PLAINTIFF'S EXHIBIT

CAP-728

"THE ANALYTICAL CHEMISTRY OF RISKS AND BENEFITS"

"AND VICE-VERSA"

A KEYNOTE ADDRESS

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TO THE AMERICAN CHEMICAL SOCIETY/DIVISION OF ANALYTICAL CHEMISTRY
WASHINGTON, D.C.

September 11, 1979

Thank you Dr. Libby. Ladies and Gentlemen. My colleagues.

Having been a mild-mannered chemistry professor in real life, I can assure you it is quite an honor for an organic chemist to be asked to address the Division of Analytical Chemistry. It is satisfying for a refugee from the organic pits of tars and fumes, the world where 15% yield means success, to address brothers and sisters who after having perfected the precision of the "short swings method," have gone on to derive meaning from stray scintillations and absorption coefficients, and retention rates flowing thru microcapillary tubes.

It is not at all embarrassing that I was invited to speak not about conformational analysis from nuclear magnetic resonance spectra--a subject

that would surely invite dicule from my political colleagues - or a Golden Fleece award. Instead I am to speak on a subject of increasing interaction between science and politics:

--the assessment of risks and benefits in the regulation of exposure to chemicals.

Your own Committee on Regulation is encouraging more input by you into the regulatory process. I wish to endorse that and further direct you to consider the legislative process as well.

In March, 1977, shortly after the F.D.A. announced it was compelled to ban saccharin because of the rigid absolute priciple of the 1958 Delancy Clause, I drafted legislation (soon cosponsored by over 200 Representatives) that would permit a suspect food additive to be approved if the benefits were found to outweigh the risks. In the ensuing debate it became clear that to those who adhere to the concept of Absolute Zero Risk as the goal of cancer prevention: no possible benefit of a sweetener or other additive could ever be worth the presumed risk of any carcinogen- no matter how weak.

Although I had understood intuitively that it would not do to weigh benefits to investors and producers over against the risks to consumers and the general public-and spelled it out that the benefit/risk comparison must be drawn upon the same sector or subgroup, i.e., consumers' benefits against consumers' risks, I did not foresee that consumer activists would so cavalierly dismiss any benefit perceived by real consumers. Their position was that, by definition, and regardless of anything else, public benefits could only be zero, and that public risk from any suspected carcinogen could only have one designated value: 100%! Thus they would accept

no degrees of risk intermediate between aflatoxin and zero. Either a chemical was a carcinogen or it was not: all or nothing.

So all must be equally banned.

This Absolute Safety Dogma may have seemed reasonable in 1958 when I was a chemistry graduate student, but today such Absolutism is Obsolete. And it's largely the "fault" of your profession.

You will recall that in 1958 our food supply was certified pure, and who could argue against keeping it that way? Analytical chemists could then boast of being able to detect as little as one-small-part-per-million, and could assure us no risk could be found. Within a decade, however, analytical sensitivity was picking up part-per-billion traces (not due to mischief, but to refining your trade). Soon the disconcerting word was getting around that some of you were finding worrisome traces of carcinogens in natural foods. Although there was no evidence to suggest any significant hazard, that was beside the point when it came to Absolute Purity versus Forbidden Taint. Either 'Tis or 'Taint!

And with the Delaney standard sacrosanct, the food industry preferred not to talk about it.

Yet in another decade, the threshhold of sensitivity, using new techniques was beginning to probe mere parts-per-trillion. And no one thinks the ultimate limit has yet been reached in your field.

An even worse problem is that the Delaney Absolute has no use for mechanisms of cancer. It makes little difference studying how some carcinogens trigger or promote tumor formation--when the only operative consideration is the "yes/no", +/-, pass/fail option of Absolute Safety. The sad consequence of this is that so much of our research resources have

been directed away from fundamental investigations of cell behavior and the like and committed instead to testing.

Not to Science but to Testing.

This very year, the Appropriations Committee is proposing to further double the money for testing, but at the expense of being able to find out fundamental scientific principles of cancer etiology.

So the rat breeders and rat feeders have the priority. The rat breeders have developed more and more sensitive strains with weak kidneys and ineffectual detoxification defenses generally...and then the rat feeders have gorged the test animals with brutal overdoses, seeking to overwhelm what little renal function remains.

Maximum Tolerated Dose has become the fashion.

The result has been a frightening catalog of several thousand suspect carcinogens, yet a politically frustrating inability to study carefully more than 20 a year or even superficially test 100 a year. Every week there seem to be a couple of new carcinogen of the Week candidates. To turn up new ones faster than the current list can be disposed of by testing strains the patience of those who seek the Golden Age of Safety Dictatorships. So they want to resort to the ancient custom of treating chemicals as "guilty until proven innocent".

It's no longer a case of just food additives. In 1976, E.P.A. tried out and (to its credit) rejected a proposal to apply a Delaney-type absolutist regulation to pollutants. Whereupon the environmental purists who promoted that became reincarnated over at O.S.H.A. where their simplistic nonscientific nonsense is now that agency's controversial plan to classify chemicals into

3 groups: carcinogens, suspected carcinogens, and the innocents (notwithstanding the fact that Absolute Safety can never be proven).

I have been moved to predict that by the time the rat breeders and feeders get through with two generation Maximum Torturous Overdose experiments, there will ultimately be only 3 classes of chemicals, irregardless of synthetic versus natural distinctions.

After all the only difference between chemicals that are natural and chemicals that are synthetic is the synthetic ones are purer.

There will be one group of chemicals that have been proven to be carcinogens; next there will be a second group of chemicals that haven't yet but eventually will be overloaded on some hypersensitive animal to cause cancer; and then there will be a third, smaller group consisting of the acute poisons, too toxic for anyone ever to overdose the rats regularly and long enough to produce tumors.

How ironic if saccharin had been a lethal poison at a dose of 1g per kg of body weight! There would have been no question of its safety at 25mg per kg, because there would be no way to question it at 2.5g per kg, and it would never have been banned.

The reasonable attitude toward all this is: we must have a policy to differentiate the serious hazards from the universal lesser hazards. Those that are potent must be treated with greater care than those whose risk is exceedingly remote. To consistently insist upon applying the Delaney Absolute to every chemical that turns up to be as carcinogenic as saccharin is to contemplate banning most of the natural food supply, most industrial jobs, and the rest of the universe. It makes no sense.

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Already we've banned DDT at home and abroad--and what is there to show for it? Increasing malaria and starvation!

Now our own Agriculture Department advocates banning nitrite cured meat. What would that give us? Bad Pork.

Others demand that hair dyes be banned, on evidence that indicates that normal use (soaking your curls once a month-not drinking 25 bottles a day) is less likely to cause cancer than would sunbathing 15 minutes a year.

Will it really serve the public interest better to ban all detectable traces of diethylstilbestrol (DES) while neglecting natural estrogens in natural foods.

Clearly there are differences, and our health policy must differentiate accordingly. It is one thing to clean up asbestos dust in shipyards from the World War II level of hundreds of fibers per cubic centimeter down to 2 fibers. That has already been achieved and has already reduced the asbestos-related cancer burden by over 200-fold. British scientists have shown that to be a major achievement. Yet, there are those who would panic school boards into billions of dollars of misguided efforts to rip out all vestiges of asbestos on the basis of your ability to now detect not just 2 fibers per cc, or even ½ but 1/1000th of a fiber per cc. That would only result in firetraps or the self-deceiving substitution with some other material whose dust would be equally irritating to the lungs.

At this point, it's customary to question thresholds. Is there an exposure level for asbestos (or vinyl chloride, or selenium, or Vitamin D, or saccharin, or benzene) below which there is No Effect? The very

question is faulty if you believe there is no Absolute Zero Risk and that pursuing it is folly. The question must be addressed though, because there are those who believe it only takes one single molecule of a carcinogen to disrupt the DNA code of a cell and trigger abnormal growth.

Even if you believe that about initiators that attack by an alkylation or epoxide mechanism, that certainly would not apply to promoters that operate by secondary effects to overload the renal function, or immunologic function, hematologic function, or DNA repair system. If it requires for even the most potent substances that there be 10,000 molecules per cell to register even the faintest, barely detectable effect, how then can one molecule have any significance? Or a million molecules? Or a billion molecules per 60kg body? Or, consider this: If our food were so pure that carcinogens were present at only one-part-per-trillion, still, because of Avogadro's Irony, every meal you eat would dose you with one trillion molecules of carcinogens!

The simple hit theory is arguable (as a matter of curiosity at the molecule level, but is meaningless as a basis for public health policy.)

Even for those who join O.S.H.A. in insisting that there are no carcinogenic threshholds (without differentiating initiators from promoters), and who make the further leap of Lysenkoism with O.S.H.A.'s proposal never to re-examine that question, there remains the focal issue of Relative Risk. Will 10,000 lives a year be in jeopardy? Or 10? Or 2? And at that level, is it justifiable to intrude government into personal decisions?

I maintain it is the only rational, scientific basis for public policy. Absolute Safety must give way to Relative Safety.

Now having considered these philosophic questions, let me urge upon you a responsibility to help shape such a rational policy for regulating car-

cinogens. I believe it is something you must do through this and other learned scientific societies of which you may be a member.

For many of you, serving as science counsellors to Congressmen, you must help lead my colleagues through this thicket. Until saccharin no politician would have listened, but now thanks to millions of consumers who spoke out for themselves, that ban has been bombed! Now they'll listen. Others of you are welcome to write on your own. Nothing focuses attention in a Congressional office like a barrage of individual letters on a subject.

Yet others of you will be called upon to serve on special panels, science courts, etc. to judge the specific cases as they come up. And others will be moved to reject the intimidating tactics of the Absolutists and to counter them in debate, helping to educate the public, without which Congress is stymied. If you do you will find yourself accused of being a shill for industry. In just 2 days, there is to be a seminar in Chicago for news media, to alarm them how chemical exposures are causing workers to drop like flies. All the academic and independent scientists on the panels are those who agree with O.S.H.A.'s premise of an epidemic of chemical toxicity, without dissent from the independent ranks. As if by design (and in fact clearly by design), the entire roster of scientists invited as of yesterday to present any other than the alarmist view are (you guessed it) industry scientists. What a convenient target that will be for the self-styled consumer activists: to denounce all dissenters as industrial kept scientists. What a lesson for the news media! Perhaps there is also another lesson about manipulation of media.

To help prepare the intended news interpretation the invitation circular quotes Labor Assistant Secretary Bingham with the outrageously phony claim

that "Each year as amany as 100,000 Americans die from diseases that can be traced to toxic exposures in he workplace," a claim based on nothing more than extended extrapolation from 422 deaths in the smelting and uranium and metal mining industries.

Just a few months ago, this very same high governmental authority wrote to "The Sciences" Journal citing a figure of 4500 deaths--which is bad enough, but lacked the nice ring of 100,000. Oddly enough, Dr. Bingham asserted therein that "hyperbole serves no one, particularly in the field of occupational health and safety." How true!

I anticipate that no one will verify that 100,000 figure, but that it will nevertheless be quoted regularly thereafter just as if it were a real number. It will rank right up there with the unfounded claim of former HEW Secretary Califano who announced with great fanfare but little evidence that 20% of all cancer is due to occupational exposure to chemicals. It turns out that what he did was to take the accepted figure of 4-5% (which is bad enough though no epidemic), supported by the International Agency for Research on Cancer, and inflated it by adding another 15% for asbestos. Since that 15% in turn was based on World War II shipyard exposures, now reduced 200-fold, the current cancer burden of asbestos would be dropped to a small fraction of a percent--which when added to the accepted figure of 4-5% leaves it unchanged, still 4-5%. Yet that more heroic 20% survives without factual basis in today's Lore of Chemophobia.

Consider carefully that if you can divert attention and resources away from the lifestyle factors that, according to I.A.R.C., cause 75% of cancer in women, over to occupational exposures that cause 5% in men, who stands to gain, and who stands to lose? And will the rat breeders and

feeders better serve society by studying the few major factors life rich diets, excessive smoking and drinking, or by testing all those chemicals in Chemical Abstracts?

For these reasons, I am convinced that individual reasonable statements by scientists are inadequate. There must be collective judgements expressed through the learned scientific societies to interpret the meaning of this scientific evidence. That will multiply the impact of the scientific interpretation, and add to its credibility, and will safeguard individuals from character assassination by the Absolutists, who demolish reputations by intimidating.

Already the National Academy of Sciences has called for abandoning the Delaney Clause and rewriting food safety laws based on relative risk assessment and a consideration of benefits, and opposing the ban on saccharin.

The Society of Toxicologists is addressing the comparability of various risks across a spectrum of relativity.

The American Diabetes Association and the Juvenile Diabetes Foundation have joined the Institute for Food Technologists in calling for such a change. The American Institute of Chemists has endorsed the concepts of my legislation.

The American Chemical Society must find its own role in this. You, like the others, cannot lobby per se, but you can express your collective judgement. I note that Bob Emerko, speaking on the A.C.S. role in regulatory affairs has raised the need for you to develop accepted standards for the frontiers of trace detection to guard against scaring the public

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and regulators with meaningless small traces. That is a most responsible and timely proposal.

At the same time another committee is weighing whether to use your information retrieval sources to catalog the types and potencies of toxic substances. That responsibility would not be without its own risks, and would strain your resources, but I for one hope that they will accept this challenge. Rather than rely on politicized federal agencies to characterize chemical hazards, in categoric more convenient to administrators, lawyers and clerks, it would be far better to do it on a professional basis of scientific objectivity.

In all this, keep in mind that I am calling upon you to participate in what are political issues. As a matter of the public interest, it is certain that scientists will not be handed sole authority for establishing health policy. But let no one else, through our abdication, be given responsibility for interpreting the meaning of scientific evidence. You must do that.