DON RITTER
15TH DISTRICT, PENNSYLVANIA

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NATURAL RESOURCES AND ENVIRONMENT

Congress of the United States
House of Representatives
Washington, D.C. 20515

124 CANNON OFFICE BUILDING
WASHINGTON, D.C. 20515
(202) 225-6411

DISTRICT OFFICES:

SUITE 1005
1 BETHLEHEM PLAZA
BETHLEHEM, PENNSYLVANIA 18018
(215) 866-0916

ROOM 212
ALLENTOWN POST OFFICE BUILDING
ALLENTOWN, PENNSYLVANIA 18101
(215) 439-8861

ROOM 705
ALPHA BUILDING
EASTON, PENNSYLVANIA 18042
(215) 258-8383

June 17, 1980

Mr. Joseph M. Hendrie
Chairman
Nuclear Regulatory Comm.
Washington, D.C. 20555

Dear Mr. Hendrie:

On May 14 and 15 hearings were held on my Comparative Risk bill, H.R. 4939. I thought you may be interested in the attached articles that resulted from those hearings.

With kindest regards, I am,

Sincerely,

Don

DON RITTER
Member of Congress

DR/vs
Enclosures

7/2..To OGC for Appropriate Action...Cpys to: RF...80-1350

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WALL STREET JOURNAL.

WEDNESDAY, JUNE 11, 1980

The Risk-Benefit Debate

By Arlen J. Large

WASHINGTON—"Maybe the time is coming when 14,000 scientists should march on Washington and say, 'We've had enough.'"

The idea seems to appeal to Donald Ritter, a metallurgical engineer who is one of the few House members with scientific training. The Pennsylvania Republican's vision of marching scientists is prompted by what he thinks are "emotional and political" government regulatory methods. He wants more "rationality" in the way federal regulators do their jobs.

And so do many others. Capitol Hill now is a-sprout with terms like "risk-benefit analysis," "risk assessment" and "risk comparison." Legislators are hoping that one approach or another may permit specific assessments of dangers to public health and safety—and that government regulations can be streamlined as a result. The general idea, says Republican Rep. William Wampler of Virginia, is to make "some sense out of a hodgepodge of regulatory systems that we find daily causing more and more confusion and chaos in our land."

Comparing one risk against another for purposes of regulatory emphasis is "common sense plus arithmetic," says Harvard physics professor Richard Wilson.

Business tends to favor the structured new forms of risk-benefit analysis, in hopes it might be spared some of the demands of wild-eyed regulators. Environmentalists and others who value business regulation are suspicious. "In my opinion the true power of these techniques is far less than it is represented to be," says David Doniger, a lawyer for the Natural Resources Defense Council. "When you try to over-formalize, you slow the process down and increase the number of hoops you have to jump through before you can regulate."

Ranking Cost-Effectiveness

Exactly what are they arguing about? Some analysts say it's possible to rank the cost-effectiveness of various government actions fostering safety and health, so that money can be aimed where it will do the most good at least cost. An example of this kind of ranking has been worked up by the Societal Analysis Department of General Motors Corp., which puts numerical values on various measures that would increase the U.S. population's average lifetime by one year.

On the GM sample list, establishment of special ambulance service for heart-attack victims would be the most cost-effective, with a low score of 182 index points. A higher cost-index of 3,250 is calculated for requiring people to use seat harnesses in cars. Lighting all expressways would achieve a one-year gain in population longevity at a much higher cost-index of 310,000. Requiring auto producers to meet next year's statutory tailpipe emission standard for carbon monoxide would require a lofty cost of 27.5 million index points. That's the least cost-effective measure on GM's list; the emission standard is a very sore point with the car companies.

Such rank ordering on the basis of efficiency provides a rather sound, straightforward perspective in which to place any [illegible] extending programs for which costs can be estimated," says Walter Alberts, head of GM's Societal Analysis Department.

[illegible] form of analysis of [illegible] to weigh risks versus benefits in the regulatory process. This notion can [illegible]

things when they talk about the "benefit" that's being measured.

Business spokesmen tend to argue that regulators should pay more attention to the benefit of the product that's being regulated when evaluating that product's risk. This point comes up when the Food and Drug Administration is trying to weigh a new drug's health benefits against the risk of possible side-effects. On the other hand, environmentalists often speak of the need to better measure the benefits of regulation itself, such as the reduced sickness resulting from cleaner air.

There's also considerable debate over the role of science in the regulatory process. Business groups hope that a greater input from detached scientists would bring more "reasoned rational decision-making," in the words of a National Association of Manufacturers witness at a recent congressional hearing. That way, warn skeptics, lies the danger of "a tyranny of experts."

Legislators are hoping that one approach or another may permit specific assessments of dangers to public health and safety — and that government regulations can be streamlined as a result.

Science ought to play just one part in a two-part regulatory job, says Philip Handler, president of the National Academy of Sciences. That private organization of scientists has considerable experience in this area because Congress has given it a specific charter to give the government advice on scientific questions.

"The *estimation* of risk is a scientific question, and therefore a legitimate activity of scientists," says Mr. Handler. "The *acceptability* of a given level of risk, however, is a political question, to be determined in the political arena."

In a rough-and-ready way, that two-part process now shapes some regulatory decisions. Canadian laboratory tests in 1977 showed that immense quantities of saccharin would cause bladder cancer in rats, and the FDA moved to ban the artificial sweetener from the market. There was a terrific uproar from diet-drink makers and fat people, and Congress voted to keep saccharin on sale pending further tests. Despite an intervening National Academy of Sciences report saying saccharin indeed poses a low-level cancer risk, Congress has just passed a new law further postponing the FDA ban. In the political arena, saccharin so far is considered an acceptable risk.

And the political decision can go the other way. In 1974 two University of California chemists, using only mathematical models, declared that man-made fluorocarbon gases used as propellants in spray cans for deodorants and bug-killers can deplete protective ozone in the stratosphere. Again, the National Academy of Sciences agreed, warning there'll be more human skin cancer if more of the sun's ultraviolet light reaches the earth. Last year the government banned these gases from spray cans, and there hasn't been a peep from Congress. Fluorocarbon propelled deodorants clearly aren't an acceptable risk in the political arena, mainly because substitute gases were readily available. Regulations have been moving much more cautiously, however, in controlling the use of fluorocarbons as refrigerants; in this use, there are no easy substitutes.

The "decisions" in those two examples look disjointed and sloppy. Because the legislative mind instinctively looks for an institutional fix, there are all sorts of proposals in Congress to forge a tidier link between scientists and regulators. Virginia's Rep. Wampler is sponsoring a bill establishing a formal conduit between regulatory agencies and a new 15-member "National Science Council." After hearing scientific pros and cons of whether a chemical, say, can cause cancer, the council would decide the question by a two-thirds majority vote. The decision would be formally handed to the regulators, who would decide whether the risk warrants depriving society of the chemical's benefits. As it is now, Mr. Wampler complains, the lawyerish regulators have been "bending science."

Pennsylvania's Rep. Ritter wants to require regulators to make "objective" comparisons between the risks of various actions. Before banning those ozone-eating fluorocarbons, for example, the regulators would have had to compare the dangers from a general increase in ultraviolet radiation with a person's deliberate exposure by sunbathing. "When the public finds out about this they may say, 'Hey, let me make the choice,'" says the freshman Congressman.

Mr. Ritter would like to insert some kind of risk-comparison requirement in a regulatory reform bill that's pending in both houses. The Senate Judiciary Committee has already approved a version that would require more agencies, as some do already, to publish estimates of both the cost and expected benefits of "major" new rules, along with alternative ways of achieving the same end.

Ponderous Reaction

Of course the regulatory bureaucracy itself can hear all this risk-assessment music, and it is in the throes of a typically ponderous reaction. As early as 1977 the major health and safety regulatory agencies formed something called the Interagency Regulatory Liaison Group, complete with task forces, to draw up risk assessment guidelines. And plans are well along for the formation of a Society for Risk Analysis, with international membership, that will publish a journal on the subject starting in 1982.

Yet some government regulators say their missions don't always square with the kind of high-precision risk assessment techniques being discussed now. "We operate with unknowns," says Bailus Walker, health standards director for the Occupational Safety and Health Administration. "We must act on the best available evidence because the alternative of waiting for perfect evidence is unacceptable."

There's an obviously growing demand for a push-button objectivity machine that would reduce the "unknowns" faced by OSHA and other agencies and make their rules seem more reasonable and acceptable. But it's likely no matter what the machine spewed out as scientific fact, someone in the political arena—a trade association, a union lobby, a powerful Senator—would be waiting to challenge it. Risk assessment is just another name for a judgment call, and that won't be changed by a scientist-match on Washington.

Mr. Large, a member of the Journal's Washington bureau, covers scientific matters.

-lealth risks: Just when are you safe enough from them?

REP. DON RITTER

ore you pop open that can of beer, stop and think
arcinogens. Before you spread that peanut butter,
d consider the dangers of aflatoxin.

Before you climb aboard that airliner or turn on your stove, think about radiation. Before you sip that glass ater, think about TCE and Kepone. And before you take ...eep breath, think long and hard about SO2 and open c...s.

Stories about new risks we never even knew existed re jolt us almost daily — risks discovered by super- otific instruments. Things we used to imagine only on ls with skull-and-crossbones now show up in our food, nd water.

Meanwhile, regulatory agencies charged with ecting our health and safety are having fits trying to le all this new information. Dealing with risks has me a nightmare of confusion and conflict.

Is there any hope for a rational way to deal with the ldering array of risks (and potential risks) to human nd health?

There is. Because now, fortunately, even in the midst reign crises and domestic political dramas, a poten- historic change is under way that can help — a ge in the way Washington regulates to protect human nd health.

The idea behind that change is simple yet powerful: to com...ng risks of alternatives before regulating — thereby getting more benefit out of our regulatory rs.

nd if this month's Capitol Hill hearings on a "risk arison" bill were any indication, Congress just may the verge of one of the most important improvements direction of regulatory reform of the past 35 years.

ongressmen from both parties and five House com- es, federal regulators, two academic thinkers and ntatives of the media, labor and industry jammed storic Space Technology hearing room for two days of g ideas about how government can compare risks regulates to protect the public in areas such as , medical drugs and pollution.

The focal point of the hearings was H.R. 4939, the Ritter "risk comparison" bill. It would set up for the first time a mechanism for U.S. regulatory agencies to compare risks to human life and health of alternatives (like coal versus oil, nuclear or synfuels); to compare the risks that would be reduced by different levels of regulation (like different allowable levels of a certain air or water pollutant); and — most importantly — to explain to the public the size of those risks in comparison with everyday risks like driving, walking down stairs, smoking or flying.

So much interest was generated by the hearings that many of the nearly 300 persons who attended had to be content with standing room. The hearings evoked broad, bipartisan support for the comparison of risks concept. In fact, four subcommittee chairmen, along with Committee Chairman Don Fuqua and Ranking Minority Member John Wydler have cosponsored the bill itself.

And comparison of risk language will be offered as an amendment to the landmark new Regulatory Reform Bill, which is expected to pass Congress later this year.

Clearly, risk comparison is an idea whose legislative time is at hand.

Adopting this concept would improve regulation virtually across the board in the 1980s. At a time of frightening inflation, public complaints about indecisive and often poorly directed regulation have grown louder. Too often government over-regulates relatively minor risks and practically ignores major ones. Comparison of risks is a reform that responds to that public grievance. Better targeting of tax dollars . . . better priority-setting . . . a more rational way to regulate; these are its goals.

Comparing risks won't cure all regulatory problems. But it's surely a step in the right direction.

Testimony at the risk hearings underscored how broad yet sensible an idea risk comparison can be. Members of five distinctly different committees — Commerce, Agriculture, Science and Technology, Judiciary and Public Works — each took turns explaining how comparing alternative risks would improve the regulatory process in his individual committee's area. Dozens of examples were outlined. For instance:

- We want to protect our families from disease. But which risk is greater — the risk of getting a serious flu or the risk of complications from flu vaccinations?
- We want safe foods to eat. But which hazard is more serious — the possibility that saccharin may cause cancer or the hazard of heart disease from obesity that may be caused by overuse of sugar?
- We want to reduce highway deaths and injuries. But which potential solution is best worth our limited resources — Seatbelts? Mandatory airbags? Better highway lighting? More emergency and medical equipment? All might help, but what should be the priorities among them?
- We want to protect our children's safety. But which danger is greater — potential fire death caused by flammable pajamas, or the possibility of cancer caused by a flame retardant in the pajamas?
- We want safe medical drugs. But when a drug developed in the United States that has spared European men from prostate surgery has to date been regulated out of the American market because it contains a substance potentially carcinogenic to laboratory animals if they receive it in very large doses, has the public good really been served?

We can't regulate away every single risk in life — that, unfortunately, would be impossible. Three days after the comparison of risks hearings, by coincidence, Mt. St. Helens exploded, smashing every air pollution standard in the book. It served to remind us that risks exist in nature itself, that they often overlap man-made risks. Yet we can't ignore risks either.

So what are we to do? And how is the public to help make judgments about risks in a free society?

We should start by looking at each risk in its proper context. Everyone takes them. As Harvard physics professor Richard Wilson put it in a fascinating "Technology Review" article published last year, "The moment I climb out of bed I start taking risks." Taking a shower in a slippery tub, drinking coffee with caffeine, driving to work on a busy highway, eating peanut butter with naturally-occurring aflatoxin . . . all these pose a laundry list of risks — risks that people choose to take for various reasons.

Since everyone takes risks, it should come as no surprise that intelligent comparisons can and should be made by government regulators.

They're going to have to start asking some basic questions about risks. If they restrict some things — such as the burning of coal — will its alternatives (like the use of more OPEC oil) be worse? Or if they set an allowable air quality limit of 1 unit on a certain pollutant, will they really protect human health appreciably more than if they had set it at 10 units?

Finally, when they consider restricting this drug or banning that product, what analogies with day to day risks can be made, so the public can understand what otherwise would be just so much scientific mumbo-jumbo.

Once we have a better handle on how comparatively dangerous each risk is, we stand a much better chance of targeting society's limited resources toward reducing the most serious dangers to our lives and health. As Professor Wilson put it, "What we are not doing, and need to do, is start comparing the risks of various activities and then reducing the largest risks — which may not be the obvious ones."

In other words, our sophisticated measuring devices should be used for more than just measuring. They should be used for comparing as well.

The future of America's jobs, economic and life- and progress toward a safer society may well depend on whether regulators start systematically comparing alternative risks. After all, history reminds us that the basic thrust toward better health and safety has been provided by the overall economic and technological advance of American society. Today, that thrust can be guided and improved by wise, intelligent regulation where necessary.

Keeping that economic advance alive — and continue to provide Americans with increased health and safety — is where comparison of risks can help.

None of this is to suggest for a moment that government shouldn't try to reduce public risks. It should.

But with Congress getting interested in comparing alternative risks, we may be witnessing the first stirrings of a more rational, science-based approach to government. That doesn't usually happen here on Capitol Hill.

But it's a welcome change when it does.

Need for comparative risk analysis debated

Even the committee members were surprised by the turnout. As Rep. George E. Brown (D.-Calif.), chairman of the House Subcommittee on Science, Research & Technology put it, "I am surprised at the large number of people interested in what I thought was a rather esoteric subject"—comparative risk analysis.

What the people who packed the committee room had turned out to hear about and comment on was a bill, H.R. 4939, introduced by Rep. Don Ritter (R.-Pa.), Congress' only Ph.D. metallurgist, which would provide a federal mechanism within the Office of Science & Technology Policy for assessing the comparative risk involved in federal regulatory actions in scientific, technological, and related fields.

A number of federal agencies do perform some type of risk assessment, but there is little consistency in how they do it, and some of the blame lies with Congress. Richard Dowd, director of the Environmental Protection Agency's Science Advisory Board, points out that the agency administers seven major pollution control laws that require some type of risk assessment. For each act Congress has provided guidance on the nature of the risk assessments that are to be used in promulgating regulations and how these assessments are to be taken into account. However, this guidance differs not only from one act to another but often from one section to another in the same statute.

For example, the Clean Air Act specifies that air quality standards should be set at a level to avoid all health effects with a suitable factor of safety, whereas the Toxic Substances Control Act specifies that the regulations should eliminate only "unreasonable risks," involving a comparison of the risks and benefits associated with the substance.

The Ritter bill would try to make the process less complicated by requiring that any comparison of the risks involved in alternative scientific, technological, or related action include: first, an evaluation of the risks to human health and life that would be incurred or increased by the proposed action or course of action in comparison with the risks that would be reduced or eliminated thereby; and second, an evaluation of the risks to human health and life that would be incurred, increased, reduced, or eliminated as a consequence of the proposed action in comparison with the corresponding risks associated with alternative action or actions. Such comparisons would be made both within and among agencies.

Ritter: step toward regulatory reform

In addition, the bill directs OSTP to find out what types of risk assessment are being done by what agencies, and gives it responsibility for integrating and coordinating such assessments. It also is to report to Congress on what federal laws and regulations may need to be changed to facilitate risk assessment activities.

As Ritter sees it, the bill represents a real step toward regulatory reform, toward fine tuning and focusing the regulatory system. The idea is to make intelligent comparisons between alternatives so that limited resources can be focused on the most hazardous conditions and the public gets the most protection for its tax dollar, he explains.

"We need to be aware," he says, "of those areas where we tend to neglect actual probabilities of harm, and remind ourselves that we may be misallocating regulatory or scientific resources to areas where risk is much less. Such an analysis would provide an objective means of deciding if the federal government is placing its efforts where the risks are the greatest."

The bill obviously has struck a chord among Ritter's Congressional colleagues, an unusually large number of whom showed up to voice support for the bill. For example, Rep. William Wampler (R.-Va.), the ranking minority member of the Agriculture Committee, which has been dealing with the problem of nitrites, told the subcommittee that "too many regulatory decisions are based on science that has been bent or is at least 'hazy.' We have got to do something to get more reasonableness back into our regulatory decisions. The Ritter bill is a significant proposal, a step in the right direction toward making sense out of the present hodgepodge of regulations."

Rep. Mike McCormack (D.-Wash.) says that it is of critical importance not only to get a method for analyzing risk in place but also a method for measuring the magnitude of the risk. Rep. James Martin (R.-N.C.) praises the bill for seeking "to modernize our regulatory approach according to modern science. We can now detect ingredients at levels so small as to be of no biological significance whatsoever. Law and regulation must take this into account."

But although the Congressmen see a need for Ritter's bill, the agencies it would apply to do not. Richard Preager of OSTP, although agreeing with the bill's objectives, believes that it is not at all necessary to codify the process into law and he strenuously objects to giving a formal role in the process to OSTP. OSTP, he says, is much too small to handle it aside from the fact that such an operational authority would detract substantially from the office's main role of providing advice to the President.

Witnesses testifying for EPA, Food & Drug Administration, Food Quality & Safety Service, Occupational Safety & Health Administration, and the Consumer Product Safety Commission all pretty much agreed that although comparative risk assessment might be useful in setting priorities, they are doing pretty well just as they are and that no new legislation is needed.

The agencies' view is supported by David D. Doniger of the Natural Resources Defense Council, who contends that H.R. 4939 appears to accept the fundamentally simplistic view of risk assessment and risk benefit analysis, understating its imperfections and thereby overstating its usefulness.

But the agencies' own view of how well they are doing their job is not shared by the industries they regulate. Both the National Association of Manufacturers and the American Industrial Health Council believe that comparative risk analysis is a must, especially to get a handle on the cost of regulations. These two groups also support the formation of an independent panel to review the scientific and technical aspects of a proposed regulation and to evaluate all evidence relevant to whether a substance or a process or a technology poses problems, and what the alternatives are for controlling perceived hazards. □