Managing the Iatrogenic Risks of Risk Management*

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Introduction

Risk management aims to protect, but many's the slip betwixt help and health. Medical care is meant to make people well, but it can harm as it heals. This is the pervasive problem of "iatrogenic" (care-induced) and "nosocomial" (hospital-induced) injury.[1] "Most treatments have side effects as well as benefits."[2] "Medical care is an inherently risky enterprise."[3] "[M]edical progress has provided physicians with an arsenal of double-edged swords."[4] The modern medical community appears, more or less, to accept iatrogenesis as a fact of life, and to work diligently to manage the risks of its own risk management measures.[5]

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1 *See* J. Ralph Audy, *Man-Made Maladies and Medicine*, 113 **Calif. Medicine** 48 (1970); Troyen A. Brennan, et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I,* 324 **N. Eng. J. Med.** 370 (1991); **Risk and Outcome in Anesthesia** (David L. Brown, ed., 1992); **Costs, Risks, and Benefits of Surgery** (J.P. Bunker, B. Barnes & F. Mosteller, eds., 1977); **Textbook of Adverse Drug Reactions** (D. M. Davies, ed., 4th ed. 1991); Andreas Laupacis, David L. Sackett & Robin S. Roberts, *An Assessment of Clinically Useful Measures of the Consequences of Treatment,* 318 **N. Eng. J. Med.** 1728 (1988); Robert H. Moser, **Diseases of Medical Progress: A Study of Iatrogenic Disease** (3d ed. 1969); David M. Spain, **The Complications of Modern Medical Practices: A Treatise on Iatrogenic Diseases** (1963).

2 Robert M. Kaplan, *Utility Assessment for Estimating Quality-Adjusted Life Years,* in **Valuing Health Care** 31, 33 (Frank A. Sloan, ed., 1995).

3 Paul C. Weiler et al., **A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation** 137 (1993).

4 Harry N. Beaty & Robert G. Petersdorf, *Iatrogenic Factors in Infectious Disease*, 65 **Ann. Internal Med.** 641, 655 (Oct. 1966).

When the state plays the role of physician-king and seeks to protect social and ecological health, it confronts the same challenge. Risk regulation by the state is inherently risky. Interventions may reduce "target risks" but may also increase "countervailing risks."[6] Examples are ubiquitous. To cite a few: Requiring airbags in cars may save adults but kill children and small adults.[7] Using hot water to clean up oil spills may cause collateral damage to marine organisms.[8] Protecting public health by cleaning up Superfund sites, or removing asbestos from buildings, may put workers at risk of exposure and occupational injury.[9] Banning one hazardous substance (such as a pesticide or food additive) may induce the use of hazardous substitutes.[10] Regulating a

5 Assertions of iatrogenic causes of illness have often encountered hostility from the medical profession, *see infra* note 25 and notes 89-93 and accompanying text. But empirical documentation has gradually engendered what appears to be a more open and pragmatic perspective. A recent example is the exhortation to physicians that "[iatrogenic events] in hospitalized patients are countable, dangerous, and evaluable events, not just a collection of unhappy accidents that strike, like cosmic rays, in ways that we cannot predict or understand." Jerry Avorn, *Putting Adverse Drug Events Into Perspective*, 277 **JAMA** 341, 341 (1997).

6 *See generally,* **Risk vs. Risk: Tradeoffs in Protecting Health and the Environment** (John D. Graham & Jonathan Baert Wiener, eds., 1995). Such "risk-risk tradeoffs" confront all decisionmakers, in private life as well as in public policy. For example, aspirin can ease a headache, but risk an upset stomach or even Reye's syndrome.

7 DOT/NHTSA, *Federal Motor Vehicle Safety Standards: Occupant Crash Protection (Final Rule),* 62 **F.R.** 798, 798 (1997) (reporting that since their introduction in the 1980s, driver-side airbags have saved 1500 lives while killing 19 drivers, and passenger-side airbags have saved 164 lives while killing 32 children). *See also* National Transportation Safety Board, **The Performance and Use of Child Restraint Systems, Seatbelts, and Air Bags for Children in Passenger Vehicles, Volume 1: Analysis,** Safety Study NTSB/SS-96/01 (1996); Asra Q. Nomani & Jeffrey Taylor, *Shaky Statistics Are Driving the Air-Bag Debate,* **Wall Street J.**, Jan. 22, 1997, at B1. *Cf.* Matthew Wald, *When Safety Devices Bite Back*, **New York Times**, Feb. 16, 1997, at E3 (reporting that aviation safety devices may increase risks).

8 *See* John Lancaster, *Weighing the Gain in Oil-Spill Cures: Harm from Aggressive Hot-Water Cleanup May Eclipse the Environmental Benefits,* **Washington Post**, Apr. 22, 1991, at A3.

9 *See* Stephen Breyer, **Breaking the Vicious Circle: Toward Effective Risk Regulation** 12-13 (1993); Health Effects Institute, **Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge** (1991); Joshua T. Cohen, et al., *Life Years Lost at Hazardous Waste Sites: Remediation Worker Fatalities vs. Cancer Deaths to Nearby Residents,* 17 **Risk Anal.** 419 (1997); Alan F. Hoskin, J. Paul Leigh & Thomas W. Planek, *Estimated Risk of Occupational Fatalities Associated with Hazardous Waste Site Remediation,* 14 **Risk Anal.** 1011 (1994); W. Kip Viscusi, *Risk-Risk Analysis,* 8 **J. Risk & Uncert.** 5, 12-13 (1994).

10 *See* George M. Gray & John D. Graham, *Regulating Pesticides,* in Graham &

substance or activity may forfeit the health and safety benefits that it provides — for example, banning asbestos to prevent cancers might also result in of its loss as the ideal lining for automobile brake pads, hence increasing highway fatalities.[11] Dams and levees to control floods may actually worsen them, and may cause siltation and subsidence downstream.[12] Police chases of suspects (who might commit crimes if not apprehended) may induce automobile accidents that kill innocent bystanders.[13] Prohibiting addictive drugs may spawn violence among drug suppliers.[14] Sentencing felons to mandatory minimum stays in limited prison space may keep more violent offenders out of prison.[15]

Risk management both helps and hurts.[16] This is increasingly accepted in medicine[17] but seems to confront more than a little

Wiener, *supra* note 6, at 173-192.

11 *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

12 *See* Jon Christensen, *California Floods Change Thinking on Need to Tame Rivers,* **New York Times**, Feb. 4, 1997, at B10; John McPhee, **The Control of Nature** 3-92 (1989).

13 *See, e.g.,* Chris Graves, *Hot Pursuit: Is It a Bigger Threat than the Crime?,* **Minneapolis Star Tribune**, Aug. 13, 1996, at 1A (reporting that roughly 1 in 4 police chases in Minnesota in 1995 ended in a collision); Teresa M. Hanafin, *Panel Hears Backers of Bill to Regulate Police Chases,* **Boston Globe**, Mar. 24, 1992, at 31 (reporting over 300 fatalities from police chases nationwide in 1990); Editorial, *When Cops Give Chase,* **Sacramento Bee**, July 19, 1995, at B6 (reporting that of 8,074 chases in California in 1994, 1,983 ended in collisions, injuring 1,306 people (of whom 409 were innocent bystanders) and killing 39 (of whom 12 were innocent bystanders)).

14 Daniel Patrick Moynihan, *Iatrogenic Government: Social Policy and Drug Research,* **American Scholar**, 351-362 (Summer 1993); Robert MacCoun, Peter Reuter & Thomas Schelling, *Assessing Alternative Drug Control Regimes,* 15 **J. Pol. Anal. & Mgmt.** 330-352 (1996).

15 *See* Sara Sun Beale, *What's Law Got To Do With It? The Political, Social, Psychological and Other Non-Legal Factors Influencing the Development of (Federal) Criminal Law;* Susan Estrich, *Hard Time Won't Fit All the Crime,* **USA Today**, July 18, 1996, at 15A (citing a CATO Institute report that calls lengthy prison terms for drug offenders "the best things that ever happened to violent criminals" who "end up being released to make room").

16 Additional discussion and examples are provided in John D. Graham & Jonathan Baert Wiener, *Confronting Risk Tradeoffs,* in Graham & Wiener, *supra* note 6, at 1-41; Breyer, *supra* note 9, at 12-13, 22-23; Christopher H. Schroeder, *Rights Against Risk,* 86 **Colum. L.Rev.** 495 (1986); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle,* 53 **Wash. & Lee L.Rev.** 851; Cass R. Sunstein, *Health-Health Trade-Offs,* in **Free Markets and Social Justice** 298 (1996); Edward Warren & Gary Marchant, *More Good Than Harm: A Hippocratic Oath for Administrative Agencies,* 20 **Ecol. L.Q.** 379 (1993); Lester B. Lave, **The Strategy of Social Regulation** (Brookings 1981); Chauncey Starr & Christopher Whipple, *Risks of Risk Decisions,* 208 **Science** 1114 (1980).

cognitive dissonance (and indignation) in the regulatory context. To be clear: The point is absolutely not that regulation always hurts, nor even routinely outweighs the help.[18] It is almost sure that risk regulation over the last three decades has, overall, helped more than it has hurt.[19] And tolerating regulation's adverse countervailing risks may sometimes or even often be worth the gains in reducing target risks. But regulatory institutions that hurt more than they help, and even those that help more than they hurt in the aggregate, could potentially do much better — could maximize overall helpfulness — by attending more carefully to countervailing risks. The point is not to skewer well-intentioned protective policies, but to recognize that good intentions are only part of the battle: They are necessary but not sufficient to design successful risk regulation. Successful policy advance requires not a choice between moral outrage and careful analysis, but a healthy combination of both.

Concern about countervailing risks has no political brand. Both conservatives, liberals and centrists worry about the dysfunctions of the regulatory state. Each may emphasize different examples — conservatives may worry about the side effects of health and environmental rules, while liberals may worry about the side effects of dams, police practices and harsh criminal penalties — but their concerns have the same analytic basis. Countervailing risks are a generic challenge. The first modern environmental law, NEPA,[20] was a response to the countervailing risks of government interventions to achieve non-environmental policy goals such as transportation and

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17 *See supra* notes 1 and 5.

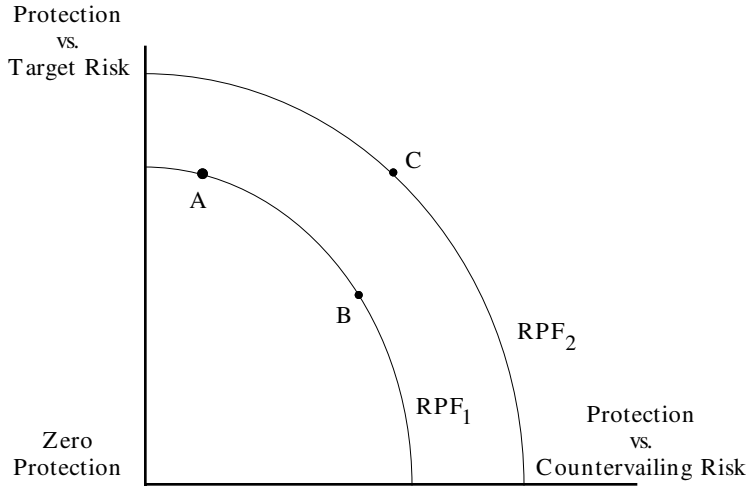
18 The list of risk-tradeoff examples is provided to show the ubiquity of countervailing risks, not to vouch for the truth of the particular examples. Each warrants careful empirical study, and some of the claims of risk tradeoffs are no doubt exaggerated. For example, the countervailing risk of occupational injury induced by asbestos and Superfund cleanups, cited in note 9, *supra,* is not the *full* risk that workers would face in the cleanup activity, but the incremental *change* in their employment risk — i.e., the cleanup risk relative to the risk they would have faced in alternative employment. *See* Stephen F. Williams, *The Era of "Risk-Risk" and the Problem of Keeping the APA Up to Date,* 63 **U. Chi. L.Rev.** 1375, 1380 (1996). Moreover, cleanup workers may incur risks more voluntarily (and hence receive more adequate ex ante compensation) than do residents exposed to unabated contaminents.

19 *See* Graham & Wiener, *supra* note 16, at 6-10. This point is difficult to test empirically because we lack thorough data on health and environmental quality indicators, and because the counterfactual (a different regulatory history) is difficult to model and test. *See id.* at 10.

20 42 USC 4332.

electrification. Worrying about countervailing risks is not anti-environmental, or anti-law-and-order, or anti-regulatory, it is pro-results; it is the sober habit of the pragmatic optimist.

Figure 1
Risk Protection Frontier (RPF)



Adapted from John D. Graham & Jonathan B. Wiener, *Confronting Risk Tradeoffs,* in **Risk vs. Risk**, 26, 28, 38, note 6.

Managing risk-risk tradeoffs is an exercise in judgment. Previously, John Graham and I sketched a model of a "risk protection frontier" drawn from the concept of a "production possibility frontier" in microeconomics.[21] A production possibility frontier traces the combinations of alternative goods that a society can provide with efficient use of limited resources; the RPF traces the combinations of protection against alternative risks that a society can achieve with efficient use of limited resources. The RPF illustrates the need to weigh tradeoffs along the frontier between alternative risks (in Figure 1, the choice between points A and B on RPF_1 — with point A representing relatively more protection against the target risk and point B representing relatively more protection against the countervailing risk). The RPF also illustrates the opportunity to move toward "risk-superior" outcomes by shifting the frontier outward through innovative approaches that reduce multiple risks in concert (in Figure 1, the move

[21] Graham & Wiener, *supra* note 16, at 25-29.

from RPF_1 to RPF_2). For example, if automobile airbag technology at point A saves adults but kills children, depowering or disconnecting these airbags is a move along RPF_1 to point B, where fewer children will be killed but fewer adults will be saved. Developing a new "smart" airbag technology is a move to a point like C on RPF_2, where both fewer children are killed and more adults are saved.

The RPF illustrates the short- and longer-term challenges of risk-risk tradeoffs, but it does not display why they *unduly* occur. If one able decisionmaker felt the full consequences of allocating regulatory attention between the target and countervailing risks, she could presumably make a sound judgment about the tradeoff. It is not clear from the RPF model why she would systematically favor one and neglect the other.

There are reasons to believe that excessive countervailing risks are systematically generated by institutions that regulate target risks. These include jurisdictional specialization and fragmentation among risk managers (from physicians to government agencies); selective attention to certain kinds of hazards and other heuristic decisionmaking biases; the distortionary influence of more vocal interest groups; and the real costs of analyzing and deliberating about intervention side effects.[22]

Iatrogenic injury in medical care is a salient subject of study by regulatory analysts for at least two reasons. First, injury caused by medical care is important in its own right, representing a large fraction of the countervailing risks induced by society's wide array of efforts to manage risks. Second, understanding iatrogenic injury in the medical setting can offer important insights in the public policy setting.

Here, I develop the analogy from medical to regulatory iatrogenesis, and make these points: (1) countervailing risks are endemic in fragmented decisionmaking; (2) countervailing risks of risk management interventions are conceptually distinct from the adverse health effects of income loss ("health-health" tradeoffs); (3) in light of countervailing risks, comparative risk analysis is not just a candidate for prioritizing independent target risks but an inescapable feature of risk management; (4) the use of "default" assumptions in risk assessment can be self-defeating; (5) risk management institutions face pressure to

[22] *See* Jonathan Baert Wiener & John D. Graham, *Resolving Risk Tradeoffs,* in Graham & Wiener, *supra* note 6, at 225-242; Sunstein, *supra* note 16.

expand and proliferate in response to countervailing risks; (6) optimal management of countervailing risks seeks neither zero tolerance of ("do no harm") nor zero attention to countervailing risks ("ignore side effects"); it rather seeks to maximize the difference between target risk reduction and countervailing risk induction, and to minimize the sum of the costs of analyzing and addressing countervailing risks (deliberation costs) plus the costs of leaving countervailing risks unaddressed (error costs); and (7) ideally this optimization is advanced over time through assigning responsibility for risk policy to institutions with low deliberation and error costs, and ultimately through the innovation of "risk-superior" regulatory approaches.

Iatrogenic Injury in Medicine

A caregiver responds to target ailments (or risk factors for a future ailments) by examining patients, diagnosing (or forecasting) and prescribing a regimen of therapy. The objective is to ameliorate or prevent an ailment. But these methods can also generate side effects. Recent examples include adverse drug reactions (from the mundane to horror stories like thalidomide), diseases spread by vaccines (sometimes rekindling the disease to be prevented), infections conveyed in blood transfusions (from common bacteria to HIV), adverse effects of diagnostic tests (such as cancers induced by mammography), and cancers induced by estrogen replacement intended to prevent osteoporosis and heart disease in post-menopausal women.[23] The problem is "as old as Medicine."[24] One of the earliest investigations of iatrogenesis was on puerperal sepsis by Oliver Wendell Holmes, Sr.[25]

[23] *See* P.E. Sartwell, *Iatrogenic Disease: An Epidemiologic Perspective,* 4 **Int'l J. Health Services** 89, 89-90 (1974); Evridiki Hatziandreu, Constance Williams & John D. Graham, *Estrogen Therapy for Menopause,* in Graham & Wiener, *supra* note 6, at 42-52.

[24] Davies, *supra* note 1, at 1. The adage "the cure is worse than the disease" has been around for at least two thousand years. *See* John Bartlett, **Familiar Quotations** 111 and n.2 (Emily Morrison Beck, ed., 15th ed., 1980) (quoting Plutarch, Publius Syrus, Francis Bacon, and others).

[25] O.W. Holmes, *The Contagiousness of Puerperal Fever,* **N. Eng. Q. J. Med. & Surgery** 1-23 (Apr. 1843), cited in Sartwell, *supra* note 23, at 89. Holmes' report "met with profound skepticism and hostility by the medical profession [until decades later when] the bacteriologists demonstrated [that the infection was transmitted by a microbe,] the streptococcus." Sartwell, *supra* note 24, at 89. Puerperal sepsis, a potentially fatal infection acquired during childbirth, was common among new

Sir William Osler intoned: "One of the first duties of the physician is to educate the masses not to take medicine."[26]

Risk management broadly encompasses all institutions geared toward protecting human and ecological health, including public health infrastructure, criminal law, hospitals and other medical care providers, and transportation safety, environmental, consumer and occupational safety regulation. The medical care delivery system is one of the largest and most important of these components. Roughly 14% of U.S. national income is spent on that system compared to just under 3% on environmental compliance.[27]

The challenge of iatrogenic injury faces physicians and patients every day. "In addition to conferring benefits, most effective therapies have clinically important side effects, and in some instances it is not clear whether the benefits outweigh the harm."[28] At virtually every juncture, physicians and patients choose between at least two alternative therapies for a given target ailment, one of which is more effective at treating the target ailment but poses more serious side effects, and the other of which poses less serious side effects but is also less effective at treating the target ailment.

Empirical study of the modern medical system suggests that iatrogenesis is serious. In the most thorough analysis to date, the Harvard Medical Practice Study Group studied a representative sample of over 30,000 hospital records from over 50 hospitals in New York State. Using carefully developed protocols and trained reviewers, it found that 3.7% of all hospitalizations induced iatrogenic health events, of which just more than one in eight (14% of all iatrogenic injuries, and about 0.5% of all hospitalizations) were iatrogenic fatalities.[29]

mothers in the 1840s because physicians typically did not wash their hands before delivering babies. *See infra* note 90 [re Semelweiss].

[26] William Osler, **Aphorisms from His Bedside Teachings** 112 (1961), quoted in **Oxford Dictionary of Modern Quotations** 165 (Tony Augarde, ed., 1991).

[27] HHS, **Health USA and Prevention Profile** (1992); EPA, **Environmental Investments: The Costs of a Clean Environment** (1990).

[28] Laupacis, Sackett & Roberts, *supra* note 1, at 1731. On the general phenomenon of iatrogenic injury, *see also* the references cited *supra* note 1.

[29] Weiler, et al., *supra* note 3, at 43-44. These research results were originally published by substantially the same authors in Troyen A. Brennan, et al., *Incidence of Adverse Effects and Negligence in Hospitalized Patients — Results of the Harvard Medical Practice Study I,* 324 **N. Eng. J. Med.** 370 (1991). The Harvard Study noted a study in California in the 1970s which found that 4.6% of all hospitalizations

Extrapolating this data to the full U.S. population, suggests a national annual total of over 1.2 million iatrogenic injuries and over 150,000 iatrogenic deaths from hospitalization — amounting to 7.5% of all deaths in the nation each year, more fatalities than are caused each year by, e.g., auto (40,000 to 50,000) and occupational accidents (about 6,000) combined.[30]

The Harvard Medical Practice Study also disaggregated its results and found, controlling for other factors, that certain characteristics were significantly associated with higher iatrogenic injury rates: higher patient age (even when controlling for illness severity), lack of health insurance, and hospital location in a poor minority neighborhood.[31] Iatrogenic injuries were thus particularly likely to befall groups that may have less effective voices in the health care system.

Adverse drug events (ADEs) — including allergic reactions, misprescribed drugs, and drug-drug interactions — are a large component of iatrogenic injury.[32] Studies in the 1970s shockingly suggested that up to 30% of all U.S. hospital patients suffered ADEs and, alone, may have accounted for as many as 140,000 deaths each year.[33] More recent studies show ADEs being suffered by 0.7–6.5%

resulted in iatrogenic injury. Weiler, *supra* note 3, at 36. Studies in the 1960s found that about 20% of hospitalized patients acquired an iatrogenic disease or injury of some kind during their stay. *See* J.T. McLamb & R.R. Huntley, *The Hazards of Hospitalization,* 60 **Southern Med. J.** 469 (May 1967); E.M. Schimmel, *The Physician as Pathogen,* 16 **J. Chronic Disease** 1 (1963); E.M. Schimmel, *The Hazards of Hospitalization,* 60 **Ann. Internal Med.** 100 (1964); Harry N. Beaty & Robert G. Petersdorf, *supra* note 4, at 641.

[30] Weiler, *supra* note 3, at 55. Death cannot be prevented, only delayed. The Harvard Study did not estimate the years of life lost due to iatrogenic injuries. It is plausible that the number of years of life lost due to a typical iatrogenic fatality would be smaller than the number of life-years lost to such causes as automobile accidents and occupational accidents, because the victims of iatrogenic injury are often elderly and often already quite ill when they arrive at the hospital, and might therefore die of the target ailment or of other causes in a short time even if medical care is provided without error. *See id.* There may also be latent illnesses and fatalities associated with exposures to toxic substances in the medical and occupational settings (and even in automobiles, e.g. gasoline vapors), which are not captured in these short-term data.

[31] Weiler, *supra* note 3 , at 47, 52.

[32] The Harvard Medical Practice Study found ADEs to represent about 20% of all iatrogenic injuries observed, afflicting about 0.7% of all patients. Lucian L. Leape, et al., *The Nature of Adverse Events in Hospitalized Patients: Results from the Harvard Medical Practice Study II,* 324 **N. Eng. J. Med.** 377 (1991).

[33] Lawrence K. Altman, *Drug Errors and Adverse Reactions Are Studied,* **New York Times**, Jan. 22, 1997, at A10; David C. Classen, et al., *Adverse Drug Events in*

of hospital patients,[34] which still implies that some 200,000 to 2,000,000 patients are afflicted each year.[35] One study estimated that suffering an average ADE is associated with roughly doubling the patient's fatality risk.[36] Somewhere in the range of 2–27% of hospital admissions appear to be instigated by prior medical ADEs.[37]

These studies understate the full adverse impact of medical care on patients, because they tend to count only short-term effects. They may omit outcomes that manifest years later; unreported injuries; and injuries in settings such as nursing homes, doctors' offices and homes. And there might also be ecological risks, e.g, associated with the handling of chemical, biological, and radioactive wastes. In sum, the medical care component of society's risk regulation regime is the source of quite significant countervailing risks.

Causation

It can be difficult to disentangle the causes of adverse outcomes.[38] The Harvard Medical Practice Study used careful protocols and trained auditors to distinguish adverse events caused by the target ailment from

Hospitalized Patients, 277 **JAMA** 301, 301 (Jan. 1997) (citing J. Porter & H. Jick, *Drug-related Deaths Among Medical Inpatients,* 237 **JAMA** 879 (1977)). The 1960s studies cited above found that about half of all iatrogenic injuries (which in total afflicted 20% of the hospitalized population in those studies) involved adverse drug events; thus ADEs were found to injure 10% of hospital patients. *See* McLamb & Huntley, *supra* note 29, at 470; Schimmel, *supra* note 29.

[34] Leape et al., *supra* note 32 (finding an ADE rate of 0.7% in New York hospitals); Classen et al., *supra* note 33, at 304 (reporting ADE rates of 2.4% in the LDS Hospital in Salt Lake City, and 6.5% in another study).

The wide differences in rates of overall iatrogenesis and ADEs reported by the 1960s studies by McLamb & Huntley and by Schimmel, the 1977 study by Porter & Jick, and the 1990s studies collected by the Harvard Medical Practice Group and by Classen et al., could result from progress over time in controlling ADEs, from differences in study methodologies, from differences in the hospitals being studied, and from other factors.

[35] Classen et al., *supra* note 33, at 304 (assuming roughly 30 million hospital admissions per year). Classen et al., did not estimate the total number of ADE-related deaths.

[36] *Id.* at 303-304 & Table 3.

[37] David W. Bates, et al., *The Cost of Adverse Drug Events in Hospitalized Patients,* 277 **JAMA** 307, 311 (Jan. 1997) (citing J.M. McKenney & W.L. Harrison, *Drug-Related Hospital Admissions,* 33 **Am. J. Hosp. Pharm.** 792 (1976), and T.R. Einarson, *Drug-Related Hospital Admissions,* 27 **Ann. Pharmacothe.** 832 (1993)).

[38] *See* Weiler, *supra* note 3, at 23-24, 33-36, 55-59. The Harvard Group ultimately decided that only 5% of the causation judgments they made were truly "close calls." *Id.* at 146.

those caused by the care provided. That a patient takes a turn for the worse after medical care does not mean the care was the cause; it is important to control for how sick the patient was (the severity of target ailment) because patients that are more ill are generally more fragile, and may also require more risky interventions to save them.[39]

Several underlying sources of iatrogenic injury appear to be important. At first blush, one might point to the probabilistic nature of side effects and the physician's incomplete knowledge of the full effects of a given therapy on a particular individual. But unless this uncertainty is somehow irreducible, the problem of incomplete prediction is really a problem of the cost of obtaining more complete predictive knowledge, the cost of sharing such knowledge, the cost of employing safer alternative therapies, and the ability of patients to monitor and reward health care providers for reducing iatrogenic risks.

Medical provider payment structures may be influential. The average ADE, for example, generates an additional $2000 or so of medical bills (and there is substantial variance around this average).[40] To a provider paid on a fee-for-service basis, the iatrogenic side effects of initial treatment might constitute an unintentional source of additional revenues (up to the point that the iatrogenesis drives the patient to choose a different provider, or to expire), and such a provider would therefore have less financial incentive to prevent iatrogenesis. The provider pre-paid a monthly sum for health maintenance, by contrast, may regard iatrogenic side effects as a drain on the provider's profits (if the side effect would be expected to occur while the patient is still

[39] *Id.* at 57, 138. This finding implies that the countervailing risk is itself partly a function of the target risk. It suggests that, other things equal, regulatory interventions to rescue more desperate or delicate situations may pose more acute countervailing risks than preventive efforts to keep healthy people and ecosystems in a healthy state. On the other hand, widespread preventive efforts (such as immunization programs, the use of preventive doses of antibiotics in "infection-prone" patients with viral infections, and "pollution prevention") can expose larger populations to countervailing risks (such as illnesses induced by immunization, and the growth of antibiotic-resistant bacteria) and can cost more as they address a larger potential target population. Beaty & Petersdorf, *supra* note 4, at 655. *Cf.* Tammy Tengs et al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness,* 15 **Risk Anal.** 369 (1995) (showing that preventive health and environmental measures may be more or less cost-effective than treatment of manifest ailments).

[40] Classen et al., *supra* note 33, at 304 ($2013 per average ADE, with a range from $677 to $9022); Bates et al., *supra* note 37, at 310 ($2595 per average ADE, $4685 per average ADE deemed preventable).

under contract), and therefore may have more financial incentive to prevent iatrogenesis. (Non-financial factors, such as the physician's professional ethics, might swamp these effects.) Controlling for other factors, do pre-paid HMOs in fact have lower rates of iatrogenic injury than fee-for-service providers? A study of iatrogenic injury rates differentiated by provider payment structure would be illuminating.[41]

Malpractice law may also be significant. Are providers more likely to be found liable for administering a treatment that induces an iatrogenic side effect, or for failing to treat the target ailment? The answer will vary by jurisdiction, by medical context, and by historical context. Disproportionate liability for failure to treat may accelerate iatrogenesis, while disproportionate liability for side effects may inhibit initial treatment. The revenue and liability structures facing the manufacturers of drugs, devices and other medical equipment, and the information and incentives that they pass on to health care providers, may also influence the rate of iatrogenesis.

But the major source of iatrogenesis appears to be fragmentation in the system of medical care delivery. Inadequate sharing of information across subunits of the hospital appears to be the most important cause of iatrogenic injury.[42] These structures have analogies in the regulatory state. One agency's mission to reduce a target risk may induce a countervailing risk in another agency's domain. Is information about adverse side effects shared across regulatory committees and agencies? Is dealing with the countervailing risks of prior regulations perceived as bureaucratically rewarding or bothersome by regulatory policymakers? Successfully managing the countervailing risks of risk regulation will

[41] Evidently no such studies have yet been conducted, and confront certain methodological challenges. Personal communications with Jeffrey Koplan, Prudential Center for Health Care Research, Atlanta GA, and Harold Luft, U.C.S.F. Medical School, August 1997. Meanwhile, HMOs may provide less effective treatment of target risks in response to cost-containment incentives. For discussion of the comparative overall safety of different provider arrangements, *see* Clark C. Havighurst, *Making Health Plans Accountable for the Quality of Care,* 31 **Georgia L. Rev.** 587, 592-94 (1997).

[42] Lucian L. Leape et al., *Systems Analysis of Adverse Drug Events,* 274 **JAMA** 35 (1995); Timothy S. Lesar, Laurie Briceland & Daniel S. Stein, *Factors Related to Errors in Medication Prescribing,* 277 **JAMA** 312, 312, 315-316 (Jan. 1997); Classen et al., *supra* note 33, at 305; Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care Systems,* 108 **Harv. L. Rev.** 381, 412-13 (1994).

require more integrated information systems and new institutional arrangements to encourage attention to potential side effects.

"Countervailing Risks" are to "Health-Health Analysis" as Iatrogenesis is to Triage

In the hospital context, the challenge of iatrogenic side effects is conceptually distinct from the challenge of triage. Triage involves allocating scarce therapeutic resources among the competing demands facing the hospital — deciding which patients warrant attention first and most intensively. Iatrogenesis, by contrast, arises even if all patients are treated identically; an unlimited supply of medicine can cause ADEs in every patient. Triage is the problem that care provided to one patient is costly, not just in out-of-pocket expenses but in the diversion of that care from other patients — in the foregone opportunity to use that care for other purposes. Iatrogenesis is the problem that even if therapy were costless, thereby enabling all patients to receive treatment, that treatment would still generate adverse health outcomes as well as beneficial health outcomes. Iatrogenesis requires a more complex calculation of therapeutic benefit, rather than an allocation of therapy among patients.

The same distinction applies in the larger social context. "Countervailing risks" of regulation are analogous to iatrogenic injuries, whereas the "social costs" of regulation are the societal version of triage. This distinction has been blurred of late under the ambiguous heading of "health-health analysis" (HHA) (or the even more generic "risk-risk analysis").[43] HHA is an analytic tool for measuring the adverse health impacts of income loss — usually, income loss caused by regulatory policies. It involves calculating the mortality associated with each dollar diverted from workers' and consumers' pockets by regulation. It is based on the empirical observation that "wealthier is healthier" — that poorer households spend less on health-promoting goods and services

[43] *See* the symposium on the health impacts of income losses, opaquely titled "Risk-Risk Analysis," and including such articles as W. Kip Viscusi, *Risk-Risk Analysis,* 8 **J. Risk & Uncert.** 5 (1994); and Randall Lutter & John F. Morall III, *Health-Health Analysis,* 8 **J. Risk & Uncert.** 43 (1994). *See also,* Frank B. Cross, *When Environmental Regulations Kill: The Role of Health/Health Analysis,* 22 **Ecol. L.Q.** 729 (1995). Other articles have used more precise terminology. *See* Ralph L. Keeney, *Mortality Risks Induced by the Costs of Regulations,* 8 **J. Risk & Uncert.** 95 (1994); W. Kip Viscusi & Richard J. Zeckhauser, *The Fatality and Injury Costs of Expenditures,* 8 **J. Risk & Uncert.** 19 (1994); Frank B. Cross, *supra,* note 16, at 915 (referring to the *Health Risks of Economic Costs*).

and have shorter life expectancies.[44] HHA is thus a translation of the "social cost" side of benefit-cost analysis into "risk" units. Instead of "monetizing benefits," it is "riskizing costs." Thus, whereas countervailing risk refers to iatrogenesis, HHA is measuring the allocation of scarce social resources among competing health-promoting investments (triage).

HHA is in a sense a more broadly applicable analytic tool than the concept of countervailing risks of risk regulation, because HHA applies to any government action affecting income (e.g., the Fed raising interest rates), not just to risk regulation. Yet in another sense "Health-Health Analysis" is a very narrow subset of the universe of countervailing risks. Income is only one of many pathways through which regulation may adversely affect health, so HHA ignores non-income-mediated countervailing risks (e.g. asbestos removal risks, cross-media pollution shifts, or police chase crashes). And HHA excludes all harms to endpoints other than human health (e.g., ecological harms).[45]

This distinction should not be conflated under the undifferentiated title of "risk-risk analysis" or similarly general headings. Countervailing risks are not merely a translation of social costs into risk units. Countervailing risks do not depend on compliance cost; a highly cost-effective regulation, or even one imposing zero or negative costs, could still induce iatrogenic risks. For example, immunizations and energy efficiency are both urged as cost-saving interventions, implying zero (or benign) income-related health impacts; but each may portend important countervailing risks (e.g., immunizations tend to induce

[44] There are methodological debates about the basis and utility of HHA calculations. *See* John D. Graham, Bei-Hung Chang & John S. Evans, *Poorer is Riskier,* 12 **Risk Anal.** 333 (1992) (showing that changes in permanent income and changes in temporary income have very different impacts on health); V. Kerry Smith, Donald J. Epp, & Kurt Schwabe, *Cross-Country Analyses Don't Estimate Health-Health Responses,* 8 **J. Risk & Uncert.** 67 (1994) (questioning cross-country evidence of "wealthier is healthier"); Paul R. Portney & Robert N. Stavins, *Regulatory Review of Environmental Policy: The Potential Role of Health-Health Analysis,* 8 **J. Risk & Uncert.** 111 (1995) (doubting usefulness of HHA); Williams, *supra* note 18, at 1381 (questioning calculation of marginal propensity to spend income on health-related goods).

[45] *See* W. Kip Viscusi, *Regulating the Regulators,* 63 **U. Chi. L.Rev.** 1423, 1448-1455 (1996) (distinguishing income-mediated HHA from other "variants of what has come to be known as risk-risk analysis").

some level of disease, and energy efficiency measures may trap air pollutants inside homes). And some very costly interventions might pose negligible countervailing risks. Countervailing risks are a neglected iatrogenic impact of regulation, irrespective of social cost triage.[46]

Conflating iatrogenic countervailing risks and income-mediated health effects threatens to forfeit the conceptual advance offered by recognizing countervailing risks. Agencies have been analyzing social costs in dollar terms all along (unless forbidden by statute, and even then probably sub rosa), but they have typically neglected countervailing risks. Countervailing risks, understood as regulatory iatrogenesis, require a more complex calculation of regulatory benefits, not a translation of social costs into income-mediated health losses. Speaking as though income-mediated health effects is what is meant by "risk-risk" or "health-health" tradeoffs will tempt analysts and policymakers to neglect yet again the pervasive income-independent iatrogenic countervailing risks of regulation.

Institutional Insights for the Regulatory State

The medical care context also offers important insights for the study of other components of the risk management regime, such as

[46] Consider a simple example: the country whose citizens take a shower every morning. The showers are an intervention to reduce the target risks of personal discomfort, sleepyheadedness, and interpersonal spillovers of body odor (the last is a classic externality, internalized by unwritten social norms of reciprocal cooperation). But there is "no free sponge"; the daily showers impose two kinds of losses on this nation: (i) social opportunity costs, including time that could be devoted to another activity (such as reading more articles on risk analysis) and the money that could be spent on something besides hot water; and (ii) the countervailing risks of the shower itself, such as soap in the eye, drying the skin and scalp, and slipping or drowning in the tub (which kills roughly 300 and injures roughly 150,000 Americans every year; *see* National Safety Council, **Accident Facts** 10, 102 (1994)). (From these bathing risks must be subtracted the risks of the alternate activity, e.g. paper cuts and anxiety from reading the risk articles). HHA measures the health detriment of item (i), the time and money diverted into bathing. This reflects the bather's triage decision among alternative health-promoting opportunities. Countervailing risks are independent of this opportunity cost allocation decision. Indeed, showering faster in order to save time and use less hot water (to reduce opportunity costs) might even increase the prospect of countervailing risks such as slips in the tub.

Similarly, even if the cost to industry and consumers of reducing levels of urban ozone (as recently mandated by the EPA) were zero, reduced urban ozone would still entail the countervailing risk of cancers from increased ultraviolet irradiation. *See* Randall Lutter & Christopher Wolz, *UV-B Screening by Tropospheric Ozone: Implications for the NAAQS,* 31 **Envtl. Science & Technology News** no. 3 at 142A-146A (1997).

government regulatory agencies. The ways in which medical care institutions generate and try to prevent iatrogenic injuries can be highly instructive for understanding the ways in which the regulatory state generates and could better avoid countervailing risks.

Many observers have analogized the regulatory state (and its failures) to the medical care system. The 19th-century pathologist Rudolf Virchow quipped that "politics is nothing but medicine on a grand scale,"[47] and Senator Daniel Patrick Moynihan has recently cast the war on drugs as an example of "iatrogenic government."[48] Radical social critic Ivan Illich, in his diatribe against iatrogenic injuries caused by the medical care system, described public health regulation as a "therapeutic bureaucracy,"[49] which he saw as likewise generating adverse effects on public health. The German political scientist Martin Jänicke, in his study of forms of "state failure," classified the adverse side effects of public health and environmental regulation as "technocratic iatrogenesis."[50]

The Institutional Sources of Countervailing Risks: Fragmentation and Deliberation Cost

The evidence from the medical care context suggests that the primary source of excessive countervailing risks lies not in malpractice but in institutional design — in particular in the fragmentation of the risk management system. Most iatrogenesis is not caused by negligent errors by individual physicians. The Harvard study of New York's hospitals found that 72.3% of iatrogenic injuries were not due to physician error.[51] In the regulatory agency context, where decisions

47 Quoted in Moynihan, *supra* note 14, at 355.

48 Moynihan, *supra* note 14, at 351.

49 Ivan Illich, **Medical Nemesis: The Expropriation of Health** 155 (Pantheon Books, New York, 1976). Illich argued that "iatrogenesis has become medically irreversible: a feature built right into the medical endeavor," *id.* at 34, and he took the same view of the adverse side effects of public health regulation, *id.* at 35. Illich's demonization of professional medicine is not unique; even pillars of the medical community have argued that iatrogenic injuries render a negative net benefit to society. E.g., Oliver Wendell Holmes, Sr., *Currents and Counter-Currents in Medical Science,* Address delivered to the Annual Meeting of the Massachusetts Medical Society, Boston, May 30, 1860, quoted in Sartwell, *supra* note 23, at 92 ("I firmly believe that if the whole materia medica as now used could be sunk to the bottom of the sea, it would be all the better for mankind and all the worse for the fishes.").

50 Martin Jänicke, **State Failure: The Impotence of Politics in Industrial Society** 39 (Alan Braley, tr., 1990).

are much more centralized and bureaucratized than in medicine, it even less likely that countervailing risks are the "fault" of "regulatory negligence" by individual officials. Instead, countervailing risks are a standard feature of helpful, well-intentioned and even well-designed regulations. They are a product of institutional structures and incentive systems, not of individual caprice. Thus, efforts should focus not on assigning blame but on designing less caustic therapies — constructive regulatory systems that achieve target risk goals while causing fewer and less severe countervailing risks.

The salient causal factors in iatrogenic injury are systemic features of the health care delivery system. Many or most iatrogenic injuries involve lacunae in hospital administration.[52] One of the principal institutional flaws was the failure to share important information across the hospital system.[53] Different medical specialties within the same hospital may fail to share information on patient characteristics (e.g., drug allergies) and on drug-drug interactions; for example, one specialist may prescribe a therapy without being informed of the danger it presents to the particular patient (of which other specialists are aware).[54] Or institutional features ancillary to therapy can act as

[51] Weiler, *supra* note 3, at 43. This statistic obviously depends on the protocol for distinguishing causes of ailments. *See supra* text accompanying notes 38-39. According to the Harvard study, most iatrogenic injury results from treatments that comply with the prevailing standard of good medical care. This reflects the adage that every medical intervention is a two-edged sword. "No drug is completely harmless, even when used correctly." McLamb & Huntley, *supra* note 29, at 471.

[52] In the Harvard Medical Practice Study, 58% of iatrogenic injuries were classified as resulting from flaws or gaps in hospital administrative procedures. Weiler, *supra* note 3, at 54; Leape et al., *supra* note 32. The Harvard study found that the rate of iatrogenic injury varied across hospitals by a factor of 40 (ranging from 0.2–7.9% of all hospital admissions), and across medical specialties by a factor of 32 (ranging from 0.5% in neonatal care to 16.1% in vascular surgery). Weiler, *supra* note 3, at 47, 53. This further suggests the potential for improvements through systematic study across institutions and settings, rather than focusing on individual physicians.

[53] *See* Lesar, Briceland & Stein, *supra* note 42, at 315 ("[I]nadequate knowledge, availability, or appreciation of important patient information and drug factors were the most commonly identified related factors or proximal causes. ... [I]t is unlikely that achieving the level of... [physicians'] education needed to dramatically reduce errors is possible. Instead, redesigning the medication ordering and use system to correct errors and improve outcomes is necessary.") (citations omitted).

[54] *Id.* at 316 ("Prescribing medications, or classes of medications, to which the patient had a documented allergy occurred frequently. Many patients are placed at risk for hypersensitivity reactions due to an inadequate provision of timely information regarding allergy history....").

disease vectors; historical examples include the spread of infections through patients' bedclothes, laundry chutes, and eyedropppers.[55] The cutting edge of medical care reform is the effort to bring a "systems analysis" approach to measuring and improving hospital functions and patient outcomes.[56] One manifestation is the increasing organization of medical care into more integrated HMOs and managed care operations in which primary care physicians are positioned to monitor and manage patients' multiple conditions and various treatments in concert.[57] Another is the call for greater sharing of information across the hospital through computers.[58]

Like hospitals, the regulatory state is also fragmented into multiple independent specialties.[59] These include numerous federal agencies such as EPA (and its internal subagencies), OSHA, FDA, NHTSA, FAA, CPSC, NRC, DOI, and USDA/FS; multiple political jurisdictions (e.g., states, cities, nations); and statutes focused on single arenas or parts of problems (e.g., regulating one pesticide at a time; or regulating outdoor air, indoor air, water, wastes, land, and other risk vectors separately). Each specialty operates without coordinating much with its neighbors. Regulations adopted by one state may induce side effects ("spillovers") on other states.[60] Clean air regulations adopted by the EPA pursuant to the Clean Air Act may induce industry to shift

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55 Audy, *supra* note 1, at 49-50 (citing the "embarrassingly long time" it took for hospitals to realize that such routine functions were the source of significant iatrogenic illness).

56 Avorn, *supra* note 5, at 341, 342; Leape et al., *supra* note 42.

57 *See* Wiener & Graham, *supra* note 22, at 243-246.

58 Avorn, *supra* note 5, at 342 (emphasizing "the enormous power that hospital computing systems can bring to bear on the detection and definition of clinical events, both wanted and unwanted."); Classen et al., *supra* note 33, at 305 ("[H]ospitals detect only about 5% of ongoing ADEs... computerized identification of ADEs offers great promise in more efficient and effective detection. [Through such systems] almost 50% of all ADEs are potentially preventable."); Sartwell, *supra* note 23, at 91 (urging use of "a more comprehensive hospital monitoring system, involving continuous surveillance, with collected data subjected to regular computer analysis").

59 *See* Wiener & Graham, *supra* note 23, at 237-240; J. Clarence Davies & Jan Mazurek, *Regulating Pollution: Does the U.S. System Work?* (RFF, 1997); Stuart L. Deutsch, *Setting Priorities: Principles to Improve Environmental Policy,* 68 **Chi.-Kent L.Rev.** 43, 51-52 (1992); Barry G. Rabe, **Fragmentation and Integration in State Environmental Management** (Conservation Foundation, 1986).

60 *See* Richard L. Revesz, *Federalism and Interstate Environmental Externalities,* 144 **U. Penn. L.Rev**. 2341 (1996).

pollution to water or waste settings, and Congress acknowledged as much when it enacted RCRA.[61] EPA regulations to prevent inhalation of asbestos fibers may create risks for highway fatalities.[62] Regulating one pesticide at a time may induce the use of risky substitutes. Moreover, like drug-drug interactions, multiple regulations adopted by different agencies might interact in unexpected ways.[63]

Fragmentation is not due to malice or incompetence. It reflects both the advantages of specialized expertise, and the structural incentives that drive the Congress to match initiatives to the narrow interests of constituent groups and thereby to proliferate subcommittee chairmanships and opportunities for legislative credit-claiming. The root cause is the cost of comprehensiveness. Agencies, committees and health care providers have scarce resources (especially time), and taking account of side effects is costly (especially in delaying attention to target risks). There is a division of labor among agencies, committees, and physicians in large part because specializing enables greater attention to the target issue at lower cost. This is a tradeoff of depth versus breadth. Regulating one symptom, one pollutant, or one arena at a time reduces the costs of gathering and analyzing information about all side matters. Each specialist agency has little incentive to monitor the effects of its interventions on other regulatory domains, and each is driven by legislative mandates drawn up by specialist legislative committees which impel the agency to take a narrow approach.[64]

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61 *See* Resource Conservation and Recovery Act (RCRA), 42 USC 6901(b)(3); Symposium on Integrated Pollution Control, 22 **Envt'l Law** 1-348 (1992); Lakshman Guruswamy, *The Case for Integrated Pollution Control,* 54 **Law & Contemporary Problems** 41 (Autumn 1991); Robert W. Hahn & Eric H. Malès, *Can Regulatory Institutions Cope with Cross-Media Pollution?,* 40 **J. Air & Waste Mgmt Ass'n** 24 (1990). *Cf.* Hilary Sigman, *Cross-Media Pollution: Responses to Restrictions on Chlorinated Solvent Releases,* 72 **Land Economics** 298 (Aug. 1996) (reporting complex impacts of different single-medium pollution controls).

62 *See* Corrosion Proof Fittings, 947 F.2d 1225.

63 In like fashion, there is growing recognition that interactions among multiple exposures (e.g., to multiple environmental toxins) can produce adverse health and ecological outcomes different from what each of these exposures would produce in isolation, but our risk assessment methods and regulatory schemes still generally focus on one hazard at a time. The narrow approach may reduce information costs but no doubt increases error costs. As we consider multiple regulations in concert, we should also consider multiple hazards in concert.

64 Free-rider problems may also hamper both the medical and regulatory regimes. For example, patients with viral infections often demand to be medicated with antibiotics, even though antibiotic drugs treat bacteria, not viruses. Physicians may feel

The implication is that solutions should emphasize reconnecting specialist risk managers. The Harvard Medical Practice Study recommends refocusing prevention of iatrogenic injury from individual physicians (targeted by the medical malpractice system) to health care enterprises as a whole.[65] It notes that modern hospital administrators are abandoning the false image of physician negligence and are coming to see iatrogenesis as a systemic challenge of risk management throughout the hospital.[66] One tack is developing more integrated information systems so that specialists can share data wherever patients go.[67] Another is renewed interest in "treating the whole patient" via primary care physicians — who dispatch patients to specialists and monitor patients' overall health.[68] Similarly, the regulatory regime should invest in integrated information and monitoring to track cross-

pressure to comply. *See* John F. Lauerman, *Homicidal Cultures,* **Harvard Magazine** (Mar.-Apr. 1997) at 18, 20-21 ("Physicians say patients feel slighted when they come away from an office visit without a prescription, and tend to keep looking until they find someone who will write one. ... '[I]t takes less time to hand out a prescription than to explain why one isn't needed.'"). A recent study indicated that 93% of parents surveyed erroneously believed that antibiotics were warranted for their children's ear infections; 71% of physicians reported receiving frequent requests from parents to prescribe antibiotics inappropriately, and 35% said they occasionally went along with these requests; and 18% of parents administered antibiotics at home before consulting a physician. D.A. Palmer & H. Bauchner, *Parents' and Physicians' Views on Antibiotics,* 99 **Pediatrics** (June 1997) at E61-E65. The catch is that overuse of antibiotics fosters new resistant strains of bacteria, harming society as a whole. *See Staph Germ on Way to Being Unstoppable: CDC Warns Doctors to Use Antibiotics More Sparingly to Slow Resistance,* **Raleigh News & Observer**, May 29, 1997, at 14A; *Resisting Resistance,* **The Economist**, May 31, 1997, at 73-74; *New Strain of Staph is Resistant,* **New York Times**, June 3, 1997, at B9; Jeffrey A. Fisher, **The Plague Makers: How We Are Creating Catastrophic New Epidemics — and What We Must Do to Avert Them** (1994). Analogously, perceived sufferers' demands for greater or episodic regulation of target risks may expose the general public to the ensuing countervailing risks.

Free riding may also explain some reluctance to accept vaccination. Each vaccination imposes some risk of side effects, and offers diminishing marginal benefits to the nth recipient as the fraction of the population vaccinated approaches 100%. Hence each patient has an incentive to refuse vaccination, but widespread non-vaccination would invite the larger population risk of the disease itself. On the other hand, a bandwagon effect (and perhaps a little altruism) may explain observed high rates of vaccination. *See* Ann Bostrom, *Lessons for Vaccine Risk Communication,* 8 **Risk** 173, 174-177, 183-184 (1997).

65 Weiler, *supra* note 3, at 145-146; *See also* Abraham & Weiler, *supra* note 42; Havighurst, *supra* note 41.

66 *See* Weiler, *supra* note 3, at 174 n.14.

67 Altman, *supra* note 33; Weiler, *supra* note 3, at 59, 147-149.

68 Wiener & Graham, *supra* note 22, at 243-244.

specialty impacts and overall outcomes. And to better "treat the whole patient," it should consider creating "primary risk managers" (for large agencies, the White House and Congress as a whole) — umbrella entities with the authority to supervise dispatching risks to relevant specialist agencies and committees, confront and supervise decisions about risk-risk tradeoffs, monitor ongoing results, and aim to head off and resolve cross-jurisdictional countervailing risks.[69]

The Imperative of Comparative Risk Analysis

The medical context illustrates the necessity of carefully comparing target and countervailing risks. The risk-risk dilemma in treatment is described in clinical decision theory as a version of the decision analyst's "standard gamble" (Figure 2).[70] Each of two alternative therapies, A and B, is depicted as having two possible outcomes, each with a different probability. Option A may yield a cure but also may yield a severe side effect, while Option B may yield a more mild side effect but also a more mild improvement. (Option B can also be understood as the no-therapy status quo, with some chance of autonomous improvement or deterioration.) For example, surgery on the carotid artery may prevent many fatal strokes but may also cause some strokes; alternative therapies appear to risk less severe side effects but to be less effective at preventing strokes.[71]

Drinking water disinfection is an analogous example in the regulatory law context: chlorination may prevent microbial disease but may cause cancer, whereas alternatives like ozonation appear to be less carcinogenic but also less effective at controlling waterborne pathogens.[72] In both contexts, the decision problem is to choose which intervention option yields the best expected outcome, based on the probabilities of the various outcomes and the evaluative weights assigned to the outcomes.[73]

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69 *Id.* at 257-259.

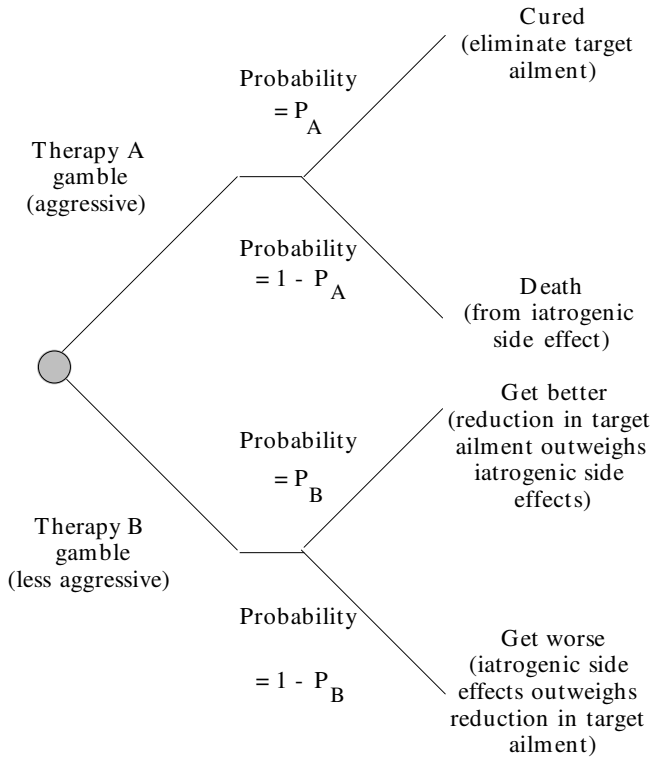
70 *See* Kaplan, *supra* note 2, at 40.

71 *See* David B. Matchar, John Pauk & Joseph Lipscomb, *A Health Policy Perspective on Carotid Endarterectomy: Cost, Effectiveness, and Cost-Effectiveness,* in **Surgery for Cerebrovascular Disease** 680 (W. Moore, ed., 1996).

72 *See* Susan Putnam & Jonathan Baert Wiener, *Seeking Safe Drinking Water,* in Graham & Wiener, *supra* note 6, at 124-148.

73 Medical schools apparently alert medical students to the fact that they will face

Figure 2
Iatrogenesis and the Medical Decision Problem



Adapted from Robert M. Kaplan, *Utility Assessment for Estimating Quality-Adjusted Life Years,* in **Valuing Health Care** 31, 40 (Frank A. Sloan, ed.1995).

Crucial to choosing among available therapeutics is the evaluation of the importance of the side effects *relative* to the change in target risk:[74] Given available options, the physician and patient must weigh and judge the preferred combination of target and countervailing risk

these difficult choices, but may not train physicians to employ a formal, analytic decision method to sort out these dilemmas in their daily practices. *See* Kaplan, *supra* note 2, at 34 ("ultimately, clinicians make some general interpretations of the [choice problem] by applying a weighting system [to the diverse outcomes]. ... [But this] typically is done implicitly, arbitrarily, and in an idiosyncratic way."); Jerome P. Kassirer, *Our Stubborn Quest for Diagnostic Certainty: A Cause of Excessive Testing,* 320 **N. Eng. J. Med.** 1489 (1989) (doctors order too many diagnostic tests, many of which are injurious to patients, because doctors are not taught to employ quantitative comparisons of therapies and iatrogenic risks). The regulatory state may not be preparing its caregivers much better.

74 *See* Kaplan, *supra* note 2, at 33-34; Graham & Wiener, *supra* note 16, at 11-12, 29-36.

inductions.[75] Alone, countervailing risk cannot be judged "significant" or "unacceptable": Very risky surgery or radiation therapy might be used to treat life-threatening brain tumors, but even minor nausea might be intolerable in treating headaches. The choice also depends, of course, on available alternatives.

Likewise, target risks cannot be deemed "significant" or "unacceptable" in the abstract, alone or by reference to bright-lines. Acceptability depends on the relative importance of countervailing risks that would arise from interventions. The choice of the best strategy to combat a target risk depends on the relative effectiveness and relative side effects of the available alternative approaches.[76]

Thus, some form of comparative risk analysis is inescapable. What makes it inevitable is not the issue that has received most attention: ranking independent risks "worst things first" in order to allocate control efforts to top-priority concerns.[77] That is a problem of

[75] "The hazards inherent in modern hospital care make it imperative that the physician weigh [iatrogenic] risk whenever hospitalization is considered and... again each time a specific drug or procedure is ordered." McLamb & Huntley, *supra* note 29, at 472.

[76] Thus, for example, Justice Stevens erred in his famous remark in the Benzene case that "[s]ome risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are two percent benzene will be fatal, a reasonable person might well consider the risk significant and take steps to decrease or eliminate it." Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 655 (1980). The statement erred — in addition to slighting such issues as population risk, costs of control, and qualitative attributes of risk — in its neglect of countervailing risks. The countervailing risks of taking "steps" to reduce the target risk might render even a high target risk (such as 10^{-3}) "acceptable," and at the same time the absence of countervailing risks might render even a small target risk (such as 10^{-9}) "unacceptable." No risk is "plainly" acceptable or unacceptable (that is, judged on the basis of the magnitude of the target risk alone); whether society should "accept" a particular risk or not depends on what society would have to sacrifice to avoid that risk. *Cf.* Baruch Fischoff et al., **Acceptable Risk** 3 (1981) (whether a risk is "acceptable" is "inherently situation specific. That is, *there are no universally acceptable options* (or risks...).").

[77] *See* **Comparing Environmental Risks** (J. Clarence Davies, ed., 1996); **Worst Things First? The Debate Over Risk-Based National Environmental Priorities** (Adam M. Finkel & Dominic Golding, eds., 1994); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis,* 92 **Colum. L.Rev.** 562 (1992); Frank B. Cross, *Why Shouldn't We Regulate Worst Things First?,* 4 **N.Y.U. Envt'l L. J.** 312 (1995). Ranking actions, rather than risks, would address countervailing risks and would target recommendations to address the risks

regulatory triage, of allocation and opportunity costs. What makes comparative risk analysis truly inescapable is the distinct problem of regulatory iatrogenesis.

That some comparison of target and countervailing risks is inescapable does not require the use of a particular form of analysis; it need not be formalized and quantitative, though quantification may assist. There is no one-size-fits-all method; the degree of sophistication in comparison should vary according to such factors as the stakes riding on the choice (higher stakes may warrant more careful analysis) and the costs of delaying the selection while performing the analysis (urgent decisions may warrant less searching analysis).[78]

Countervailing risks does suggest that the use of "conservative default assumptions" in quantitative risk assessment of the target risk (e.g., using the most sensitive test animal or conservative animal-human interspecies scaling factors) can be self-defeating. A main purpose articulated for the use of conservative assumptions to address uncertainty is to make risk policy "better safe than sorry" by "reduc[ing] the probability of errors of underestimation" and thereby encouraging "the prudent avoidance of unnecessary public health risks."[79] If more stringent regulation of target risk induces even greater countervailing risks, then conservative default assumptions may yield more rather than less overall risk.[80] If the goal is prudent avoidance, it may make more sense to treat risks more evenhandedly.[81]

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that can be controlled most effectively at least cost. *See* John D. Graham & James K. Hammitt, *Refining the CRA Framework,* in Davies, *supra* note 77, at 93, 97-103.

78 *See infra* notes 111-115 and accompanying text.

79 Adam M. Finkel, *The Case for "Plausible Conservatism" in Choosing and Altering Defaults,* Appendix N-1 in **Science and Judgment in Risk Assessment** 601, 603-607 (1994).

80 "Better safe than sorry" and the "Precautionary Principle" both err in addressing only the problem that inaction can entail target risks, and in neglecting the problem that action can entail countervailing risks. *Cf.* Howard Margolis, **Dealing with Risk** 75-79 (1996) (pitfalls of "better safe than sorry"); Frank Cross, *supra* note 16, at 856-58. Compare the medical context: if physicians used default assumptions that systematically overestimated patients' ailments, and consequently prescribed more and bolder therapy, the rate of iatrogenic injury would increase. (Critics might allege that this is in fact what physicians do.) Patients might well prefer a more "prudent" medical care regimen that considered both sets of risks on an evenhanded basis; so might the wards of the regulatory state.

81 *See* Williams, *supra* note 18, at 1378-79. One might reply that both target risks and countervailing risks could be estimated using conservative default assumptions,

The comparison of target and countervailing risks is complicated, among other things, by uncertainty in estimating the probabilities of the various possible outcomes, and by the fact that risks come in diverse qualitative forms and contexts, so that weighing a target risk versus a countervailing risk is not a simple linear arithmetic calculation.[82] Among other attributes, the type of risk (e.g., acute injury vs. cancer) may matter to people even if the quantitative likelihood of death is equal.[83] The same challenges of comparison arise in public regulation. "Expert" and "public" evaluations of risks may diverge, perhaps because they bring different values to their conceptions of "risk,"[84] and perhaps because people (including patients, physicians, citizens and regulators) may have a difficult time bringing a clear analytic perspective to bear on risk choices (especially under the conditions of mental stress that may accompany serious illnesses, intimidating hospital settings, and public policy debates).[85] The response to these difficulties cannot be to reject risk comparisons altogether, for there is no way to avoid making some judgment. Not to compare is to compare arbitrarily. Countervailing risks cannot be wished away. The response must be to take better account of the quantitative, qualitative and contextual differences among risks.[86]

yielding parallel overestimations. In practice, the more typical "double standard" is to treat target risks "as at least as bad as the most ephemeral evidence could support" (i.e., to use quite conservative default assumptions) but to ignore countervailing risks or to treat them as "only as serious as hard evidence can uncontrovertibly demonstrate." Howard Margolis, *Book Review,* 15 **J. Pol. Anal. & Mgmt.** 685, 686 (1996). Parallel treatment would be some improvement. But systematically overestimating all risks seems a weaker basis for policy, more prone to error and more prone to inflaming public misunderstanding, than dealing with uncertainty on all sides with a more equanimous approach.

82 *See* Graham & Wiener, *supra* note 16, at 32-34; Davies, *supra* note 76; Cass R. Sunstein, *Incommensurability and Valuation in Law,* 92 **Mich. L.Rev.** 779 (1994).

83 *See* **Valuing Health for Policy** 341-342 (George Tolley, Donald Kenkel, & Robert Fabian, eds. 1994) (reporting that given equal probabilities of death by acute injury and by cancer, people say they would prefer death by acute injury to death by cancer by about a factor of 2).

84 *See* K.S. Shrader-Frechette, **Risk and Rationality** (1991); Clayton Gilette & James Krier, *Risk, Courts, and Agencies,* 138 **U. Penn. L.Rev.** 1027 (1990).

85 *See* John Conlisk, *Why Bounded Rationality?,* 34 **J. Econ. Lit.** 669 (1996); Roger Noll & James Krier, *Some Implications of Cognitive Psychology for Risk Regulation,* 19 **J. Legal Stud.** 747 (1990); Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases,* 185 **Science** 1124 (1974).

86 *See* Graham & Wiener, *supra* note 16, at 32-33 (arguing that risk-risk

Risk-Superior Moves

The medical context demonstrates that risk-risk dilemmas can be eased by the development of new therapies which are both as or more effective against the target ailment and less risky in terms of side effects. These are "dominant" or "risk superior"[87] options, innovations which escape the previous dilemma by reducing multiple risks in concert. They can be depicted graphically as pressing outward from the previous frontier of available risk protection portfolios (RPF_2 in Figure 1). A countervailing risk worth tolerating today may be worth reducing tomorrow given a risk-superior option; a dynamic system should create incentives for continuous medical and regulatory improvements.

Surgery is a case in point. Surgery to correct fractured bones, diseased organs and other exigent maladies raises at least two kinds of countervailing risk: the pain of the surgical procedure itself, and the latent infection that may take hold in the surgical wound. Pain during surgery not only injures the patient but can disrupt the surgical procedure, impeding the therapy for the target ailment. Nosocomial (hospital-induced) infection can be disabling or fatal. In Great Britain in the mid-1800s, for example, when amputations were frequently employed to treat gangrene, severe fractures, and other limb problems, 25–60% of civilian amputations (and 75–90% of military amputations) resulted in death by nosocomial infection.[88] That is, roughly half of the surgeries killed the patient by exposing the open wound to infection; the average patient undergoing a life-saving amputation faced a mortality risk of roughly 1 in 4 to 1 in 2 from the subsequent infection. This made for arduous choices.

The serendipitous development of anesthesia by nitrous oxide and ether inhalation in the 1840s enabled surgery without pain.[89] Joseph

comparison is inescapable and that the better route is toward better methods of comparison, not a retreat to assertions of incommensurability); Williams, *supra* note 19, at 1378 (arguing that risk-risk comparisons may be more tractable than risk-money comparisons, but that people make both kinds of comparisons every day).

87 *See* Graham & Wiener, *supra* note 16, at 36-41. In the "shower" example above, *supra* note 45, risk-superior options to ease the tradeoff between body odor and soap in the eye, dry skin, slipping in the tub might include, e.g., milder soaps and bathmats.

88 Leo M. Zimmerman & Ilza Veith, **Great Ideas in the History of Surgery** 464 (Dover Publications, New York, 2d ed. 1967) (citing Sir Rickman John Godlee, **Lord Lister** (3rd ed. 1924)).

Lister's methodical development of antiseptics in the 1860s enabled surgery with much less risk of infection.[90] Lister reported in 1870 that the death rate from nosocomial infection in one hospital he studied fell from 45% (within two years after amputation performed without antiseptics) to 15% (within three years after amputation performed with antiseptics).[91] Lister's innovation was not quickly accepted in London. Surgeons took umbrage at the notion that their own incisions caused harm, and Lister's recommended antiseptic regimen was "widely derided as finical, ladylike and affected."[92] Antisepsis was more immediately adopted on the Continent and, roughly two decades later, in England as well.[93]

Nevertheless, both anesthesia and antisepsis illustrate the point that there remain risk-risk choices along the higher risk protection frontier. Anesthesia risks heart failure and other adverse side effects.[94] And

89 *Id.* at 438, 461.

90 *Id.* at 461, 464-466. Lister was among the first to see and address the connection between contamination and nosocomial infection. In the 1840s, O. W. Holmes had recognized the nosocomial source of puerperal fever, *see supra* note 25, and Ignaz Philipp Semelweiss had reduced the fatality rate among new mothers due to puerperal fever from 18% to 1% by the then-revolutionary step of requiring hospital staff to wash their hands in a disinfectant before delivering newborn babies. Richard Gordon, **The Alarming History of Medicine** 67-68 (1993). Pasteur and Koch did not identify microbes as the source of such infections until the 1860s. *Id.* at 18-22, 68.

91 Zimmerman & Veith, *supra* note 87, at 466, citing 2 **The Collected Papers of Joseph, Baron Lister** 129 (1909).

92 Gordon, *supra* note 89, at 56. Even in the 1960s, despite "an overwhelming number of references" to iatrogenic disease in the medical literature and "a constant barrage of warning letters from pharmaceutical companies and the FDA," observers lamented that "most physicians appear to feel secure in the belief, that 'iatrogenic disease' is a consequence of carelessness or ineptitude on the part of some other physician." Beaty & Petersdorf, *supra* note 4, at 641.

93 The resistance in England persisted for twenty years, until "many of the senior members of the profession had been replaced by a younger and more malleable generation." Zimmerman & Veith, *supra* note 87, at 466. This instantiates Max Planck's lament that "a new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die, and a new generation grows up that is familiar with it." Max Planck, **Scientific Autobiography and Other Papers** 33-34 (F. Gaynor, tr., 1949), quoted in Thomas S. Kuhn, **The Structure of Scientific Revolutions** 151 (2nd ed. 1970).

94 *See* Brown, *supra* note 1. Early attempts at anesthesia by chloroform often killed the patient. *See* Gordon, *supra* note 89, at 86. But an alternative, ether, caused vomiting and was flammable, *id.* at 83, 87. Both were ultimately replaced by risk-superior anesthetics, such as narcotics (which still pose their own risks). Today the search continues; in the 1980s, the Harvard hospitals installed alarms on monitoring devices to alert anesthesiologists to patients' breathing problems. This move both

Lister recognized that caustic antiseptic wound dressings not only kill invading bacteria but also injure the patient's own tissues, impairing the body's own defense mechanisms. He therefore experimented for two decades with various compounds and spraying methods to try to maximize its effectiveness and minimize its own iatrogenic effect.[95] One response to this dilemma of antiseptic dressings was the innovation of aseptic surgery, in which tools and materials are heat-sterilized in advance — another move to a higher protection frontier.[96]

Numerous other examples of risk-superior innovations in medicine can be cited. The combination of estrogen and progestin, and a new drug called raloxifene, were developed to mitigate the iatrogenic cancer risks of estrogen alone.[97] Vaccines prevent epidemics, but can themselves induce some individuals to contract the disease; Edward Jenner's smallpox vaccine was made compulsory in England in 1853, but voluntary again in 1948 when it turned out that the vaccine was causing more cases of smallpox than was the virtually extinct virus itself.[98] Recognizing this risk-risk tradeoff, new risk-superior vaccines are being designed to minimize their iatrogenic risks.[99]

In short, the history of medicine has been a search for risk-superior innovations. Iatrogenic risk is not just a pesky nuisance of medical treatment, or an insult to the profession; it is a motivating force in developing new and better treatments. Countervailing risks of risk

reduced patient fatalities due to anesthesia and saved the hospitals significant expenses. *See* Abraham & Weiler, *supra* note 42, at 411-13.

95 *See* Zimmerman & Veith, *supra* note 87, at 468. This risk-risk tradeoff is reminiscent of the oil spill cleanup problem mentioned above, *supra* note 8: Hot water spraying not only cleans off the oil, but also injures aquatic microbes, in turn impairing the ecosystem's ability to clean itself and to recover from the oil.

96 *Id.* at 467. Aseptic and antiseptic surgery, and low rates of nosocomial infection, are the norm in modern American hospitals, but lax attention to aseptic and antiseptic protocols can still generate significant increases in infection rates today. *See* Weiler, et al., *supra* note 3, at 58 (1993); *see also* Beaty & Petersdorf, *supra* note 4, at 645 ("Iatrogenic disease not infrequently presents in the form of infections" resulting from contamination of implements, superinfection due to large doses of antibiotics, and suppressed immune response due to cancer chemotherapy).

97 *See* Hatziandreu et al., *supra* note 23, at 46; Jane E. Brody, *Study Finds a New Estrogen Offers Benefit Without Risk,* **N.Y. Times,** Dec. 4, 1997, p. A19 (reporting that raloxifene "can strengthen bones... without fostering cancers").

98 *See* Gordon, *supra* note 89, at 50-51. In 1971 routine vaccinations for smallpox were discontinued in England; in 1977 the virus was deemed eradicated. *Id.*

99 *See, e.g., New Whooping Cough Vaccine Is Said to Eliminate Side Effects,* **New York Times**, Nov. 25, 1994, at A20.

regulation should be similarly regarded, not as an annoyance or ignominy but as the spur that drives regulatory innovation.

Risk-superior innovations are not magic bullets. First, there is a cost in putting social resources into development of risk-superior innovations. But innovation can yield larger net benefits than incremental steps to address target and countervailing risks separately. For example, the combination of pre-Listerian surgery and follow-on treatment for wound infections was quite cost-ineffective compared to antiseptic surgery. Strategic investments in risk-superior innovations can be "risk-profitable," and actors facing appropriate incentives to take account of countervailing risks can be expected to invest strategically in such moves. Second, moving to a higher RPF is not an escape from tradeoffs; a risk-risk dilemma will eventually arise again, as new alternatives to the new therapy are introduced with different target and countervailing risk outcomes, and perhaps as new countervailing risks are discovered to be arising from the innovative therapy.

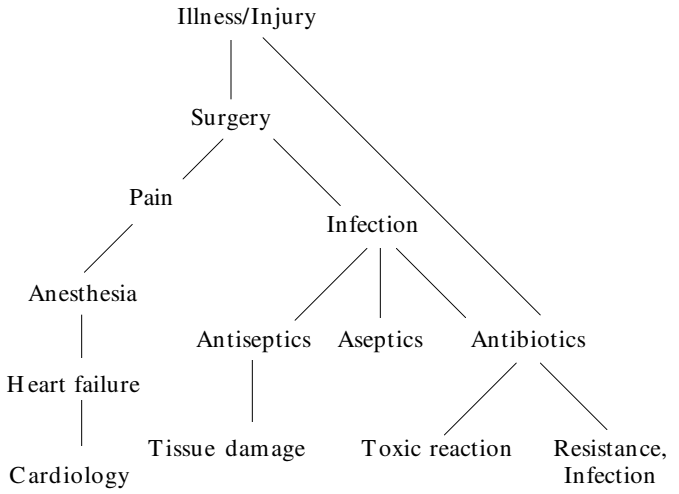
Expansion and Optimization

Expansion. The medical care context suggests that the risk regulation regime might face pressure to expand in response to countervailing risks. In this scenario, the therapeutic path actually taken in response to iatrogenesis involves follow-on treatments for each new symptom in a cascade of countervailing risks resulting from a prior therapies. In response to each iatrogenic injury, medical care may thus generate an expanding web of specialists; each countervailing risk may become a target risk for the next medical specialty. Surgery causes pain, which warrants anesthesia, but anesthesia risks heart failure, which increases the demand for cardiologists. Surgery causes infection, which can be prevented with antiseptics, but antiseptics can impair the body's own defenses. And antibiotics treat infection, but may also generate toxic reactions, superinfections, or populations of resistant bacteria that spawn new illnesses.[100] (See figure 3.)

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[100] *See* Beaty & Petersdorf, *supra* note 4, at 642-648 (toxic reactions and superinfections induced by antibiotics); *see supra* note 64 (overuse of antibiotics spawns resistant new strains of bacteria).

Figure 3
Iatrogenesis and the Expanding Protective Regime



An analogous dynamic may be at work in the regulatory state: Initial laws generate countervailing risks, which create demand for new laws; the bureaucracy spawns its own proliferation. Enactment of NEPA was a response to the adverse environmental effects of government projects; the enactment of RCRA was in part a response to the rising tide of solid waste generated by compliance with the Clean Air and Clean Water Acts. Worse is a potential vicious circle. Deliberation costs induce regulatory politics to fragment decisionmaking into specialized agents. Specialization yields adverse effects outside the decisionmaker's domain. This fosters the proliferation of new institutions to deal with the countervailing risks of the first interventions. Proliferation increases the number of regulatory actors, which increases the deliberation costs of shaping comprehensive, collective solutions. The pressure for additional countervailing risks is thus embedded in the response to initial risks. The rate of expansion would depend in part on the costs of deliberation and the ease of fragmentation; high deliberation costs and easy fragmentation could entail worsening side effects and accelerating expansion. (To be sure, there are constraining forces as well, e.g, the budget costs of creating new agencies and the industry lobby against new regulation. Even if the expansion hypothesis has empirical merit, it does not indicate a normatively desirable reach of the regulatory state.)

Optimization. What is the optimal scope of risk regulation in the face of countervailing risks? The process of treating (regulating) the target risk and adding follow-on treatments (additional regulations) for the countervailing side effect may be worthwhile, if each step yields net gains. Not regulating the target risk (to avoid the countervailing risk) could be more worrisome than regulating and incurring the side effects of regulation. This suggests that the optimal scale of the regulatory state, in light of countervailing risks, could be "larger." On the other hand, follow-on regulations might not reduce overall risk as much as would less initial regulation; they might even make matters worse.[101] If so the optimal response might be to advocate reining in the risk regulation regime — a "smaller" optimal regulatory state. In the short term, this might make sense: If the side effects are severe, one may prefer fewer and less aggressive interventions — e.g. less surgery, depowered airbags, slower police chases — even though the target ailment would thereby remain somewhat more worrisome. In the long term, neither an expanding web of follow-on regulations to address countervailing risks, nor a retreat from target risks, seems ideal, if intelligent risk-superior options are available. And the scalar suggestion of a "larger" or "smaller" regulatory state is distracting or misleading; the more important issue is the design of "smarter" regulations.

At a first approximation, just as optimal medical treatment would maximize the difference between the expected gain and the expected side effect (see Figure 2), optimal risk regulation would maximize the difference between the reduction in the target risk (ΔTR) and the increase in countervailing risks (ΔCR), that is, max(ΔTR-ΔCR).[102]

This optimizing condition does not correspond to the adages typically invoked to deal with adverse side effects. The Hippocratic Oath teaches physicians "Primum Non Nocere" or "First of all, Do No Harm," and that prescription has also been suggested as a helpful

[101] "[I]n an effort to extricate himself from complications of diagnosis and therapy, the physician may compound the problem by having to employ maneuvers that are in themselves risky." Beaty & Petersdorf, *supra* note 4, at 655.

[102] For ease of exposition, I use simple notation here and abstract from the realities that risks are qualitatively diverse and are estimated with uncertainty. I also frequently use the change in the risk (Δ) rather than marginal analysis, for ease of accessibility to multidisciplinary readers. The values of ΔTR and ΔCR should be understood here as absolute values.

general aspiration for sound risk regulation.[103] But if enforced as a formal criterion, this adage would be overkill: it would require zero countervailing risks even where tolerating an increment of countervailing risk would enable society to make much greater gains against a target risk. Regulatory options with $\Delta CR = 0$ might have low (ΔTR-ΔCR), compared to other options with positive ΔCR but much larger ΔTR. If countervailing risks are truly omnipresent, no regulatory option can ever truly "do no harm." Plainly, physicians and patients do not adhere to the strict letter of "Do No Harm" — and neither should regulatory agencies.[104]

The contrasting prescription is to "ignore side effects." This was the gist of Lindblom's famous advice to "muddle through:" he specifically urged that regulatory agencies avoid "comprehensive" analysis in which "every important relevant factor is taken into account," and instead take an incrementalist approach in which "analysis is drastically limited" and "important possible outcomes are neglected."[105] Lindblom added that the practice of "ignoring important possible consequences" might seem "a shocking shortcoming" but that it was superior to "futile attempts to achieve a comprehensiveness beyond human capacity."[106] He argued

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[103] *See* Dale Hattis, *Drawing the Line: Quantitative Criteria for Risk Management,* 38 **Environment** (July-Aug. 1996). *Cf.* John Rawls, **A Theory of Justice** 114 (1971) (recommending "do no harm" as a duty all persons owe each other). Models of unanimous decisionmaking and full Pareto-optimality require that policy do no (uncompensated) harm to anyone. *See* Dennis Mueller, **Public Choice II** 38, 385 (1989) (describing unanimity/universal gain postulates of Knut Wicksell and Wilfredo Pareto).

[104] *See* Christopher H. Schroeder. *Rights Against Risk,* 86 **Columbia L.Rev.** 495, 495, 555 (1986) (arguing that while "do no harm" may be a worthy aspiration, justice does not require absolute zero harm to others); Jonathan Baron, *Blind Justice: Fairness to Groups and the Do-No-Harm Principle,* 8 **J. Behav. Decision Making** 71 (1995) (seeking zero side effects can yield unjustifiable judgments that increase overall harm); Mueller, *supra* note 103, at 400-407 (describing Amartya Sen's theorem that full Pareto-optimality [no harm to anyone's utility] is an impossible decisionmaking rule, necessitating resort to some overriding principle such as tyranny or liberal tolerance, or necessitating resort to interpersonal utility comparisons that let some be hurt for the greater benefit of others). *Cf.* James Buchanan & Gordon Tullock, **The Calculus of Consent** 63-84 (1962) (arguing that moving toward unanimity reduces harm to others but increases decisionmaking costs, so that optimal social policy employs non-unanimous voting and hence allows some harm to others).

[105] Charles E. Lindblom, *The Science of "Muddling Through,* 19 **Public Admin. Rev.** 79, 81 (1959).

[106] *Id.* at 85. His objection is that deliberation about countervailing risks is costly. I address the issue of deliberation cost below, and show that Lindblom's recipe is

that other agencies would address the adverse side effects of each agency's actions, in a "division of labor [in which] every important interest or value has its watchdog."[107]

But ignoring countervailing risks is plainly suboptimal; those can outweigh the gains in target risk reduction ($\Delta CR > \Delta TR$, or $\Delta TR - \Delta CR < 0$). Lindblom's confidence that every interest will be represented in a fragmented but coordinated regulatory system is misplaced; the costs of information flow across agencies; more fundamentally, the costs of political organization ensure that many interests (especially the diffuse interests of the public, and the interests of disenfranchised groups such as minorities) are omitted from the debate.[108] In that context, "Ignore Side Effects" is tantamount to a license to "Do Infinite Harm," at least to those whose interests are unrepresented in regulatory politics. For both reasons of efficiency and equity, neither physicians nor agencies should tolerate countervailing risks blithely.

Between "doing no harm" and "ignoring all harm" is a far better middle ground. A variant of the Hippocratic Oath is the proposal that regulations must do "more good than harm"[109] — i.e., a requirement that $\Delta TR > \Delta CR$, or $\Delta TR - \Delta CR > 0$. This condition is necessary but not sufficient. It precludes truly irrational choices, but it gives no guidance in selecting the best option from among the subset of options that all do more good than harm (for all of which $\Delta TR > \Delta CR$).

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suboptimal whenever the error cost of ignoring a CR outweighs the deliberation cost of addressing the CR.

[107] *Id.* Lindblom asserted that this "system often can assure a more comprehensive regard for the values of the whole society than any attempt at intellectual comprehensiveness. ... [A] high degree of administrative coordination occurs as each agency adjusts its policies to the concerns of other agencies in the process of fragmented decisionmaking." *Id.* at 85-86.

[108] *See* Wiener & Graham, *supra* note 22, at 230-33 (discussing "omitted voice" as a cause of countervailing risks); Mancur Olson, **The Logic of Collective Action: Public Goods and the Theory of Groups** (1971) (collective organization is costly, biasing public policy in favor of small groups with concentrated interests); Colin S. Diver, *Policymaking Paradigms in Administrative Law,* 95 **Harv. L.Rev.** 393, 423-425, 432, 434 (1981) (Lindblom's view is dubious in light of collective action problems and consequent political distortions); William N. Eskridge, Jr., *Politics without Romance: Implications of Public Choice Theory for Statutory Interpretation,* 74 **Va. L.Rev.** 275 (1988) (costs of political voice skew policies away from diffuse general interests).

[109] *See e.g.,* Warren & Marchant, *supra* note 16; Sunstein, *supra* note 16, at 314 ("Agencies generally ought to be required to show that they are doing more good than harm.").

Thus, in this first approximation, an optimal policy would maximize the difference between the two risks (i.e., max(ΔTR - ΔCR)).[110] This implies a key point: ΔCR matters even if it does not exceed ΔTR — i.e., even if the regulation yields "more good than harm" — because even a small ΔCR diminishes the overall net benefits, thereby making alternative interventions with higher overall net benefits relatively more attractive. The best policy, A, is the one with the maximum overall net benefit — the one for which (ΔTR-ΔCR)A > (ΔTR-ΔCR)B, where B represents every reasonable alternative to A. And whenever the social opportunity cost of the intervention — resources diverted from other productive endeavors — is not zero, the condition for optimality must be to maximize (ΔTR - ΔCR - social costs), or set marginal overall benefits (combining TR and CR) equal to marginal social costs. Even a modest ΔCR (much smaller than ΔTR) may still exceed the difference between ΔTR and social cost, yielding negative net overall benefits for that policy. (I.e., it is easily possible for it to be true that ΔTR > ΔCR but also true that ΔCR > (ΔTR - costs), or ΔTR - ΔCR - costs < 0.)

A second approximation is necessary to account for deliberation costs. It was argued above that regulators specialize and neglect adverse side effects partly because it is costly in money and time to consider and manage those side effects — and could mean a period of inaction against target risks.[111] Lindblom's fear that seeking comprehensiveness would entail high administrative costs deserves respect, even if ignoring side effects is an overreaction.[112] The tradeoff between ΔTR and ΔCR can be posed as balancing the cost of incorporating ΔCR into policy reformulation (deliberation cost) against the cost of ignoring ΔCR and making a decision which thereby generates ΔCR (error cost). Optimal

[110] Or, in marginal terms, intervene up to the point that the marginal increase in CR equals the marginal reduction in TR.

[111] Or a period of overregulation, depending on the default rule undergirding the regulation. That is, if the default rule is no licensing of a product or project until the regulation has been fully analyzed (as under pre-approval requirements for drugs subject to the FFDCA, pesticides subject to FIFRA, and federal projects subject to NEPA), delay to consider the countervailing risks may mean overregulation.

[112] *See* Diver, *supra* note 106, at 428; Cross, *supra* note 16, at 922; Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform,* 10 **Yale J. Reg.** 369, 386 (1993) (warning against "supersynopticism").

regulatory policy would minimize the sum of deliberation costs and error costs.[113] Equivalently, optimal policy would address countervailing side effects up to the point that the next unit of resources would be better spent on another pursuit (e.g., addressing other risks) — it would reduce countervailing risks to the point that the marginal deliberation cost rises to equal the marginal benefit in reduced countervailing risk (i.e., reduced policy errors).

The same point can be described as an "optimal stopping problem" in determining the efficient amount of additional information to obtain for decisionmaking. The problem is to balance the decision-improving value of additional information (VOI) about the countervailing risk against the costs of gathering and incorporating that information (COI — the foregone opportunities to devote that time and effort to other problems). In concrete terms, it reflects the question of how far agencies and their reviewers (chiefly OMB and courts) should go in analyzing consequences before promulgating a regulation.[114]

In conceptual terms, however, the optimal information problem confronts two analytic difficulties. First, estimating the VOI for each next side effect requires estimating what those side effects would be, which in turn necessitates expending the COI (or a portion of the COI on a best guess). Some deliberation is necessary to estimate the error

[113] *See* Anthony I. Ogus, *Information, Error Costs and Regulation,* 12 **Int'l Rev. of Law & Econ.** 411, 416 (1992) ("to increase social welfare the legal system should aim at minimizing the sum of information costs and error costs"); Isaac Ehrlich & Richard Posner, *An Economic Analysis of Legal Rule Making,* 3 **J. Legal Studies** 257 (1974) (similar); Herbert A. Simon, *On How to Decide What to Do,* 9 **Bell J. Econ.** 494, 495 (1978) ("the least-cost or best-return decision [requires] a tradeoff between the marginal computational cost and the marginal improvement in the substantive decision it is expected to produce"); Ejan Mackaay, **Economics of Information and Law** 110 (1982) (similar). *Cf.* Buchanan & Tullock, *supra* note 104 (the optimal voting rule minimizes the sum of incompleteness costs and decisionmaking costs). Cass Sunstein has called this insight "the central contribution of economics to law." Remarks at Federalist Society conference, Duke University, Mar. 1, 1997.

[114] *See, e.g.,* Gas Appliance Manufacturers' Ass'n, Inc. v. Department of Energy, 998 F.2d 1041, 1047 (D.C. Cir. 1993) (remanding to agency to obtain more information prior to setting mandatory appliance performance standards, with instructions to "consider the costs and benefits of testing options, taking into account the importance of the [performance] hypothesis [to the regulatory decision], its uncertainty, the likelihood that testing would resolve the uncertainty [i.e., reduce policy errors], and the cost of testing. While of course we would defer to any reasoned decision [by the agency] on incremental testing, here we cannot discern even the faintest glimmer of an effort to make such a decision [about the optimal degree of additional information to gather].").

cost of not deliberating. If the net effect of the regulation is the summation of an expansion series of n terms, with each term representing the next-order effects, then the paradox is that in order to know whether to analyze the nth term one must balance the deliberation cost of that analysis against the error cost (i.e., the cost of ignoring the nth term), but in order to estimate the error cost of ignoring the nth term one must already have analyzed the nth term to know its magnitude. Intuitive truncation points are elusive: deliberation costs may rise substantially even as the error cost of ignoring the next term declines, because a small countervailing effect may nonetheless be quite difficult to investigate and calculate. And error costs may not decline as the expansion series grows, because in a world of complex interrelated systems, the nth-order effects may well be larger than the 2d- or 3d-order (or even 1st-order) effects.

A partial solution to the problem just described is to construct a probability distribution of the possible values of information that might be discovered, and use the "expected VOI" to decide ex ante. Still, this necessitates some notion of the VOI probability distribution, which implies some COI.

The second difficulty is deeper. Incorporating deliberation cost is complex because adding deliberation cost to the optimization model, as described above, means constructing a more complex model — with added deliberation costs of its own. We are now required not only to optimize the original choice, including the costs of deliberating about it, but also to optimize how much deliberation to put into the question of how much to deliberate about the original choice, and so on. Recursive deliberation about deliberation yields an infinite regress with no mathematically precise solution.[115]

[115] *See* Conlisk, *supra* note 84, at 682-683, 686-688. As a default approach, Conlisk suggests stopping at the second-order optimization problem, that is, optimize the choice given deliberation costs, but ignore the deliberation cost of solving this more complex model. *Id*. at 688. *Cf*. R. B. McKenzie, *On the Methodological Boundaries of Economic Analysis*, 12 **J. Econ. Issues** 627, 634-635 (1978) (quoted in Mackaay, *supra* note 113, at 112-113 & 237 n.56) (seeing an infinite regress in information economics because in order to optimize, one needs information, which requires optimizing how much information to use, which requires information, ad infinitum; "At some point, the individual must assert in some noncalculating way how he will use resources to establish what he wants: He must, in effect, take a stab in the dark…").

Institutional Progress. Perfection may be illusory, but improved decisionmaking is not impossible. The "optimal stopping problem" and its informational paradox confront us every day when we have to decide whether to buy something or continue comparison shopping; or whether to read the next page of the newspaper, or instead do something else. Dealing with these choices requires exercising judgment about potential next-order consequences and the associated deliberation costs. Institutional rather than mathematical solutions to the paradox seem most promising. For example, agencies and the White House could experiment with stages of risk analysis to help illuminate whether initial suppositions about the importance of, and costs of estimating, next-order effects are good or poor predictors of the value and costs of full-blown analysis.

More generally, the institutional solution to the paradox of recursive deliberation can draw on the analysis of the related problem in regulating market externalities (target risks). In a world of real transaction costs, and of uncertainty about which private party is the least-cost harm avoider, the most efficient allocation of entitlements may be approached by assigning liability for harm to the party with the lowest transaction costs of reallocation to the true least-cost avoider.[116] Similarly, in a world of real deliberation costs and of uncertainty about which regulatory entity is the least-cost avoider of errors (countervailing risks), the most efficient result may be approached by assigning policymaking responsibility to the regulatory institution with the lowest deliberation costs of addressing and managing such potential errors. This suggests that for regulatory contexts in which countervailing risks are worrisome, policy choices should usually be handled by institutions designed to deliberate cost-effectively (and that institutions which must deal with risk policy should be renovated to reduce deliberation costs).

It is hard to find examples of policy institutions that exhibit low deliberation costs. Legislatures typically lack analytic infrastructure (and of late the Congress has been dismantling what it has),[117] and

[116] *See* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral,* 85 **Harv. L.Rev.** 1089, 1096-1097 (1972); Guido Calabresi, **The Costs of Accidents** 135-73 (1970).

[117] The 104th Congress abolished the Office of Technology Assessment and the Administrative Conference of the United States, two of its main sources of analysis of regulatory policy.

courts incur high deliberation costs (in the form of other cases crowded out of court) when they investigate complex regulatory matters. Regulatory agencies are an analytic infrastructure poised to deliberate, but as argued above, the fragmentation of the regulatory state yields high costs of deliberating about side effects. Perhaps greater attention to countervailing risks will motivate improvements in regulatory institutions to reduce deliberation costs, just as attention to iatrogenic injury has motivated improvements in hospitals' oversight and information sharing systems.

Regulatory institutions with low deliberation costs still need to be guided to consider side effects appropriately. Clearly decisionmakers should not try to consider all the infinitely possible side effects of an intervention; they cannot know all the ripples throughout the system (especially given that the "system" has no objective boundaries, but is defined by the scope of the relevant next-order consequences, and more precisely because the deliberation costs of trying to know all the ripples would rise rapidly). Neither should decisionmakers consider none of the side effects, thereby ignoring the costs of errors. Between supersynopticism and blind incrementalism is the pragmatic middle ground which minimizes the costs of each.[118] Risk managers should engage in reasonable consideration of the side effects[119] — consideration which maximizes its net benefits by minimizing the sum of the costs of deliberation and the costs of errors. Thus, Executive Orders, Congressional statutes and reviewing courts should neither ignore countervailing risks nor mandate endless analysis of countervailing risks; they should require agencies to make a judgment about the reasonable degree of attention and redress to be given to regulatory side effects.

Recent legal developments have begun to move in this direction. President Clinton's Executive Order on Regulatory Review requires agencies to include in their benefit-cost analysis of each regulation the

[118] *See* Diver, *supra* note 107, at 429-430 ("The solution to synoptic failures is not a blind retreat to incrementalism. What is needed is a sense of balance.... We need not cast all our weight on one side, for incrementalism and comprehensive rationality each offer unique advantages as well as conspicuous limitations.").

[119] This deliberative exercise should take appropriate account of the qualitative and contextual aspects of risk. *See* Jonathon Baert Wiener, *Risk in the Republic,* 8 **Duke Envtl. Law & Policy Forum** 1 (1997).

"adverse effects [of the proposed regulation] on... health, safety and the natural environment."[120] This requirement is subject to the general instruction to "base... decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."[121] The "regulatory reform" bill that passed the House but not the Senate in the 104th Congress would have required agencies, among other things, to evaluate the "significant substitution risks" generated by new agency regulations.[122] The Safe Drinking Water Act Amendments of 1996 (passed 98-0 by the Senate and 392-30 by the House) provide that EPA may depart from the ordinarily required "maximum feasible" control level if the maximum feasible control on one contaminant would generate countervailing increases in other health risks, and that EPA may in such circumstances set drinking water standards to "minimize the overall risk of adverse health effects by balancing the [target and countervailing risks]."[123] Recent case law also implied that the bar on "arbitrary and capricious" rulemaking in the Administrative Procedures Act may require agencies to confront countervailing risks.[124]

Ultimately, the effort to maximize the difference between ΔTR and ΔCR will succeed partly by designing institutions that reduce deliberation and error costs, and partly by stimulating innovative risk-superior methods that enable both target and countervailing risks to be

[120] E.O. 12866, Sept. 30, 1993, §6(a)(3)(C). No such item on countervailing risk was enumerated in President Reagan's E.O. 12291. (As a member of the senior staff at the Council of Economic Advisers in 1993, I assisted in the drafting of this and other provisions of EO 12866.)

[121] *Id.* §1(b)(7).

[122] H.R. 1022, 104th Cong., §§105(4), 110(4). The term "significant" seems to direct the agency to calibrate its analysis to the seriousness (error cost) of each substitution risk, but might not account for the difficulty of analysis (deliberation cost) of each substitution risk.

[123] 42 USC 1412(b)(5) (1996).

[124] *See, e.g., Corrosion Proof Fittings,* 947 F.2d 1201; Competitive Enterprise Institute v. NHTSA, 956 F.2d 321 (D.C. Cir. 1992). Analogizing from the medical arena, courts might also impose tort liability for "regulatory malpractice," ideally as "enterprise liability" inducing the regulatory state as a whole to adopt systematic safeguards against countervailing risks. *Cf.* Abraham & Weiler, *supra* note 42 (advocating medical enterprise liability); Havighurst, *supra* note 41 (same). But such a move could yield overdeterrence of worthwhile regulation, in part because, unlike physicians, public agencies do not earn financial rewards for their target risk reduction services. Moreover, because courts have high deliberation costs, the first resort should be to more integrated analysis in the Executive Branch rather than to litigation.

addressed more effectively. Joseph Lister sought not only the optimal level of surgeries given a fixed risk of nosocomial infection, but new ways to make surgery a more attractive therapy by reducing the countervailing risk. Similar innovation is occurring all the time in medicine. The ideal resolution to regulatory side effects may be not more or less regulation, but new ways to mitigate countervailing risks and thereby to make risk regulation a less caustic and more appealing tool. And it will involve structural integration of risk regulation institutions to remedy the fragmented decisionmaking now rampant in the regulatory state, both among Executive agencies[125] and among Congressional committees.[126] Just as hospitals are moving to a more integrated model that connects medical specialties through a common dispatch and monitoring system, the regulatory state should create structures to "treat the whole patient" rather than attacking one symptom or subsystem at a time. These structures should include interagency working groups with greater authority to manage multiple risks in concert, a supervisory "primary risk manager" for the entire regulatory state, an integrated Congressional committee on risk, and an integrated statutory framework on risk.

Toward a Risk-Superior Regulatory State

If a central challenge of medicine is to manage iatrogenic threats, a central challenge of risk management is to deal with the iatrogenic impacts of our regulatory regime. But we should not attempt to do so based only on anecdotal and impressionistic accounts, like the list of conjectural examples proffered at the outset of this article. We need a careful study of regulatory iatrogenesis and remedies, in the tradition of Joseph Lister's studies of nosocomial infection and the Harvard Medical Practice Study of New York hospitals. Also, more than just a study of the adverse outcomes of risk regulation, we need studies on *all* outcomes, both beneficial and adverse, to both human and ecological health. This enterprise might be launched by a federal Commission on Risk Outcomes and Management, or by a White

[125] *See* Wiener & Graham, *supra* note 22, at 252-260.

[126] *See* Wiener & Graham, *supra* note 22, at 250-251; Sunstein, *supra* note 16, at 314.

House office, or by an academic group. We need an ongoing monitoring system to generate a series of health and environmental outcomes data, on both target risk reductions and countervailing risk increases, akin to the varied and detailed data series collected on the performance of the financial economy.[127] And we need a science of "risk management epidemiology" to link these risk outcomes to explanatory factors in social, economic, and regulatory choices.

The medical model of iatrogenic effects suggests that countervailing risks are pervasive and can be studied analytically and empirically. It suggests that such risks are not inherent in technology[128] nor in economic activity,[129] but arise from the limitations of institutional design and the costs of regulatory deliberation. It suggests that we should not blame the physician or the regulator, but rather that we should empathize with the exceedingly difficult choices that all decisionmakers must make when confronting risk-risk tradeoffs — and demand better. We should find institutional arrangements that reduce deliberation costs and error costs, and encourage and reward integrated analysis and synergistic approaches.

Concern about countervailing risks is warranted whether one views the regulatory state as a limited guarantor of private liberties, a scientific social adjuster, or a proactive parental caretaker. Risk management requires judgment and compassion — compassion not only for the victims of target risks who capture today's headlines, but also for the victims of the countervailing risks, particularly likely to be underrepresented in the hubbub of regulatory politics.[130] From this vantage, the politically divergent movements for "regulatory reform" and "environmental justice" share a common basis in concern about

[127] *See* Amartya Sen, *The Economics of Life and Death,* **Scientific American** 40-47 (May 1993).

[128] *See* Edward Tenner, **Why Things Bite Back: Technology and the Revenge of Unintended Consequences** (1996) (emphasizing inherent technological causes).

[129] *See* Viscusi, *supra* note 44, at 1448-1455 (emphasizing substitution effects, behavioral "lulling," the risks of compliance and cleanup activities, and income losses as the main causes of risks induced by regulation).

[130] Not every countervailing risk afflicts disenfranchised minorities, but the connection is important; it is in large part the weak political influence of both disenfranchised groups and the diffuse general public that renders their interests secondary to the target risks put on the political agenda by better organized factions. *See* Wiener & Graham, *supra* note 22, at 230-233; Diver, *supra* note 106, at 432, 434.

countervailing risks. Better addressing countervailing risks would improve both the efficiency and fairness of our risk management system. Indeed, good government may have a particular responsibility to make up for political distortions by showing special concern for the involuntary victims of countervailing risks. Consider the case of passenger-side automobile airbags: although they save more adults each year than they kill children, the children who have been killed by airbags can be seen as involuntary innocents with no political voice, while the adults saved are often unbelted voluntary risk-takers with choice in markets and potential voice in politics.[131] Much the same might be said of the victims of police chase crashes or environmental injustice.

Advocates of risk regulation should care about preventing countervailing risks for a strategic reason, whether or not they feel compassion for the victims of countervailing risks. If countervailing risks are left unaddressed, they may undermine public support for the regulatory state. Neglecting CRs can breed resentment and distrust of the entire regulatory regime, undermining its legitimacy and inviting a clumsy backlash against protective regulation.[132]

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[131] Since 1986, passenger-side airbags in the U.S. appear to have saved 332 passengers who would otherwise have died — but also killed 52 who would otherwise have survived, of whom 49 were children. (Driver-side airbags apparently saved 2,288 drivers but killed 35.) *See* Matthew L. Wald, *U.S. Agency to Permit On-Off Switches for Car Airbags*, **N.Y. Times**, Nov. 18, 1997, p.A1 (reporting latest U.S. Department of Transportation data). On balance the fatality risk for children in the front seat is increased 21 to 88% by installing a passenger-side airbag. John D. Graham et al., *The Cost-Effectiveness of Airbags by Seating Position*, 278 **JAMA** 1418, 1421 (1997). Because passenger-side airbags have saved several times as many adult passengers as children killed, at first glance it seems that $\Delta TR > \Delta CR$ ("more good than harm"). But the years of life lost are higher when children die than when adults die, so the countervailing risk is higher on a life-years lost basis than on a lives lost basis. And perhaps society could maximize $\Delta TR - \Delta CR$ by reducing the CR further. Moreover, the CR afflicts involuntary innocents: 12 of the children killed were babies in rear-facing infant seats placed in the front passenger seat (despite product warnings not to do so), *see* Wald, *supra*. And perhaps 2 of the older children killed were properly restrained in the front seat with seatbelts, compare Wald, *supra* (none of the children killed were properly belted) with John D. Graham & Maria Segui-Gomez, *Airbags: Benefits and Risks*, 5 **Risk in Perspective** no. 7 (Harvard Ctr. for Risk Anal., July 1997), at 2 (at least two of the children killed were properly belted). Even unbelted older children may be involuntary victims of airbag risks (e.g. if placed in jeopardy by their parents). Of course, even adult passengers may not be wholly "voluntary" risk-takers (e.g. if poorly informed).

[132] Senator Moynihan has made a similar point about welfare reform: "'whenever the critics said, correctly, that the welfare system was doing more harm than good, and

The medical model illustrates the institutional pressure for risk management systems to grow larger, more complex and more uncoordinated as they respond piecemeal and reactively to the side effects of prior piecemeal interventions. But the implication that optimality requires "less" medicine or regulation is unsatisfying. The optimal long-term solution to nosocomial infection from surgery is neither less surgery, nor more post-operative treatment for infections (though both of those made sense before antiseptics), but rather a new way of performing surgery that mitigates the risk of infection, such as Joseph Lister's. As discussed above, simple innovations such as washing hands before surgery, installing breathing monitors and alarms to alert anesthesiologists, and sharing information across the hospital, can prove to be dramatically "risk-superior." Similarly, the optimal long-term solution to countervailing risks of regulation is unlikely to be "less" or "more" regulation — neither, for example, a less powerful or deactivated airbag that spares children while sacrificing adults,[133] nor additional regulations prohibiting children from the front seat [134] (though each of these may make sense in the short term). It is rather a set of "smarter" information flows, analytic requirements and bureaucratic reward structures that stimulate creative, innovative and tailored "risk superior" interventions that reduce multiple risks in concert — such as a "smart" airbag which senses the speed of the collision or whether the occupant is belted or not (or even the occupant's stature) and adjusts the deployment threshold and force accordingly.[135]

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suggested that it be rethought, its defenders screamed 'racism' and 'slavefare.' They did that until there was no public support left at all. Now they are stunned at what they are getting'" in the 1996 welfare reform law, which Moynihan viewed as "'approaching an Apocalypse.'" R.W. Apple, Jr., *A Democrat: His Battle Now Lost, Moynihan Still Cries Out,* **N.Y. Times**, Aug. 2, 1996, at A10. Likewise, neglecting countervailing risks may be an invitation to overblown "deregulatory" legislation.

[133] *See* Janet L. Fix, *New Airbags Safer for Kids, Riskier for Adults,* **Atlanta J. Const.,** Mar. 15, 1997, p.A1 (discussing "depowered" airbags).

[134] France and Germany have until recently required children under a certain age (10 or 12 years) to sit in the back seat. Children have lower fatality rates in the back seat than in the front seat, even without counting fatalities from passenger-side airbags in front. *See* Graham et al., *supra* note 131, at 1424.

[135] A smart airbag which raises the deployment threshold when the occupant is belted is available in some Mercedes-Benz automobiles. *See* Jayne O'Donnell & James R. Healey, *Should Air Bags Deploy in Low-Speed Collisions?,* **USA Today**,

The optimal path is toward a set of "smarter" institutions. Optimal regulatory arrangements will involve more coordinated, holistic regulatory approaches that "treat the whole patient" from the outset. They will involve new institutional structures, new decisionmaking frameworks, and new policy instruments. Spurred by concerns about cost and iatrogenic injury, medical care is shifting from a framework in which heroic individual specialists treat particular diseases to one in which teams of health care providers work in concert to promote overall patient health.[136] Taking countervailing risks seriously, the regulatory state should likewise progress from its current atomized focus on particular target risks toward a teamwork, multitasking, integrated approach which promotes overall public and environmental health.



Mar. 17, 1997, at 4B. But such a smart airbag may be costly. *See supra* text accompanying notes 110-113. A dual-deployment airbag that inflates more gently in lower-speed collisions was available on some General Motors cars in the 1970s, but is not available today. *See* Robert C. Sanders, *Misplaced Blame for Air Bag Debacle,* (letter), **Regulation,** Spr. 1997, at 3.

136 *See* Audy, *supra* note 1, at 49; Havighurst, *supra* note 41.