measure administrative costs, as soon as possible. . . . There will . . . have to be a shared responsibility for reaching the 25% objective. I am optimistic that we can achieve this partnership since 17 Member States have already announced administrative cost reduction measures in their Lisbon National Reform Programmes. Through the newly created High Level Group on Better Regulation we are working closely with experts from all the Member States to prepare this ambitious project'. Günter Verheugen, Vice President of the European Commission responsible for Enterprise and Industry, Better Regulation for Jobs and Growth, Former Members Dinner, European Parliament Former Members Association, Brussels, 10 May 2006, SPEECH/06/287, available at <http://ec.europa.eu/commission_barroso/verheugen/speeches/speeches_en.htm>.

[167] 44 USC s 35; OMB Circular A-130, Management of Federal Information Resources, at <http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html>.

and individuals in filling out each form, works to reduce that time, and requires new surveys and other information-gathering projects to receive OIRA approval. But OIRA has gone beyond that task—as directed by EOs 12291 and 12866—to assess the full social costs and benefits of policies.

Better Regulation should address administrative costs, but should not focus solely or predominantly on administrative costs. 'Cutting red tape' is popular, but does not assess the full costs or benefits of a policy. The political targets of 20 or 25 percent reductions in administrative costs are like Procrustes' insistence that guests be cropped to fit his bed: these targets arbitrarily crop information-based programs without considering the benefits of such information collection or the other costs that might increase if information collection is curtailed. Even granting that administrative costs are too high in many countries, the 20 or 25 percent reduction targets have not been based on an analysis of the optimal reduction in such costs. In some countries or sectors the optimal reduction in administrative costs might be greater than 25 percent; in others it might be less than a 20 percent reduction, or even an increase in administrative costs if gathering new information would yield net benefits.

Focusing exclusively on cutting administrative costs could be perverse. It could forfeit the large social benefits of some information disclosure programs, such as the US Toxics Release Inventory[168] and similar European pollutant discharge registries.[169] Cutting administrative costs could be accomplished by swiftly adopting highly precautionary regulations, based on little information or analysis, that impose high social costs in foregone innovation. Administrative costs could also be cut by eschewing the information demands of BCA and proceeding to adopt regulations that impose lower administrative costs but greater social costs.[170]

[168] See James T Hamilton, *Regulation through Revelation: The Origin, Politics and Impacts of the Toxics Release Inventory Program* (Cambridge: Cambridge University Press, 2005).

[169] See Peter H Sand, 'Information Disclosure' (2003) 63 *Heidelberg Journal of International Law* (*Zeitschrift für ausländisches öffentliches Recht und Völkerrecht*) 487–502 (revised as Peter H Sand, 'Information Disclosure and the Atlantic Divide' in Jonathan B Wiener *et al* (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (forthcoming 2006)).

[170] Consider these four hypothetical policies and their associated costs and benefits:

Policy A: Admin cost 10, Full cost 13, Benefit 20. Net Benefit = 7.
Policy B: Admin cost 7, Full cost 10, Benefit 19. Net Benefit = 9.
Policy C: Admin cost 4, Full cost 7, Benefit 12. Net Benefit = 5.
Policy D: Admin cost 2, Full cost 16, Benefit 10. Net Benefit = −6.

To reduce administrative costs alone, one would prefer option D. To reduce full costs alone: prefer C. To maximize benefits alone: prefer A. To maximize net benefits: prefer B.

Vice President Verheugen's remarks (just quoted) express optimism that administrative costs 'can be cut without affecting the objectives of the legislation itself', but in many cases administrative costs support valuable information collection efforts that are necessary for policies to yield benefits or reduce other costs. The 20 or 25 percent targets to reduce administrative costs do not appear to take these benefits and other savings into account.

To reduce administrative costs while avoiding these potentially counterproductive results, rather than simply setting targets to cut administrative costs alone, European Union institutions and member states should use IA and BCA to assess the full social costs and benefits of policy changes to reduce administrative costs. This point was recently recognized by the European Commission: On 15 March 2006 the Commission inserted a warning to this effect, as a new 'Box 11' in the updated version of the IA Guidelines. Box 11 now reads:

> The fact that one option would impose lower administrative costs is *not* in itself a sufficient reason to prefer it. For example, a measure . . . likely to impose relatively fewer administrative costs [by mandating specific technical standards, instead of requiring labels that disclose product data] . . . could give manufacturers less flexibility and could reduce consumer choice, [so that] its overall costs may be higher than the 'administrative' requirement to display data . . . [171]

This Box 11 was not present in the June 2005 IA Guidelines. Its addition in the updated 2006 Guidelines indicates that the Commission is responding to the zeal for cutting red tape and tempering that zeal with attention to full costs.[172] The Commission should now go further to add explicit consideration of benefits as well as costs, and should address this issue in the member states as well.

Simplification

The EU and several member states have also embarked on ambitious programs of simplification. In October 2005 the European Commission announced 'a three year programme to simplify the existing thousands of pages of EU legislation ("acquis") adopted since 1957', including a

[171] See EU IA Guidelines 2006, Part III, s 5.1, at 39, Box 11.

[172] As the Commission remarked, 'Regulatory costs, of which administrative obligations are just one element, must be analysed in a broad context, encompassing the economic, social and environmental costs and benefits of regulation'. European Commission, Communication from the Commission on an EU common methodology for assessing administrative costs imposed by legislation, SEC(2005)1329, COM(2005) 518 final (Brussels, 21 October 2005), at 3.

proposal 'to repeal, codify, recast or modify 222 basic legislations and over 1,400 related legal acts in the next three years' and 'to tackle administrative burden, especially for small business, by simplifying cumbersome statistics form-filling or by modernizing the customs code to facilitate electronic exchange of information'.[173] The Communication issued to launch this policy outlined each of these strategies (repeal, codify, recast, modify), as well as efforts to make greater use of information technology, to use performance standards instead of technical design standards, and to replace some EU 'directives' (which call on member states to transpose their instructions into national law—akin to 'cooperative federalism' in the US) with EU 'regulations' (which are effective throughout the EU without such transposition—akin to federal pre-emption in the US), in order to achieve more uniform and hence simpler rules across the European single market.[174]

The best understanding of simplification is that it attempts to modernize a body of law by editing, pruning, organizing, and streamlining the laws so that they are more clear, understandable, and effective as well as less burdensome to navigate. It may well be that legal rules in some countries in Europe (and in the US) are so labyrinthine that businesses and individuals must incur high costs just to figure out what the law means. Simplification in the EU is thus reminiscent of the codification movement in the US led by David Dudley Field in the mid-1800s, and the effort in the last several decades in some US states and the federal government to write laws in plain understandable language. This was one of the goals of the Clinton–Gore 'National Performance Review' and the Presidential Memorandum of 1 June 1998. As simplification moves beyond consolidation and codification to undertake the repeal of obsolete or superfluous laws, it is also expressing the view that venerable vintage is not a sufficient reason to preserve a law—perhaps best crystallized by US Supreme Court Justice Oliver Wendell Holmes, Jr:

'It is revolting to have no better reason for a rule of law than that so it was laid down in the time of Henry IV. It is still more revolting if the grounds upon which

[173] See DG Enterprise and Industry, 'Better Regulation—Simplification', 25 October 2005, posted at <http://ec.europa.eu/enterprise/regulation/better_regulation/simplification.htm>.

[174] European Commission, Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Implementing the Community Lisbon Programme: A Strategy for the Simplification of the Regulatory Environment', COM(2005) 535 final (Brussels, 25 October 2005), available at <http://ec.europa.eu/enterprise/regulation/better_regulation/simplification.htm>.

it was laid down have vanished long since, and the rule simply persists from blind imitation of the past'.[175]

But in the EU simplification effort there is also an unmistakable bent of,

advanced stage in governing regulation—is aimed at preserving the existence of rules in a certain sector, while making them more effective, less burdensome, and easier to understand and to comply with .... Therefore, by simplification we refer to the process of reform of existing regulation, which seeks to streamline administrative procedures and to reduce the burden of compliance on citizens, businesses and the public sector itself, while preserving the intended (political) goals of the regulation.[177]

But sometimes the original intended goals of the legislation also become obsolete. Changes in economics, technology, and social values may well call for repeal or replacement of old laws. The key, again, is the criteria for such choices. Standing alone, the simplification initiative lacks clear criteria for identifying and modifying laws.

Instead, I suggest applying IA and BCA to decide on the rescission or revision of existing laws. IA and BCA should be used to evaluate existing regulations as well as new regulations, and to evaluate deregulation and simplification as well as new regulatory proposals. Such evenhandedness would reduce the current new/old bias in regulatory review. It would also correct the bias toward cutting regulatory costs or repealing old laws without considering benefits. Some existing laws and regulations should be phased out, and others strengthened, depending on new information and learning, but this process should be guided by sensible analysis rather than only by political impulses. More blunt approaches—such as predetermined 'sunset' dates at which regulations automatically expire, or political targets to cut administrative costs by a certain percentage, or deregulation without BCA, or simplification programs to rescind laws on the ground that they have not been used recently—are crudely effective but arbitrary; they neglect the benefits of existing policies and administrative requirements (including costly policies that generate worthwhile benefits, and laws that have not been used recently because compliance is universal as long as the law is in effect). Applying BCA criteria to the review of existing policies would be better: it would put the focus on benefits as well as costs, and it would enable net benefits to be maximized by strengthening, revising, weakening, or eliminating these policies, as the merits warrant.[178]

[177] Mandelkern Group Report (2001), n 2 above, at 33.

[178] The Commission appears to be heading in this direction: 'Simplification is not merely an exercise in improving accessibility and readability. It is intended to operate within the Competitiveness policy and for this reason a reinvigorated simplification programme, to be launched in 2006/7, will reinforce the mechanisms for identifying legislation that requires simplification; namely legislation which careful assessment shows to be disproportionately burdensome for EU citizens and businesses in relation to the public

One promising tack for simplification programs would be to rescind perverse subsidies.[179] Governments spend billions of taxpayer dollars (and euros) on subsidizing agriculture, energy, mining, water use, logging, and many other industries. Such policies often endure long after their initial usefulness has ebbed, yet continue to support activities that are both environmentally harmful and economically wasteful. They are resilient in part because they are supported by concentrated beneficiary constituencies, and impose diffuse costs on the general tax-paying public who face free-rider incentives not to complain. To surmount these rent-seeking pressures in favor of subsidies, the EU and the US could consider setting up non-political commissions to identify subsidies for rescission (based on BCA), with the recommendations to take effect unless the relevant legislature acts to preserve them. Transitions to systems of support payments that are not tied to output could be added to assist dependent communities to wean themselves off subsidies. This approach would be similar to the US military base closure commission. And it would use the power of simplification under Better Regulation to address a problem of enormous domestic and international concern. Such a 'subsidy-closing commission' could not only save costs and the environment in the US and EU, but also benefit farmers in poor countries, and make progress in the stalemate over international trade liberalization.

Oversight

All of this analysis and reform will not make Better Regulation succeed if it does not influence policy decisions. Impact assessment can change minds, but it can also become merely cosmetic—a 'relookage' as they say in France—if there is no oversight mechanism to ensure that the analysis is taken into account in decisions. Some mechanism to check, review, and shape legislation is needed in the EU institutions.

In the US, environmental impact assessment under NEPA has persistently faced the criticism that agencies do the EIA, but merely attach it to

interests that the legislation aims to safeguard. . . . It is only when the assessment of proportionality clearly confirms that public interests might be equally well served by simpler means that the repeal or modification of the legislation should be considered'. DG Enterprise and Industry, 'Better Regulation—Simplification', 25 October 2005, posted at <http://ec.europa.eu/enterprise/regulation/better_regulation/simplification.htm>.

[179] See Norman Myers and Jennifer Kent, *Perverse Subsidies* (Washington, DC: Island Press, 2001); Barton Thompson, n 92 above (suggesting rescission of perverse subsidies in order to protect biodiversity).

the decision they would have made anyway. This is despite the availability of judicial review of NEPA law, including the courts' power to issue injunctions halting projects. One reason is that judicial review is infrequent enough to be a weak deterrent. Another is that NEPA has been held by the US Supreme Court to be 'purely procedural', a 'stop and think' law, requiring agencies to assess environmental impacts but not imposing substantive criteria or constraints on the ultimate decision.[180]

By contrast, RIA is sometimes criticized as overly influential, binding agencies too much as they seek to satisfy OIRA's criteria for BCA; and yet sometimes criticized as inadequately influential, because only about half of agency RIAs monetize the benefits and costs. Still, OIRA's own data show that net benefits have increased over time in response to the RIA and BCA requirements.[181] Yet there is no judicial review of RIAs (although courts can and do take note of RIAs in their decisions under other laws, such as the 'arbitrary and capricious' standard of the Administrative Procedure Act). The reason for even the partial success of the RIA process is undoubtedly the role of OIRA in reviewing the RIAs and returning proposed rules when the criteria are not met. OIRA is more successful at supervising RIA than the courts are at supervising EIA because judicial review is decentralized and non-expert, whereas centralized executive branch oversight is expert and potent while helping to obviate judicial oversight.[182]

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is an effective ability to influence decisions. As the Mandelkern Group wrote:

'[T]he issue of appropriate **structures** is an absolutely **crucial topic**. The success of efforts on better regulation will ultimately depend on this very issue . . . . Based on the experience in various administrations there are four main elements that seem to be essential for the chosen structure to be effective:

— **Strong political support**. Better regulation programmes need very strong political support to produce the desired outcome;
— **Support from the centre**. The best results are often achieved with the Head of Government personally and/or at least institutionally interested and involved;
— **A horizontal approach**. Very clearly, an all-government approach is necessary; sectoral approaches limited to individual Ministries or Directorates-General will not achieve optimum results and a coherent, horizontal approach is needed; and
— **A strategic approach**. Close connection to the strategic planning of the government/administration is of real benefit.'[184]

This body/structure must, by virtue of its qualified staff with a range of expertise, its specific position in the administration, its recognised authority and its expertise in managing regulatory quality tools, be able to ensure adherence to the process that contributes towards improving regulatory quality. At the same time this body/structure must have an appropriate level of autonomy, as well as objectiveness with regard to the policy officials who prepare regulations . . . . the body/structure might also be given a gate-keeping function.'[185]

Yet despite this advice from 2001, and the US model in place since at least 1981, the European Commission appears still to be searching in 2006 for the best way to handle the oversight question. Constructing an oversight mechanism is a work in progress. Vice President Verheugen recently declared:

I will be campaigning for three major new initiatives: First, President Barroso and I will significantly strengthen central oversight in the Commission to police the

— A primary unit based in a part of the administration other than the centre (e.g. Public Administration or Economic Affairs Ministry), probably with a network of satellite units;
— An inter-ministerial co-ordination committee;
— A network of units/responsibilities across the main Ministries or Directorates-General, with or without support from a primary unit; and
— A body external to the administration (a body of such type may especially be apt to be integrated into the evaluation of the consequences of already existing regulation)'.

[184] Mandelkern Group Report (2001), at 47–8 (emphasis in original).
[185] Ibid at 49.

quality of our Impact Assessment. While the Impact Assessments must be carried out by the services responsible for the development of the proposals, we must also ensure that they are rigorously scrutinised by an 'independent party' within the Commission but with no involvement in the preparation of the file. This is why as a first step, we are creating a standing committee of senior officials who will be tasked with ensuring that the Impact Assessments are in full conformity with the exacting requirements we have set ourselves. These officials should report directly to the President and myself. In this way we can strengthen the system of checks and balances in the Commission.[186]

Where this independent review will be located is still an open question. Within the European Commission, the office of the Secretariat General has the authority to perform this function, but does not yet have the expert staff to review IAs, and has not yet issued an 'avis negatif' based on an IA. Perhaps it will soon bolster its capacity. Other options for a central oversight body include the Bureau of European Policy Advisors attached to the Presidency; a new Presidential office; or a shared group of DGs or an interinstitutional body linking several units such as DG Enterprise, DG EcoFin, DG Environment, DG SANCO, the Legal Service, and others with expert staff.

But none of these has yet been adopted at the EU level.[187] The structure of power in the Commission to some extent inhibits a strong central role, because the President of the Commission is not popularly elected and remains one member of the College of Commissioners, all of whom are appointed at the same time and are expected to work together. Moreover, the objective of the European Union is in substantial part to prevent conflicts among the countries of Europe, and as a result the collegial and courteous style of work within the Commission seems, at least to an outsider accustomed to the tough debates within the White House 'family', to be unreceptive to the sharp and hierarchical confrontations over policies that central regulatory oversight might entail. The question is whether a Commission could decide collegially to establish an oversight office with real power, an office that would sometimes oppose the position of one or another individual Commissioner, or whether instead such a reform must await more radical governance reform such as the advent of a popularly elected European President who could install such an office.

[186] Günter Verheugen, Vice-President of the European Commission responsible for Enterprise and Industry, Better Regulation for Jobs and Growth, Former Members Dinner, European Parliament Former Members Association, Brussels, 10 May 2006, SPEECH/06/287, available at <http://ec.europa.eu/commission_barroso/verheugen/speeches/speeches_en.htm>.

[187] Several have been tried at the member state level. See Hahn and Litan, n 18 above. The UK has a central expert body in its Better Regulation Executive. Finland assigns the

Meanwhile, filling the open niche, DG Enterprise has developed substantial staff expertise and appears to be acting, in effect, as the 'lateral' oversight arm. If so, this is progress, but it is not yet the ideal. Lateral oversight offers staff capacity, but typically lacks the power to enforce supervisory decisions on other co-equal units. And lateral oversight lacks the perspective and legitimacy of central oversight. Even if DG Enterprise does a very fine job, its lateral posture will yield the appearance (if not the reality) of factionalized or parochial review, if it appears to represent the interests of business rather than of full social impacts, in turn raising questions about its credibility and hence its sustainability.[188] The review function (including staff with expertise) should thus be relocated to the center, that is, to the Presidency of the Commission. DG Enterprise could continue its review activities in support of this central office, or the current review team at DG Enterprise could (along with others) be promoted to become the staff of the central office.[189]

This central oversight office should not be just a referee, nor simply a check on regulation percolating up from the DGs. That is too reactive a posture. The central oversight office should be closely attached to the Presidency of the Commission and should carry out the President's strategy for regulatory policy (such as Better Regulation using IA).[190] Of course the Commission President could lead this initiative along with one of the Vice Presidents (just as the US Executive Orders originally designated the Vice President to oversee OMB/OIRA, a role now transferred to the White House Chief of Staff by EO 13258). In addition to waiting

oversight role to its Trade Ministry, and Hungary to its Justice Ministry. Recently, France shifted its Better Regulation office from the office of Réforme de l'Etat, attached to the Prime Minister, to the Ministry of Finance, Economy and Industry. Although this creates a lateral review rather than a central office, its objective was to combine regulatory review with fiscal budgetary review in the Finance Ministry and thereby to add effective teeth to the review function.

[188] Radaelli, n 27 above, at 940, argues that 'credibility is the Achilles heel of impact assessment. [If] RIA is tilted towards one actor's preferences to the detriment of others, there is no economic analysis that can compensate for the credibility deficit'.

[189] I emphasize that I am not criticizing the individuals at DG Enterprise, nor the quality of their work; they are filling a niche left open and a role that the Better Regulation initiative demands be filled, and by all accounts are doing so quite ably. The point here is about institutional structure.

[190] See Kagan, n 17 above, ('We live today in an era of Presidential administration . . . presidential control of administration, in critical respects, expanded dramatically during the Clinton years, making the regulatory activity of the executive branch agencies more and more an extension of the President's own policy and political agenda'); James F Blumstein, 'Regulatory Review by the Executive Office of the President' (2001) 51 *Duke LJ* 851. For doubts whether the Presidential agenda and expert BCA can fully coexist in regulatory review, see Stuart Shapiro, 'Politics and Regulatory Policy Analysis', (summer 2006) *Regulation* magazine 40–5.

for regulatory proposals to arrive from the DGs for review, the central oversight office should play an early role in shaping the regulatory priorities of the Commission, working with DGs to identify subjects warranting regulation, to improve their policy proposals, to reconcile tradeoffs, and to ensure best practices across DGs. It should issue 'prompt' letters to stimulate new regulation that its expert analysis deems desirable, and 'return' letters (or *avis negatifs*) to reject regulations where the analysis is inadequate.

In the EU system the Commission initiates new legislation, so IA within the Commission is important, especially at a central oversight office that can reconcile competing interests across the DGs. Otherwise the lead DG may simply carry the day, or there may be horse trading among DGs (among Commissioners) in which each gets its priority initiatives adopted but none is truly assessed for overall net benefit to the EU.

> 'Complicated regulation arises in large part from current practice of the Commission, by which regulation is drafted primarily by more than 20 Directorates-General, with an imperfect degree of co-ordination among them. This does not optimise collegiate action and often forsakes the benefits that could be gained by a more deliberative form of decision-making. On this crucial topic, it has been widely observed that different DGs draw up draft directives in themselves perfectly compatible with the objectives and administrative culture of a particular DG, but compatibility with general EU interests is weakly ensured.'[191]

Central oversight of the IA process in the Commission would thus be important to ensure that EU-wide net benefits are considered in important regulatory policies.

Even if the Commission does establish centralized review, there may also be a need for an external check on the Commission because of the Commission's monopoly on initiating legislation. This external check could be situated in the Council, the Parliament, or an Interinstitutional body.

The Council is currently ill-suited to this task because the Council members who meet on a particular matter, although ostensibly representing each member state's prime minister or government, in fact tend to be the ministers from the single ministry concerned with the specific issue of the legislation (eg all the Environment ministers), and therefore tend to support the legislation. 'At the European level, even if the proposals have to come from the Commission, which, operating in collegiate fashion, seeks to weigh the various demands and interests, the competent

[191] Mandelkern Group Report (2001), at 64.

Council is composed of just the sectoral ministers, who are in charge of the final decision. This asymmetry leads to a systematic tendency towards the growth of regulation.'[192] The Council's role in IA could be strengthened if the member states insisted on a full consideration of impacts before deciding on instructions for their delegates to the Council, and, furthermore, if the member states conducted their own IAs. There is now talk of member state parliaments doing so in order to assess EU directives before they are adopted and must be transposed into member state law. The Council's role in EU-level Better Regulation could be best supported if the member states created a network or pool of member state experts (drawn from each member state's own central regulatory oversight office)—the Council's own 'regulatory analysis review group', to borrow the title of President Carter's interagency body—available to conduct IAs for the Council and to deliberate together on regulatory proposals. The Commission's Communication of 16 March 2005, at 10, announces a 'group of high-level national regulatory experts', although this group may or may not be in a position to advise the Council.

Apart from the Council, external oversight would be left to the European Courts or the European Parliament. The Courts are not equipped with the staff or expertise to perform IA, and they tend to defer to the Commission and the Council (as in the *Pfizer* case discussed above). But if the other EU institutions do not effectively oversee regulatory policy, the courts may step in. The European Parliament, meanwhile, has the motivation to check legislative initiatives coming from the Commission, but so far does not have the political clout. In the US, the adoption of the Congressional Review Act in 1996 authorized a special procedure for Congress to reject an agency regulation (a power Congress always had via legislation, so long as the President did not veto the law or Congress could override the veto), but Congress did not create an expert body to conduct IA, so exercise of the CRA remains an essentially political act. And it remains rare—of almost 42,000 rules including 610 major rules promulgated in the last ten years, the Congressional Review Act has only been used to reject one: the ergonomics rule rescinded in March 2001.[193] Adding an expert body equipped to perform IA in the US Congress and in the European Parliament (as a counterpart to IA by the

[192] Mandelkern Group Report (2001), at 64.

[193] Statement of Morton Rosenberg, Congressional Research Service, before the House Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, Concerning Oversight of the Congressional Review Act on the Tenth Anniversary of its Enactment, 30 March 2006, <http://judiciary.house.gov/media/pdfs/rosenberg033006.pdf>, at 3.

White House and the Commission) could raise the Parliament's stature and enable it to engage actively in reasoned debate over regulatory policy (to reject, revise, or prompt policies, as the net benefits warrant). In the US, such a body could also, perhaps even more importantly, enable IA of legislative proposals in Congress, which currently are not subject to IA. But if no such expert IA body is created, then Congressional or Parliamentary review of regulatory policy could be seriously dysfunctional: driven by the vicissitudes of political winds and caprice, unrelated to societal net benefits, it could mark a return to horse trading among parties and parochialisms that would harm rather than help yield Better Regulation.

In sum, a central oversight office is needed in the EU regulatory system, but the unique features of EU governance imply that 'centralized' could be within the Commission (overseeing the DGs), at the Council (with support from the member states), at the Parliament, or in a new interinstitutional body. This oversight office needs the capacity to conduct excellent analysis, embracing the broad set of topics outlined above, with skills not only in economics but in other fields as well, including the science underlying benefits estimates and risk assessments. It needs the power to influence decisions: to say no (return), yes (prompt), or revise. It needs to follow clear procedures of transparency, posting its meetings and decisions for public view, to avoid the appearance of backroom deals.[194] And it needs the expertise not only to evaluate regulatory proposals and IAs, but also to assist the DGs with their policy development and analyses:

> Education as to the usefulness of the tool in assisting the policy process is vital—policy officials need to see what is 'in it for them' in using the system. But there must also be a credible deterrent element—if the process is not completed properly (timing and quality), the progress of the policy can be delayed, halted completely or challenged subsequently.[195]

At present, the most likely candidate for such a central oversight office is within the Commission, either in the Secretariat General or in a new body attached to the Presidency (and a Vice President). The Commission's Competitiveness Council might play this role, if it were equipped with an expert staff and if it took a full-portfolio view of overall impacts rather than focusing only on competitiveness. But over time the creation of oversight mechanisms in the Council and the Parliament could supplement and check the Commission's oversight role. A new interinstitutional body

[194] This was a key improvement made in EO 12866 in 1993, and redoubled by OIRA after 2000 when it posted all its activities on a public website at <www.omb.gov>.

[195] Mandelkern Group Report (2001), at 24.

remains the least well-defined option; it would be the most 'central' but perhaps the least potent. Failing all these options, the courts may begin to take a tougher role in reviewing EU regulatory policies.

Ex Post Evaluation and Adaptive Management

Do policies actually work? With what results? This question is often neglected, perhaps because agencies have scarce resources which they prefer to devote to new initiatives. Most wealthy countries currently conduct some kind of *ex ante* assessment through IA, but few conduct *ex post* review. In the US, EO 12866 requires *ex ante* review of major rules but does not require *ex post* evaluation.

One reason to conduct *ex post* evaluation is to improve policies over time based on the updated information about effectiveness, benefits, costs, and unintended countervailing or ancillary effects.[196] The use of performance monitoring data to revise policies is often called 'adaptive management'. A second reason to conduct *ex post* evaluations is to determine how accurate the *ex ante* RIA estimates were, and to validate and improve the *ex ante* methodologies for subsequent decision-making. As noted above, initial retrospective studies by OMB and by Harrington *et al*,[197] while not representative samples, find both over- and underestimates in the *ex ante* analyses.[198]

[196] Charles Herrick and Daniel Sarewitz, 'Ex Post Evaluation: A More Effective Role for Scientific Assessments in Environmental Policy', (2000) 25 *Science, Technology, and Human Values* 309–31.

[197] See OMB, n 102 above; Harrington *et al*, n 102 above. An early call for such evaluations was W Kip Viscusi, *Risk by Choice: Regulating Health and Safety in the Workplace* (Cambridge, Mass: Harvard University Press 1983), 162–3 (criticizing the absence of *ex post* evaluation of cost estimates, and urging creation of a staff group to conduct these analyses).

[198] *Ex post* evaluations face methodological challenges. See James K Hammitt, 'Risk Assessment and Economic Evaluation', ch 112 in William N. Rom (ed), *Environmental and Occupational Medicine* (4th edn) (Philadelphia: Lippincott-Raven, 2006), 33–6 (noting that 'retrospective values are also estimates because, although one can observe some of the consequences once the rule is implemented, one cannot observe what the consequences would be if the rule had not been adopted and so the counterfactual situation must be estimated. In addition, the health benefits of a regulation may remain quite uncertain in cases where the individuals suffering the health effects due to the agent that is regulated may not be identifiable'). One should not draw the conclusion from *ex post* evaluations that *ex ante* predictions can always be easily improved. *Ex post* evaluations may yield 'hindsight bias'—the misimpression that outcomes were more easily predicted *ex ante* when in fact they were difficult to predict *ex ante*. Terrorist attacks and corporate fraud may look predictable in hindsight when *ex ante* clues are turned up, but those *ex ante* clues may have been buried among many other clues pointing in other directions. See Scott A. Hawkins and Reid

As it implements Better Regulation, the EU and its member states should take the opportunity to build in regular *ex post* evaluations of policies and of *ex ante* IAs. In the future, *ex post* evaluation exercises should address a representative sample of past IAs rather than a convenience sample. They should quantify the degree of error rather than just whether the *ex ante* IA over- or underestimated. They should address countervailing risks and ancillary benefits (both those forecast *ex ante* and those observed *ex post*). Eventually, *ex post* evaluations should be undertaken as a routine matter for every major rulemaking, both to improve *ex ante* methods and to revise policies through adaptive management.

Some observers urge more *ex post* evaluation and adaptive revision, and less reliance on *ex ante* evaluation via BCA.[199] But why not do both? One cannot just do *ex post* analysis alone—because one needs some way to choose which policies to adopt at first, and then review later. One still needs some sensible criteria for initial choices.[200]

The adaptive management aspect of *ex post* review corresponds to the 'provisional' character of precautionary regulation, meant to be updated as science evolves. But this still leaves open the question of who will conduct the additional research and who will apply that research to *ex post* policy evaluation and revision. JB Ruhl worries that 'decisionmakers need to be in a position to adjust decisions based on reliable monitoring feedback [and] in a manner that is transparent and accountable [and] subject to some objective boundaries', but in practice this gets bogged down by interest groups and judicial review; it 'cannot flourish . . . in the conventional [US] administrative law context', so we need 'new institutions . . . that allow agencies to use adaptive management while ensuring adequate agency accountability'.[201] *Ex post* review using BCA could serve this role.

Hastie, 'Hindsight: Biased Judgments of Past Events after the Outcomes are Known', (1990) 107 *Psychol Bull* 311, 312; Mitu Gulati, Jeffrey J Rachlinski, and Donald C Langevoort, 'Fraud by Hindsight', (2004) 98 *Northwestern University Law Review* 773.

[199] Sidney A Shapiro and Robert L Glicksman, *Risk Regulation at Risk: Restoring a Pragmatic Approach* (Stanford, Calif: Stanford University Press, 2003).

[200] Cf Ackerman *et al*, n 96 above (arguing that BCA mistakenly skews decisions against environmental protection, as illustrated by the authors' *ex post* reconstructions of *ex ante* BCA rejecting selected past decisions that they contend were good). But on what criteria do they determine that the initial decisions were good? If *ex post* BCA shows that the decisions were good but *ex ante* BCA would not have done so, this is the kind of *ex post* review that can be used to improve the methods of *ex ante* BCA. A more complete sample would also include cases where BCA did favor adoption of the policy *ex ante* but would not *ex post*, and cases where BCA would have favored adoption of the policy *ex ante* but was not used and hence the policy was not adopted.

[201] See J B Ruhl, 'Regulation by Adaptive Management—Is it Possible?' (2005) 7 *Minn J Law, Sci & Tech* 21, 53–5.

And perhaps Europe, with a less ossified system of judicial review, could do better at this task than the US.

Such *ex post* evaluation should also apply to the choice among regulatory instruments. There is ample theory on the different costs and effectiveness of technology standards, emissions trading, taxes, information disclosure instruments, environmental contracts, and other instrument options. But there is insufficient empirical evidence on how these tools operate in practice. *Ex post* evaluation of these interventions could go a long way to improving future policy choices.[202]

The move toward regular *ex post* evaluations of regulations has been slow, but recent activity is promising. US EPA only began to conduct *ex post* evaluations in the late 1990s,[203] including a major retrospective study of the Clean Air Act required by Congress.[204] US OMB/OIRA is now beginning to conduct *ex post* evaluations of agency RIAs, as noted above.[205] The OECD held a meeting on *ex post* evaluations in

[202] One recent effort is Winston Harrington, Richard Morgenstern, and Thomas Sterner (eds), *Choosing Environmental Policy* (Washington, DC: RFF Press, 2004), collecting *ex post* studies of the impacts of technology-based and incentive-based environmental policies in the US and Europe.

[203] According to a GAO report, of the more than 100 major rules issued by EPA from 1981 to 1998, only five were subject to *ex post* evaluations, with all of those five reviews occurring after 1997. GAO, 'Environmental Protection: Assessing the Impacts of EPA's Regulations through Retrospective Studies', GAO/RCED-99–250 (September 1999). GAO concluded: 'While EPA devotes substantial resources to cost-benefit analyses when developing new regulations, the agency seldom looks back at the actual costs and benefits after those regulations have been implemented'. Ibid at 13. GAO recommended that EPA develop a plan for systematic *ex post* evaluations, ibid at 14. See also Thomas O McGarity and Ruth Ruttenberg, 'Counting the Cost of Health, Safety, and Environmental Regulation' (2002) 80 *Tex L Rev* 1997 (criticizing *ex ante* cost estimates and the lack of *ex post* evaluation).

[204] US EPA, 'The Benefits and Costs of the Clean Air Act, 1970–1990, Section 812 Retrospective Study' (October 1997).

[205] OMB, n 102 above. Scholars' *ex post* evaluations of BCA include Harrington *et al*, n 102 above; James K Hammitt, 'Are the Costs of Proposed Environmental Regulations Overestimated? Evidence from the CFC Phaseout' (2000) 16 *Envtl & Resource Econ* 281–301; P W Kolp and W Kip Viscusi, 'Uncertainty in Risk Analysis: A Retrospective Assessment of the OSHA Cotton Dust Standard' (1986) 4 *Advances in Applied Microeconomics* 105–30. For more general reviews of OIRA's influence on regulatory policy (as opposed to *ex post* validation of BCAs), see eg OMB/OIRA Annual Report 2005, n 102 above (finding that OIRA *ex ante* reviews have yielded rules promising substantial net benefits); Steven Croley, 'White House Review of Agency Rulemaking: An Empirical Investigation' (2003) 70 *U Chicago Law Review* 821 (finding that OIRA has had a discernible and beneficial influence on rules, with little evidence of bias); Hahn and Muething, n 60 above (finding fully monetized BCA in about half of US agencies' RIAs); Scott Farrow, 'Improving Regulatory Performance: Does Executive Oversight Matter?' (draft July 2000, available at <http://www.aei-brookings.org/admin/authorpdfs/page.php?id=123>) (finding little impact on rejections of rules); Stuart Shapiro, 'Unequal Partners: Cost-Benefit Analysis and Executive Review of Regulations' (2005) 35 *Envtl L Rep* 10433 (arguing that

2003.[206] The European Environment Agency has attempted to conduct *ex post* analyses (of effectiveness and cost-effectiveness, though not necessarily of BCA), but has been hampered by lack of comparable information across member states.[207] To address that need, the EU IA Guidelines now direct attention to planning for *ex post* review in the initial policy design and *ex ante* IA.[208]

The lesson for Better Regulation is to learn from medicine: Treat the whole patient, not just one ailment at a time, and measure success by 'evidence-based' *ex post* review or 'outcomes studies' of patients after treatment.[209] Better Regulation should develop large-scale outcomes studies to track the effects of regulatory policy choices over time, and across jurisdictions (where policies vary spatially). These *ex post* outcomes studies could be conducted by regulatory agencies and oversight offices, but could also be delegated to an independent body to ensure greater objectivity. In this effort, the US and EU could collaborate on a transatlantic policy laboratory—a joint effort in the *ex post* epidemiology of regulatory interventions and their empirical impacts.

Conclusions

In many respects, the Better Regulation initiative promises salutary reforms, such as wider use of regulatory impact assessments (IAs) to evaluate regulatory decisions *ex ante*. In other respects, including some of its

BCA has had little effect on rulemaking because OIRA has put more emphasis on coordinating Presidential priorities); Bagley and Revesz, n 107 above (arguing that BCA has had a significant impact on rulemaking, but that OIRA should instead put more emphasis on coordinating Presidential priorities); Richard D Morgenstern (ed), *Economic Analysis at EPA: Assessing Regulatory Impact* (Washington, DC: RFF Press, 1997) (finding beneficial impact). A challenge in these studies is to identify the counterfactual baseline of what would have happened absent regulatory review. See Cary Coglianese, 'Empirical Analysis and Administrative Law', (2002) *Univ Illinois L Rev* 1111.

[206] OECD, *Regulatory Performance: Ex Post Evaluation of Regulatory Policies* (Paris, 22 September 2003) (noting at p 5 the increasing interest in evidence-based empirical evaluation of policy impacts).

[207] European Environment Agency (EEA), 'Reporting on Environmental Measures: Are We Being Effective?' Environmental Issues Report no. 25 (November 2001) (calling for greater attention to data collection and comparability to enable *ex post* evaluations); EEA, 'Effectiveness of Packaging Waste Management Systems in Selected Countries: An EEA Pilot Study', Report 3/2005 (2005) (noting at p 8 that 'The sixth environment action programme of the European Community (6EAP) highlights the need to undertake "*ex-post* evaluation of the effectiveness of existing measures in meeting their environmental objectives",' but finding such analysis inhibited by non-comparable data across member states).

[208] IA Guidelines 2006, at 44–6.

[209] See Wiener, n 151 above (advocating evidence-based outcomes studies for risk regulation, as in medical care). See also Cary Coglianese and Lori Snyder Bennear, 'Measuring

rhetoric, its focus on administrative costs and simplification, and its institutional structure, the EU initiative speaks more of deregulation than of better regulation. Questions also remain whether particular regulatory programs, such as those regarding genetically modified foods and chemicals (REACH), can be reconciled with the tenets of Better Regulation.

Truly better regulation—maximizing societal well-being—would involve reducing or eliminating some regulations, but strengthening or expanding others, depending on the full social consequences of each choice. Better Regulation will often mean cutting costs. But it will also sometimes mean more regulation, or more comprehensive regulation: of issues that BCA shows warrant more regulation; of risks understated by risk assessment; of multiple simultaneous risks; of countervailing risks induced by intervention to reduce a target risk; and of risks addressed through more cost-effective instruments that reduce costs and hence make the optimal degree of regulation more protective. The 'less versus more' dichotomy is fairly unhelpful in making regulatory policy choices. 'Better' can be neither less nor more.

The EU is borrowing the concepts of Better Regulation from US regulatory reform and from initiatives in the EU member states, but Europe can make Better Regulation even better. Regulatory tools and institutions can be improved based on learning from past approaches, and tailored to suit European governance. The problems with impact assessment and benefit-cost analysis to date appear to be institutional: not that they are used too much, but rather too little and too narrowly or one-sidedly. IA and BCA in Europe would be more successful and credible if they were expanded to become self-reflective proportionate Warm Analysis of full portfolio impacts, to say yes to the good as well as no to the bad, to apply to a wider array of public policies (such as trade and counterterrorism) beyond the current focus on risk regulation, to embrace multiple countervailing risks and ancillary benefits, and to guide administrative simplification to consider benefits as well as costs. In addition, Europe should establish a centralized expert oversight body with the authority to use IA to influence decisions, and a system of *ex post* policy evaluations for adaptive revision and for improvement of *ex ante* assessment methods. These reforms would help Better Regulation become even better and achieve its true objective: better, not less or more.

Progress: Program Evaluation of Environmental Policies' (2005) 47(2) *Environment* magazine 22–40 (lamenting lack of *ex post* evaluation and advocating establishment of systematic program evaluation to measure policies' actual impacts); Cary Coglianese and Lori Snyder Bennear, 'Program Evaluation of Environmental Policies: Toward Evidence-Based Decision Making', in *Social and Behavioral Science Research Priorities For Environmental Decision Making* (Washington, DC: National Research Council, National Academies Press, 2005) 246–73.

Europe should experiment with these institutional innovations under its Better Regulation strategies, and evaluate their performance over time. Europe has an opportunity to develop new and improved approaches to regulation, not only borrowing but also adapting and creating anew. The innovations suggested here can help Europe manage its regulatory system, facilitate trade in the Single European Market, and advance European competitiveness, while ensuring that Better Regulation really means better. In turn, the US could improve its own regulatory regime by monitoring and borrowing from Europe's successes.

The exercise of legal borrowing involved in Better Regulation, and the normative evaluation of that borrowing that I have offered, show that—at least in this case—the focus is, and should be, on the particular merits of legal ideas, not on abstract ideology or supposedly fixed national legal mentalities. Blake overstated the case: 'To generalize is to be an idiot. To particularize is alone the distinction of merit.'[210] That itself is a hasty generalization, perhaps unintentionally proving its point, because some generalizations are useful.[211] But the point remains that particularization adds insight; the details matter, even when they are difficult to grasp. Observed La Rochefoucauld: 'Pour bien savoir les choses, il en faut savoir le détail, et comme il est presque infini, nos connaissances sont toujours superficielles et imparfaites.'[212] Better Regulation itself consists in large measure of knowing the important details, without seeking perfection in every last detail, and in using those details to offer and to test different reasons for alternative regulatory choices, toward a considered judgment about the better course of action. Mr Franklin's advice to avoid 'rash steps' by a prudential evaluation of the consequences now finds fruition in what Mr Blair has called 'regulation after reflection'.

[210] William Blake, Annotations to Sir Joshua Reynolds' *Discourses* (1814).

[211] For a provocative discussion, see Frederick Schauer and Richard Zeckhauser, 'Regulation by Generalization', AEI-Brookings Joint Center, Working Paper 05–16, August 2005.

[212] La Rochefoucauld, *Maximes* (Montreal: Les Editions Variétés, 1946), no 106 (p 61) (translated into English, 'To know things well, one must know the details, but as these are almost infinite, our understanding is always superficial and imperfect.').