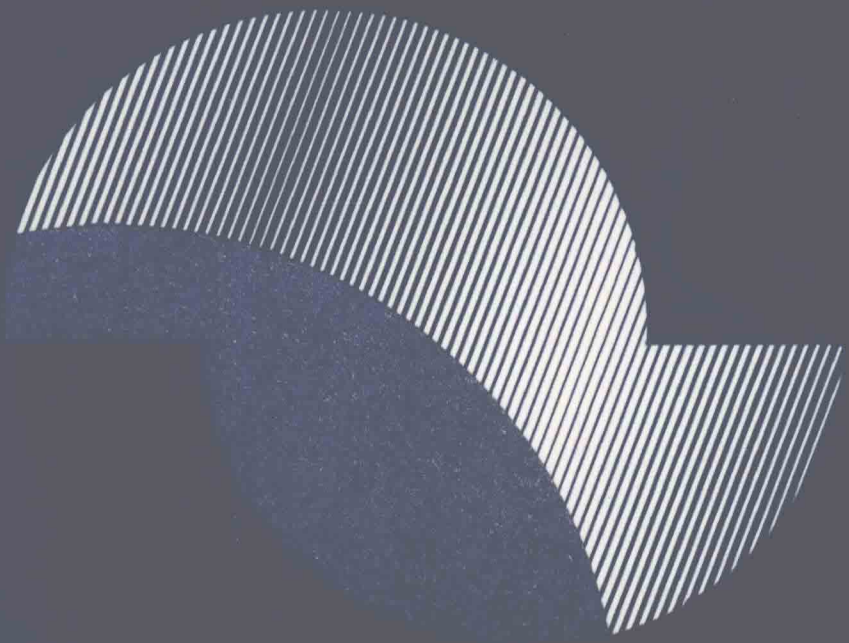
Breaking the Vicious Circle

TOWARD EFFECTIVE RISK REGULATION



Stephen Breyer

BREAKING THE VICIOUS CIRCLE

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the bequest of Oliver Wendell Holmes, Jr.,
Harvard Law School Class of 1866.

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To Joanna

PREFACE

This book is about federal regulation of substances that create health risks. We read almost daily about chemicals that threaten our air, our water, our lives—asbestos, benzene, PCBs, EDB, Agent Orange, Alar, and many others. We hear charges and countercharges: callous industry, greedy lawyers, lives unnecessarily lost, billions of dollars wasted in a pointless search for perfect safety. Were Milton alive, he might describe our present regulatory system as one where "Chaos umpire sits, and by decision more embroils the fray by which he reigns."

How should government deal with such problems? Which substances should we regulate? In what order? To what extent? Who should decide, and how? I shall approach these questions not as a scientist, or an economist, or a regulator, or a member of the public, but as a lawyer interested in the design of governmental institutions. Chapter 1, a substantive analysis, draws on the scientific, technical, and regulatory literature to describe three serious problems with the present regulatory system. Chapter 2, a political analysis, describes possible causes of these problems. Chapter 3, an institutional analysis, draws connections between problems, causes, and potential institutional solutions.

There is a subtext in this book, a subtext that seeks to respond to Oliver Wendell Holmes's admonition to look for the "general" in the "particular." The book suggests a general form of analysis—of underlying substance, political causes, and institutional solutions—that may apply to other public policy problems. I also hope that the book will encourage students of the law to become interested in the general kind of public policy problem I describe, a problem that combines substance, procedure, politics, and administration. Lawyers trying to help create better

institutional solutions to important social problems need not simply reason deductively from first principles of procedural fairness or democratic theory. Rather, they can impose those principles as proper constraints, within which they work toward the Platonic goal of every institution—uniting political power with wisdom—so as better to resolve the human problems of our times.

This book, more than most, owes its virtues to the help of many others, who were generous with time, information, and commentary. Let me mention a few of them: members of the Carnegie Commission Task Force on Science and Technology, including its chair, Helene Kaplan, as well as Alvin Alm, Richard Ayres, Douglas Costle, E. Donald Elliott, Richard Merrill, Gil Omenn, Irving Shapiro, and Patricia Wald, and staff members Jonathan Bender, Steven Gallagher, David Robinson, and Mark Schaefer; my colleagues at Harvard, Charles Fried, John Graham, Phil Heymann, and Richard Zeckhauser; scientific and regulatory experts, among them Richard Belzer, Devra Lee Davis, Adam Finkel, Richard Li, Charles Powers, and Richard Stewart; research assistants and helpers, including Kate Adams, Henk Brands, Robert Brauneis, Susan Davies, Jacques deLisle, Simon Frankel, Jeff Lange, Elizabeth Moreno, Aaron Rappaport, Kim Rucker, Simon Steel, and Michael Wynne; and my editor, Michael Aronson.

BREAKING THE VICIOUS CIRCLE

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SYSTEMATIC PROBLEMS 1

We regulate only some, not all, of the risk that fills the world. Any one of us might be harmed by almost anything—a rotten apple, a broken sidewalk, an untied shoelace, a splash of grapefruit juice, a dishonest lawyer.[1] Regulators try to make our lives safer by eliminating or reducing our exposure to certain potentially risky substances or even persons (unsafe food additives, dangerous chemicals, unqualified doctors). When the regulator focuses upon reducing exposure to a particular substance, when the risk is to health, when the risk is fairly small or uncertain, the regulator typically uses a particular system—a "heartland" regulatory system, the common features of which underlie many different statutory programs.

I focus upon this heartland system, using as an example the regulatory effort to reduce exposure to cancer-causing substances, both because of its illustrative power and because the public's fear of cancer currently drives the system. Still, much of what I say about cancer and similar health risks has broader application to other regulatory screening efforts, for example, whether or not to require seat belts for infants in airplanes, or how to regulate swimming-pool slides.

You need four pieces of background information. First, you need some idea of what I mean by "small risk," the subject of many regulatory programs. The best device I have found for explaining the term is the "risk ladder" prepared by Robert Cameron Mitchell, of Clark University (Figure 1).[2]

About 2.2 million persons die each year in the United States, out of a population of 250 million.[3] Knowing nothing about an individual person, one can assess a crude individual risk of death as just under 1 in 100, or

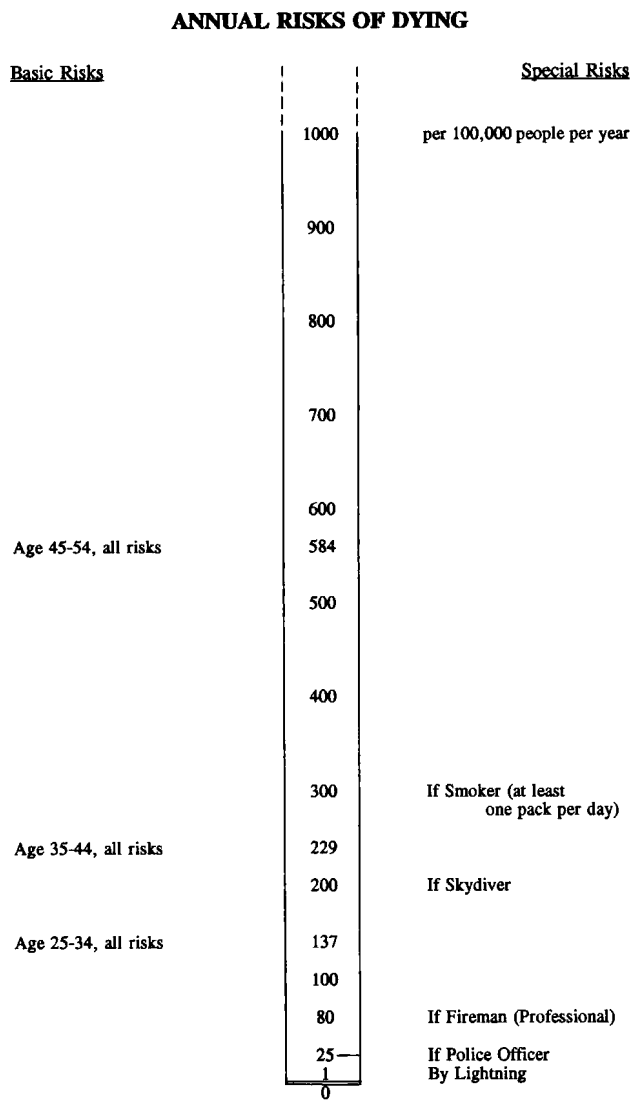
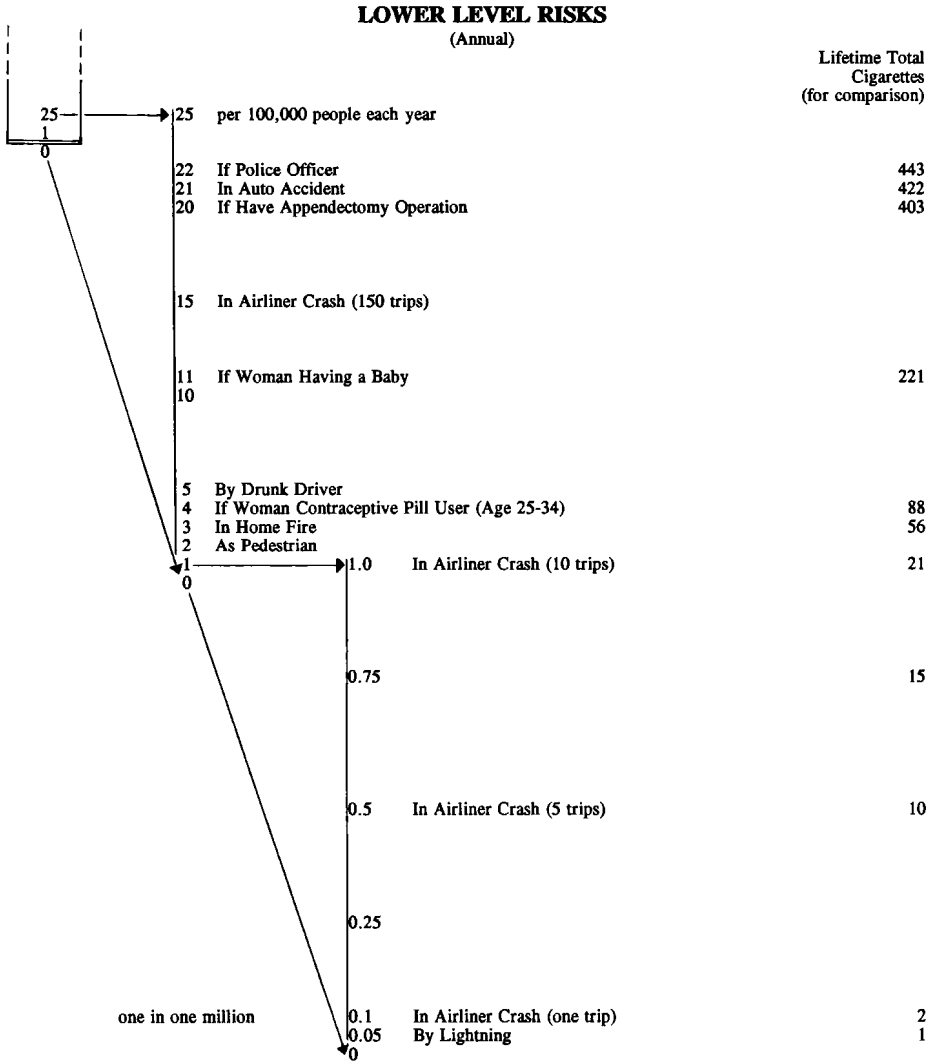


Figure 1. Risk "ladder" showing annual death rates for basic and special risks. *Source:* Robert Cameron Mitchell, Clark University.


LOWER LEVEL RISKS
(Annual)
Lifetime Total Cigarettes (for comparison)
25
1
0
25 per 100,000 people each year
22 If Police Officer 443
21 In Auto Accident 422
20 If Have Appendectomy Operation 403
15 In Airliner Crash (150 trips)
11 If Woman Having a Baby 221
10
5 By Drunk Driver
4 If Woman Contraceptive Pill User (Age 25-34) 88
3 In Home Fire 56
2 As Pedestrian
1
0
1.0 In Airliner Crash (10 trips) 21
0.75 15
0.5 In Airliner Crash (5 trips) 10
0.25
one in one million
0.1 In Airliner Crash (one trip) 2
0.05 By Lightning 1
0

1,000 out of 100,000, as shown at the very top of the figure. If one knows a person's age, one can make a more refined assessment, such as 137 out of 100,000 for all persons between 25 and 34. Certain individuals incur special risks of death because of their professions or their activities. A skydiver, for example, incurs a special annual risk of 200 in 100,000. Those special risks are shown at the right. The enlarged segment of the bottom of the ladder shows special small risks such as the risk of being killed by a drunk driver (5 in 100,000) or being hit by lightning (1 in 2,000,000).

Most people want to ask, "One in a million—is that a lot or a little?" There is no good answer to that question. If one focuses upon statistics, it may seem very little; if one tries to focus upon the 250 or so individual deaths that this number implies (in a population of 250 million), it may seem like a lot. Mitchell, who is an expert in trying to communicate this kind of information neutrally (he employs this chart to help elicit public reactions), uses a "cigarette equivalency" table, shown at the right of the lower-level risk ladder. It indicates that the risk of being hit by lightning is the same as the risk of death from smoking one cigarette once in your life, and it grades other risks accordingly. For present purposes, you should keep in mind that many of the regulatory risks at issue here are in the "blown-up" small-risk portion of the ladder.

Second, you should know a few facts about cancer, the engine that drives much of health risk regulation. Of the 2.2 million Americans who die each year, about 22 percent, or 500,000, die of cancer.[4] Just how many of these deaths are caused by exposure to substances that the government does, or might, regulate (such as chemical pesticides, various pollutants, or food additives) is the subject of considerable scientific dispute. Two leading authorities, Richard Doll and Richard Peto, in the early 1980s published important findings about the causes of cancer deaths (Table 1).[5] The table suggests that "pollution" and "industrial products" account for under 3 percent, or less than 15,000, and "occupation" accounts for a further 4 percent, or 20,000, of all cancer deaths.[6] Other, related scientific work indicates that substance exposure could account for up to 10 percent, or 50,000 deaths. The range of expert estimates seems to be roughly 10,000 to 50,000 deaths. Experts believe that only a relatively small portion of non-occupational cancers are "regulatable."[7] By way of comparison, con-

Table 1. Proportions of cancer deaths attributed to various factors.

Factor or class of factors	Percent of all cancer deaths	
	Best estimate	Range of acceptable estimates
Tobacco	30	25–40
Alcohol	3	2–4
Diet	35	10–70
Food additives	<1	–5[a]–2
Reproductive and sexual behavior	7	1–13
Occupation	4	2–8
Pollution	2	<1–5
Industrial products	<1	<1–2
Medicines and medical procedures	1	0.5–3
Geophysical factors[b]	3	2–4
Infection	10?	1–?
Unknown	?	?

Source: Richard Doll and Richard Peto, *The Causes of Cancer* 1256 (1981). Reprinted by permission of Oxford University Press.

a. Allowing for a possibly protective effect of antioxidants and other preservatives.

b. Only about 1 percent, not 3 percent, could reasonably be described as "avoidable." Geophysical factors also cause a much greater proportion of nonfatal cancers (up to 30 percent of all cancers, depending on ethnic mix and latitude) because of the importance of UV light in causing the relatively nonfatal basal cell and squamous cell carcinomas of sunlight-exposed skin.

sider that smoking-related cancer accounts for 30 percent, or about 150,000, of those 500,000 deaths.[8] You should also be aware (though this statement is more controversial) that the number of deaths from most of the major types of cancer does not seem to have been increasing, although there is some evidence of increases in the incidence of some, mostly less common, types of cancer.[9] The graph shown in Figure 2, from the American Cancer Society, shows an enormous increase in lung cancer, a decline in stomach and uterine cancers, and a roughly constant incidence of other forms of cancer.[10] In other words, the number of people who die each year from types of cancer whose incidence seems likely to be reduced by regulation is below an estimated ceiling that itself varies between 10,000 and 50,000; it is probably less than 2 percent to 10 percent of all cancer deaths; it is 7 percent to 33 percent

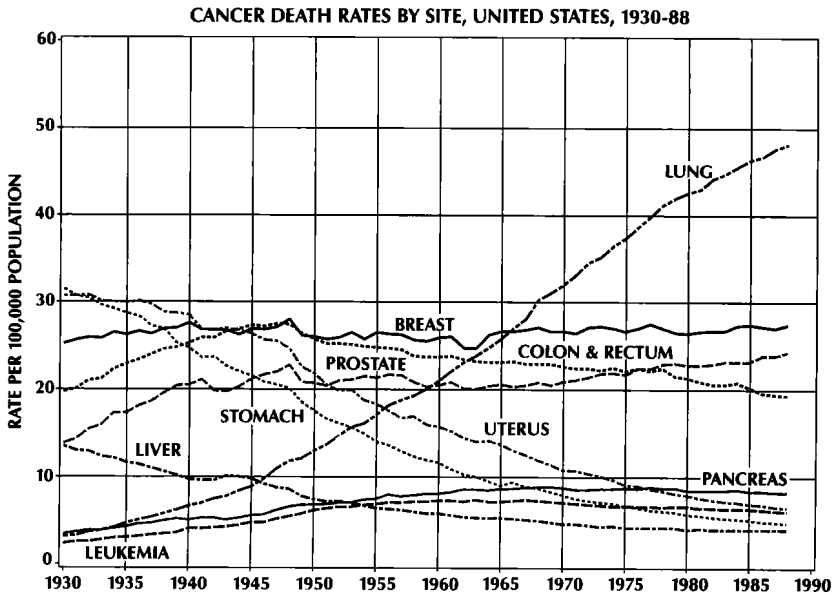


Figure 2. Cancer death rates by site of cancer, United States,1930–1988. Rates are adjusted to the age distribution of the 1970 census population. Rates are for both sexes combined, except breast and uterine cancer (female population only) and prostate cancer (male population only). *Source:* American Cancer Society, Inc., *Cancer Facts and Figures, 1992*. Used by permission.

of deaths associated with smoking. The numbers must range from less than 1 percent to less than about 3 percent of our 2.2 million annual mortality total.

Third, you must keep in mind that regulation designed to screen out risky substances, including cancer-causing substances, is embodied in many different regulatory programs—indeed, in at least twenty-six different statutes administered by at least eight different agencies.[11] This alphabet soup of agencies and programs includes such old friends as EPA, DOL, HHS, and NRC, administering, for example, CERCLA,[12] TSCA,[13] FIFRA,[14] CAA,[15] OSHA,[16] FDCA,[17] and AEA.[18] The rules and orders may vary from program to program, sometimes denying permission to market a product, sometimes insisting upon a cleanup, often setting some kind of "dilution" standard above which a product's maker, shipper, or user must provide special handling conditions. Regardless of the precise procedures and rules, however, each agency examines a