Monsanto news

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Bob Downey
~~Dick Saucier~~
Jim Woeff

THINKING SENSIBLY ABOUT CONSUMER RISKS AND BENEFITS

Address by John W. Hanley
Chairman and President
Monsanto Company
To Executives' Club
Chicago, April 29, 1977

Twenty-six years ago, I landed at Midway one night as the first step in moving my family from Richfield, Minn., to Chicago. While I'd been selling soap in such far-distant places as Sleepy Eye, Minnesota, Musselshell, Montana and Turtle Lake, North Dakota, I didn't picture myself as a small town boy. I didn't stare out of the cab windows at the tall buildings going downtown to the Stevens — principally because it was dark!

I do remember early in the ride asking the cabbie, "What's that funny smell?" "Money" he replied! (Later I discovered it was the stockyards.) But he was right — it was money! This is the Big League and I learned a whole lot — mostly the hard way.

I've always believed that the tough experiences I gained here had a lot to do with the opportunities that later came to me in corporate life, first at Procter & Gamble and now at Monsanto. So I retain pleasant memories of Chicago and the business community that is represented by The Executives' Club.

I'm flattered to have been asked to speak to this club and to represent Monsanto before one of the nation's top leadership groups. The ideas generated here are studied and talked about throughout the country. So one approaches your podium with an appropriate respect for this forum's national stature.

It's in that spirit that I selected the topic, "Thinking Sensibly About Consumer Risks and Benefits." You might at first wonder if the nature of Monsanto's business doesn't insulate us from the controversy that today surrounds the issue of risk and benefit in the consumer marketplace. We are, after all, essentially a supplier of intermediates and raw materials for industry and agriculture.

FDA action "capricious"

Let me assure you that no industry in today's environment can be completely isolated from that controversy, least of all the chemical industry.

The consumer firestorm ignited by the proposed ban on saccharin by the Food and Drug Administration followed by only a few days the suspension of Monsanto's innovative plastic beverage bottle. We and Coca-Cola had successfully introduced what we call our Cycle-Safe® bottle in a number of major midwestern and eastern markets—and it was going to glory!

That regulatory action against us—termed "arbitrary and capricious" in a stay subsequently issued by a Federal Appeals Court—was based on the same kind of studies that brought about the threatened saccharin ban. In both cases, rats were fed doses of substances under examination at rates that are remote from human experience.

Not surprisingly, consumers have sharply protested what they see as an unreasonable application of government authority to force accepted products—like saccharin and others—from the marketplace, without due consideration of benefits as well as risks.

Had risk-benefit analysis of the Cycle-Safe situation been made by the FDA beforehand, it would have revealed that in the Chicago area, for instance, Monsanto would be forced to close down our new Park Forest South bottle-making operation with the consequent loss of almost 1,000 jobs here and at other Monsanto locations.

J. W. Hanley

But I want to speak to you today not as some embattled or embittered manufacturer crying "foul" in defense of narrow economic interests. Rather, I speak as a concerned citizen who sees a growing tendency for irrationality to be substituted for reason in discussions of, and actions relating to, consumer safety and acceptable risk.

So let's examine some of the more serious consequences, including the long-term effect upon innovation and creativity. Then I hope to offer a more realistic perspective against which we can evaluate risk and safety. And, finally, to propose what we at Monsanto believe is a positive contribution to enhancing scientific understanding and the eventual resolution of these important matters as they affect human health.

At the outset, let me underscore the fact that we at Monsanto defer to no individual or group in our concern for the quality and safety of our products. There is too much at stake—morally, ethically, financially—to defend unsafe products. But, I contend, the process of safeguarding human health—and, in the specific case I cite today, our food supply—can and should be a rational one.

It began with cranberrys

Where did it all begin? The first signal of an evolving climate may well have been the Cranberry Crisis of 1959. Remember that? Few of us could recite the specific details of that incident—which dealt with the suspected contamination of cranberry shipments in two western states—but most of us recall that consumers all over the country were thoroughly confused at Thanksgiving time. (And the government didn't help much when it proposed sauerkraut as a cranberry substitute!)

Then came the ban on cyclamates, the only other synthetic sweetener besides saccharin—an action vigorously debated within the scientific community, worldwide, to this day.

I could go on and on with examples that seem to haunt the marketplace. There was the interlock seat-belt controversy—a public safety-consumer risk question of the first magnitude where the public loudly and firmly expressed its view. Then there is the synthetic food coloring controversy and questions about aerosol sprays and the ozone layer. And more—and more—and more!

Impact of regulatory forces

The net effect is confusion and a growing disruption of creativity and innovation—that typically American life-giving process which painstakingly brings products from the idea stage to commercialization. The *total* process involves careful commitments of human and financial resources to develop new products in a fashion that will best serve consumer needs while providing a realistic return to investors, inventors and others involved in the cycle.

One does not have to look far afield to gauge the impact that regulatory force has had upon the innovation process. In the pharmaceutical industry, to use a prominent example, the costs of discovering and developing a new ethical product have soared eighteenfold, with about half the increment attributable to FDA regulation. The average number of new drugs approved by FDA declined by roughly 70% between the 1957-61 period and the 1972-75 span.

I cite these pharmaceutical industry examples to underline the divergent as well as critical impact this bridle on innovation has upon American life. Within Monsanto's own direct experience, the suspension of our new plastic beverage container is a vivid example of stifling creativity—in ways that are not fully known to the American consumer.

Let me explain what I mean in some detail, because our experience may spell valued lessons for your organization—as it has for mine.

The controversial action centers on a chemical substance known as acrylonitrile, or "AN" as we call it. This substance has been used in a variety of food-contact applications for more than 30 years and is an ingredient in our plastic bottle.

Long before the bottle reached the marketplace, academics, public interest group representatives and outside scientific testing agencies were given extensive data with which to make their own evaluation of the environmental consequences of this new container—the plastic from which it was fashioned, its energy consumption, convenience, safety, recyclability and so forth.

Bottle preferred by consumers

During the product's long gestation period, we organized a scientific symposium which brought together those who opposed as well as those who favored the bottle. At that time we said, "It is Monsanto's belief that when industry anticipates any action that can have large scale effects, it is desirable that the scientific basis for this action should be subjected to scientific peer review and criticism."

And so it was. These experts, and others inside and outside government, concluded that Monsanto had carefully tested and was continuing to test all the impacts of the bottle, including possible migration of AN from the wall of the bottle into the beverage.

Following FDA approval of the bottle as a container for carbonated beverages in February 1975, we and Coca-Cola committed considerable resources and effort to the introduction of this wholly new packaging concept. Consumer tests quickly demonstrated that the lightweight, shatter-resistant plastic bottle was overwhelmingly preferred by shoppers. At the same time, it represented contemporary contributions to those interested in easier distribution, recyclability and energy savings as compared with glass bottles.

Interim tests at variance

In mid-January of this year, the Manufacturing Chemists Association presented FDA with an interim report from an industry-sponsored chronic feeding study of AN. It showed that some rats, fed three different levels of

To Monsanto marketing personnel:

In his recent speech before the Executive's Club of Chicago, Mr. Hanley outlined Monsanto's commitment to be a leader in demonstrating to the public the risks and benefits of chemical products. This commitment is an important part of the corporation's social responsibility objective.

I believe it is appropriate for you to read his speech in order to gain a greater insight into the role Monsanto is undertaking in these important matters.

We are openly seeking support for our efforts from industry, and your contacts in the marketplace offer an opportunity to reach this audience. I urge you to use this speech, as you feel appropriate, as a handout to your accounts and prospects.

Bart MacDonald
director, corporate marketing coordination

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AN in their drinking water, did develop tumors. But to ingest an amount of AN equivalent to even the lowest level fed to the test animals, a child would have to drink more than 3,000 quarts of beverage every day for one year from Cycle-Safe bottles.

We pointed out to the FDA that we were *concerned* by the findings—but that they were preliminary and inconclusive...that they were at variance with *other* tests on acrylonitrile...and that Monsanto would immediately begin with further AN feeding studies at levels that would provide more realistic evaluation. Our plans drew a favorable response from the FDA.

But a month later, the agency announced its intention to suspend approval of carbonated beverage bottles made from AN.

Ironically, the same week that the FDA acted on our bottle, the Canadian government approved acrylonitrile for use in plastic soft drink containers.

But where innovation has suffered a double blow in this instance is that Monsanto and Coca-Cola were poised to introduce a *refillable* plastic beverage container—a bottle that both the FDA and EPA had said publicly was the most environmentally desirable method of packaging soft drinks yet conceived—perhaps as a meaningful answer to some of our nation's litter problems. Obviously, we cannot move ahead with this unique answer to the "throwaway" question now that the fate of the container business has been jeopardized by the FDA order.

It is at junctures such as these that all of us—consumers and concerned citizens—must ask if reason and common sense are being brought to bear on decisions that not only concern human safety but also affect jobs and the commitment of vast resources.

To challenge, as I most certainly do, the advisability of product bans based on evidence that is subject to widely different interpretation within the scientific community, is not to challenge the government's right and obligation to protect and safeguard public health where facts so justify.

What is safe???

It is appropriate then, to raise the questions, "What is safe?" and "How great is the risk?"

Not for a moment would I suggest that these are simple questions. Or that those who may disagree with our viewpoint are motivated by malice or ignorance. These are enormously complex issues on which men of good sense and good will can, and often do, differ. But what is missing from the current dialogue, in my judgement, is a rational perspective on consumer risk.

Just to illustrate—and not to make light of concerns for toxins in our food supply—scientists tell us that four pounds of raw cauliflower, eaten at one sitting, contain enough toxins to produce serious, if not fatal, effects in humans. Doesn't it seem as unreasonable to assume that anyone is going to drink thousands of quarts of a beverage every day for a year as it is to assume that anyone will eat four pounds of raw cauliflower at one sitting?

The Delaney Amendment

Even when a toxic chemical does migrate from a container to the contents, it doesn't necessarily mean that a human health hazard exists. Fine crystal glassware, which has been used safely for centuries, is about one-third lead. Lead has been found to cause cancer in animals and, in excessive amounts, is toxic to humans as well. But it migrates from glass only in the most minuscule amounts, so FDA has quite properly felt there was no problem to be concerned about.

What has happened, in part, is that our ability to measure and interpret the effect these substances *have on human* health has outstripped the laws that regulate their use.

It was two decades ago that the so-called Delaney Amendment to the Food, Drug and Cosmetic Act became law—the clause which prohibits the use of chemicals in foods if cancer can be induced in test animals at any feeding level no matter how massive. At the time, our *scientific understanding* of trace quantities and their effect upon human health was, by today's standards, unsophisticated.

In the intervening years, we have introduced such tools and methods of detection as the electron microscope, mass spectroscopy and neutron activation analysis which can pinpoint trace quantities as small as *one part per trillion*. That's one bad apple in two billion barrels of apples.

Needed. . . a more balanced effort

Our nation's scientific genius has become, in effect, a double-edged sword. Just as we now have the technology to identify infinitesimal trace quantities, we also know infinitely more about how human systems cope with toxic substances. But the issue becomes magnified and beclouded when we lose perspective on what these quantities mean when translated *into human terms*.

For instance, the rationale for the recent ban on saccharin, as in the case of the plastic bottle, was the discovery of tumors in rats—rats that had been fed the synthetic sweetener in amounts that would exceed a consumer drinking *800 twelve-ounce diet sodas daily for a lifetime.*

Is that a "risk" worth taking? I suggest that a fully informed American people should, at the very least, have a right to choose. In the words of a New York Times editorial which recently called for replacement of the Delaney Amendment, "The unqualified nature of the Delaney clause prohibits rational decision-making. In effect, it says that *if* any risk of cancer can be demonstrated, then *that is that.* There is no room for weighing the benefits," the Times went on, "against its costs. Yet such cost-benefit analysis is basic to any sensible judgment."

The Times concluded by stating that the Delaney clause "has *long* needed replacement by a more balanced effort to protect the public against carcinogens." With this, most reasonable citizens would agree.

Needed. . . a clearer perspective

So what can the public, business and government do to bring a more clear-minded perspective to this growing national debate?

I suggest these five steps:

First, the Delaney Amendment must be reconsidered and updated in light of modern technology and our understanding of the effect trace quantities of chemicals and other substances have and do not have on human health.

Second, we must put an end to regulatory policy established in an ad hoc fashion—whereby the conditions of acceptability literally change overnight without full debate among the parties directly affected.

Third, risk-benefit analysis must be brought to the decision-making process. The costs throughout industry of the punitive measures I've described range into the hundreds of millions of dollars. In human terms—jobs and economic dislocation—the costs are often immeasurable.

Fourth, all of us must come to understand that these decisions cannot be reached by scientist battling scientist over interpretations of test data—even within the concept of a Science Court which would permit a formalized forum for scientific debate, and which I think has merit. Ultimately, these are public decisions which should be made after deliberative consideration of benefit versus risk. Importantly, the consumer must be heard in this process.

And finally, industry and government, public interest groups and the scientific community, must lay before the American people *all* the evidence, relating to questions of product safety and human health, in an open and forthright manner.

How much IS a "part per million" or a "part per billion"???

These calculations may surprise you.

	1 part per million (1 ppm)	1 part per billion (1 ppb)
LENGTH	*1 inch per 16 miles*	*1 inch per 16,000 miles*
TIME	*1 minute per 2 years*	*1 second per 32 years*
VOLUME	*1 drop vermouth per 80 fifths of gin*	*1 drop vermouth per 500 barrels of gin*
AREA	*1 sq. foot per 23 acres*	*1 sq. foot per 36 sq. miles*
ACTION	*1 bogey per 3,500 golf tournaments*	*1 bogey per 3,500,000 golf tournaments*
QUALITY	*1 bad apple per 2,000 barrels*	*1 bad apple per 2,000,000 barrels*

$500,000 grant to train toxicologists

It is to advance such scientific fact-finding that Monsanto has just approved a half-million dollar grant to increase our nation's understanding of the effect our products have upon human health.

We intend to do this by supporting at the graduate and post-doctoral levels the training of toxicologists–those specialists who deal with the origin, nature and properties of harmful materials.

We are, of course, fully aware that toxicologists, by themselves, will not solve all the problems I have alluded to today. This will take bio-chemists and specialists *in a wide range of disciplines.* But toxicologists can be an important factor in accumulating data that will be helpful in judging risks and benefits.

With society's ever-increasing attention to questions of human safety, as well as the passage of the industry-supported Toxic Substances Act, our nation is faced with a critical shortage of qualified personnel to carry out the careful scientific studies associated with toxic substances and human health and safety.

To cite a few examples that point up the critical nature of the situation:

- The latest annual report of the Society of Toxicology placement bureau shows that in 1974, roughly half of the advertised openings for toxicologists were filled. In 1976, only one-fourth of the openings were filled. The entire Society of Toxicology, incidentally, includes only 850 members—about half the enrollment of societies in comparable disciplines.
- In some special areas of toxicology, the disparity between supply and demand is even more acute. Another professional placement service recently listed 100 openings for inhalation toxicologists—with no applicants at all.

Through Monsanto's philanthropic foundation—the Monsanto Fund—grants will be made to selected universities on an unrestricted basis. We will have no vested interest in graduates of the programs we help finance. Recipients of funds will be able to pursue whatever careers may interest them most—in government, academia or industry. The need is equally critical in all areas.

The grants will go to those universities that are already doing a commendable job in the field of toxicology, and have demonstrated the capacity of doing still better.

This grant program is designed to encourage other companies to contribute *in like manner.* Indeed, so great are the dimensions of the program that only a broadly-based effort can cope with it successfully.

As this effort moves forward, we must confront the question of consumer risk in a manner free from the old suspicion and irrationality that too often have characterized the debate over the proper interest of industry, government and the consumer.

I believe Monsanto has demonstrated, and is demonstrating forcefully, that a program of support for education on the question of consumer risk can be addressed in a responsible and constructive fashion.

I hope government, the public interest groups and the citizenry will join us in this same spirit so that we can answer many of the questions and resolve many of the doubts that currently cloud our ability to find a reasonable approach to the issue of acceptable consumer risks and benefits.

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10/13/77

CBC present: J F Malone, D L Kent, L B Downey, M Schneiderman
R. Steller;

1) Labels → R Steller asked 6/17/77 : To check out
D Kent.

2) EPA — 9/30 Steering Committee decided a) resolve posture toward VC std: take to court vs. Conciliatory — : Attempt to get Mr. Shapiro ① together w/ Castle. Date set 10/11 & Shapiro was called to postpone to Nov 5 (WCH found out they will be too late. Regroup to try to meet OPT. ch. w/ Castle.
— New Approach ② P/R Committee to get to key legislators ③ EPA Committee oversight (Bais & Bucklew to do.
: Appears won't get to Castle :
③ HWC, Becker & Cohen will go to Research Triangle to establish definitions of new issues (Represent BFG directly)

3) NJ — NS →

4) Bayport (RBP) — WCB - talked to land use experts this week. Salute to Industry (RDS. West.
- boat trip down channel.
: praised BFG efforts (incl some Galveston Bay Group) Grove, Savage, Cerka going 1:1 instead of group mtg
Oct 14 — & Nov 1 — TCAB. in Gal Bay to research air permits
ground rule mtg for Nov 1 mtg. WC to attend.

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Hinderer → TOSCA → ; invite when appropriate.

(5) Mick Cot. Natts.
→ R Steller
Malone
} attack last 10 minutes

(6) Barry Commoner → Plastic Pails.
- OK to do something;
will do → SPI Oct 5 - CW. put attack on it be talking.

① will try to get McCurdy to circ to newspapers.

② H&K → Chas Chastain rebuttal put in booklet form

③ Peter Drucker → Pete Kahn } What would happen if we went back @ all Nader/EDF/Carter

④ PEG → broad approach

⑦ PVC siding - styrene foam : DLK-
@ Steering Committee from Styrene block.
- thought of fighting in marketplace
- Expand info getting more SWRI test results

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(8) DLK - Addison School - 38 fireman taken to hospital (stage curtains thought to be PVC.) BFG took samples of curtain (analyzed to be PVC)
- will discuss w/ Chief Barry on Monday
- Chief wants mutual deducted

N.E. Ohio Fire Chief Assoc.
F. L. C. DLK Chief

PVC curtain formulation inherently flame retardant.
Rayon curtain dec'd

DLK → wants 1
CCS →

→ FK →

Oct 31st → @ 100 check.

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