

Environmental engineer Ed Bouwer is sure about one thing: When it comes to health risks, uncertainty rules the day.

The *Illusion* of Certainty

By Fern Shen



WILL KIRK

Bran flakes or bacon this morning? Schedule that mammogram, or skip it for now? Start up with that powerful new cholesterol-busting drug, or pass on it?

An environmental engineering professor from Johns Hopkins University is probably not the *first* person most of us would turn to for help in making these potentially life-changing health decisions.

Edward J. Boucher's expertise is in urban pollution. His typical workday might include scooping muck samples from Baltimore's Inner Harbor or assessing how much toxicity was left behind in New Orleans by Hurricane Katrina.

Boucher, the chair of Geography and Environmental Engineering at the Whiting School, is careful to note in the preface to his new book on risk assessment that it does not purport to offer medical advice. (Neither he nor co-author Erik Rifkin, a Baltimore-based environmental risk consultant, is a physician.)

Still, *The Illusion of Certainty: Health Benefits and Risks* (Springer, 2007) is meant to influence patients' decision making. Boucher would love it if his book taught people how to review the literature objectively and impelled some to decide that, *for them*, it's best to skip the mammogram or the statins... and even that it's OK to indulge in that strip of bacon.

That is pretty far from the message most of us get from our personal physicians, or from Googling articles and looking for citations from the National Cancer Institute or highly regarded academicians conducting multi-center trials. Their statistics-backed advice always seems so definitive:

Keep cholesterol levels down to lower your chance of getting heart disease. Get a yearly mammogram to increase the chance of catching cancer early and saving your life. If the bran and exercise don't work, take cholesterol-lowering meds to lower cholesterol and risk of heart attack.

But these solid-sounding axioms are often actually riddled with uncertainty, argues Boucher, who has taken the time to look at the research in detail. "These health recommendations seem like they're based on fact, but to a great degree they are based on a judgment call, on somebody's determination of what risk is acceptable or unacceptable," he says.

So how does Ed Boucher have the chutzpah

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to, in effect, step into the exam room with you and your physician? It's because, he says, he has seen in his work on environmental hazards how much uncertainty there is in the research, and how that uncertainty gets lost when regulations are established, the media covers issues, and commercial interests spin the research findings.

"When you know the data and you see how it gets communicated, it's very clear," he says, "Uncertainty is not being explained."

While Rifkin and Bouwer have been immersed for nearly 25 years in risk management issues regarding environmental contaminants like PCBs, lead, and mercury, the specific impetus for their project was their own health issues.

"I have high cholesterol and [he] has high cholesterol and we were both told we had to lower it," says the 52-year-old Bouwer, who exercises, doesn't smoke, and has a serum cholesterol level that hovers between 230 mg and 250 mg. Rifkin's doctor wanted to put him on statins.

When the two of them dug into the subject, he says, they found that "the benefits of lowering cholesterol are not nearly what we are led to believe." The co-authors reviewed the data from large studies, such as the Multiple Risk Factor Intervention Trial (MRFIT), which looked at more than 350,000 males over a period of six years. What they found was that out of 1,000 people with high cholesterol (around 280 mg) there will be one additional death per year due to coronary heart disease, compared to 1,000 people with normal levels (between 210 mg and 220 mg.)

"That's an annual risk of 1 in 1,000 or 0.1 percent," Bouwer says. "Is it worth it, for that kind of risk,

to modify your diet, change your lifestyle, and take expensive drugs?"

They wrote up their findings and submitted the paper to medical journals. Every one of them turned it down. "We got laughed at because we weren't medical doctors," Bouwer recalls.

Undeterred, they wrote a book instead, recognizing they had a larger story to tell about how and why patients aren't getting all the information they need about health risks. Cholesterol remained as a chapter in the book and a prime example.

One of the major insights Bouwer and Rifkin offer readers is that risks are often characterized in *relative* terms, which makes them sound more dramatic. They demonstrate this with a hypothetical case of a new diabetes drug. The company might say, correctly, that a study showed the drug lowered the risk of getting diabetes by 50 percent.

That's *relative* risk reduction and it sounds pretty significant—until you see the actual numbers and figure out the *absolute* risk reduction. Of 20,000 subjects in the hypothetical study, half got the drug and half got a placebo. At the end of five years, two in the placebo group got diabetes compared to one in the drug-taking group.

That means one person out of 10,000 benefited over five years.

Put another way, the death rate dropped from two in 10,000 (0.02 percent) in the control group to 1 in 10,000 (0.01 percent) in the group taking the drug. Subtract 0.01 percent from 0.02 percent and you have the drug lowering the absolute risk by 0.01 percent.

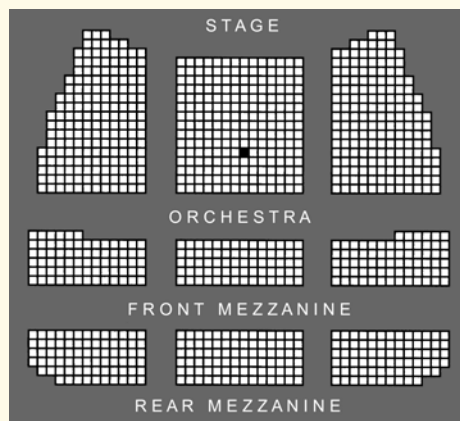
Viewed now in absolute terms, the study seems less meaningful, the drug's beneficial effect less certain. It's much less compelling than being told the new drug will halve your chance of getting diabetes.

Why is risk so rarely presented this way?

In the case of cholesterol, for instance, public health agencies and physicians routinely tell people to lower their levels because they are looking at risks on a nationwide scale, the authors explain. That 0.1 percent risk means that if there are 50 million Americans with elevated cholesterol, "then 50,000 lives might be saved annually by lowering those people's cholesterol levels."

Drug companies trying to sell drugs to lower cholesterol, meanwhile, have an obvious financial motivation to present the risks of high cholesterol in the most dramatic way possible. Screening tests and other forms of cholesterol-reducing care are also revenue producing. "And if you look at their ads, they always use relative numbers," Bouwer notes.

Included in the book are numerous charts using Risk Characterization Theater as a concept for unique graphics. For instance, if there were 1,000 people sitting in a theater with significantly elevated cholesterol levels of 280 mg, there will be one additional death per year from coronary heart disease as compared to 1,000 people with normal cholesterol. This leads the authors to conclude: "The benefits of lowering cholesterol are not nearly what we are led to believe."





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Risky business: Engineering's Ed Bower, with co-author Erik Rifkin, a Baltimore-based environmental risk consultant.

Patients themselves bear some responsibility, he also argues. Some might not want to take the time to sort out statistical issues or prefer not to have their faith in medical authorities shaken. And then there's the issue of how perception of risk can be skewed by its presentation. The authors cite a 1999 study, for example, in which patients, told that a drug has a 98 percent chance of having no serious side effects, will take that drug. But told that 2 percent of people *do* experience serious side effects, many of the same patients will refuse the drug.

According to Bower, another reason uncertainty tends to get lost is that so much of our health care advice comes via the news media, which is inclined to tell the story in the simplest and most dramatic way.

An October feature on mammography in *The Baltimore Sun*, for example, had a sidebar recommending mammograms every one to two years for women 50 or over.

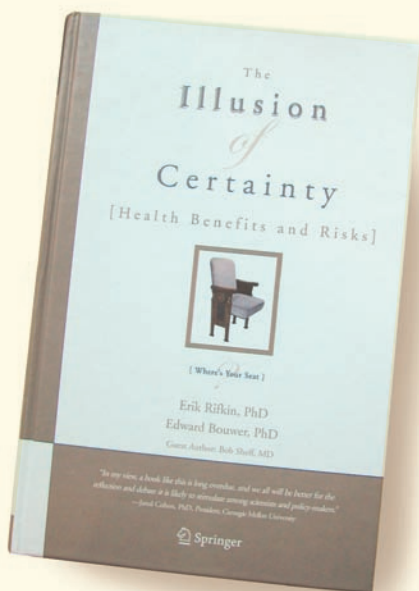
The article makes no reference to a subject discussed at length in *The Illusion of Certainty*, the controversy over the value of regular mammography to screen for tumors, the rate of false positives and negatives, the side effects of the test, etc. Several chapters in Bower's book address the benefits and risks of other screening tests, including those for colorectal and prostate cancer.

"What I do not like... is the lack of any information on the benefits (absolute numbers) of the various screening tests discussed," Bower notes. "The edict is, 'you should have all of these tests done.'"

Rifkin and Bower see their book as an analytical toolkit, enabling patients to pull away hype and oversimplification and get a clearer view of the facts. They include a tool that they call the "Risk Characterization Theater," which uses a seating chart for a 1000-seat theater to help readers more effectively visualize risks (see illustration on page 22).

For patients trying to decide whether to take certain drugs, undergo chemotherapy, get screened for cancer, Rifkin says, there's a lot at stake.

"These drugs are all expensive, they may result in all sorts of adverse side-effects and costs," he says. "Patients have the right to have the best information available."



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