Testimony before
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Congress passed a law in 1960 which required that color additives be tested for safety before being added to our food supply. The "provisional listing" section of that law allowed manufacturers marketing dyes or dyed food at the time of enactment to continue sale "pending the completion of the scientific investigations needed as a basis for making determinations" as to the safety of the dyes. A 2 1/2 year period was specified for completion of these tests, subject to an extension "with the objective of carrying to completion ... the scientific investigations." Today, 12 years after Congress demanded proof of safety, the dyes are still on the provisional list, without proof that their use is safe. FDA has granted extensions of time for testing with routine abandon, ignoring the law it is supposed to enforce.

Nowhere are the consequences more alarming than in the case of FD&C red dye #2, a coal-tar dye used to color candy, baked goods, soda, ice cream, pet foods and virtually every other artificially-red food product, to say nothing of lipstick and pill coatings.

This dye has been pumped into our food for many years without any scientific determination of its long-range safety to the consumer. It offers no benefit to consumers. Its benefit accrues soley to the food manufacturer who can mask the absence of natural or quality ingredients in his product. A manufacturer who wants to sell cherry soda, for example, can cover up the total absence of cherries by adding this dye. Manufacturers of "strawberry" ice cream who often add only a couple of strawberries, if any, can disguise the absence of strawberries by using this dye. Pet food producers who want their grain products to look like meat, also use the dye.

For these alleged benefits, the unknowing consumer, who has paid his money, endures significant risk of reproductive impairment and possible risk of birth defects and cancer. In the face of these risks, in obeisance to a fake-red food industry of $15 to $25 billion annually, FDA has just proposed to extend its provisional listing yet again, allowing on the market not only a product which has not been shown to be safe by adequate testing but a product that presently has evidence that it may be downright dangerous.

Two and a half years ago, Russian studies showed cancer in rats, and showed fetal death in rats fed low levels of Red #2, 1.5mg/kg body weight/per day. Over a year later FDA scientists found that the dye causes fetal toxicity in rats at a dosage of 30 mg/kg/day. (Unfortunately, FDA did not test at the lower dosage of 1.5 mg/kg). FDA also found that Red #2 "has drastic effects regarding mortality and gives evidence of a teratogenic effect in low concentrations administered to chick embryos (25 parts per billion and 10 parts per million)". The results were unusual since they indicated that red #2 was more toxic in low levels of ingestion than in middle levels. FDA cancer tests are currently underway, but FDA scientists have already concluded:

> It would be prudent to limit drastically the uses of FD&C Red #2 only to indirect or incidental applications involving food; that is limit use of the color to such applications as food packaging where migration to food is nil, color marking of animal food additives, and to external uses only in drugs and cosmetics (Memorandum Nov. 18, 1971).

Rather than act in accordance with his own FDA scientists, the Commissioner referred the question of Red #2 safety to the National Academy of Sciences Food Protection Committee. (The NAS initially refused to consider the matter because its routine character made it appropriate for intra-agency decision, but the industry liason committee -- composed of scientists in food industry employ -- insisted that it take the case). FDA officials commonly refer food safety questions

to the NAS Food Protection Committee when they get pressure from their scientific staff to restrict a substance. Higher officials know that the Food Protection Committee will not recommend action which would significantly inhibit the industry. The committee has no NAS members on it. It is well-known for its bias for industry affairs at the expense of consumer protection. The committee is heavily influenced by its industry-liason group, and has consistently received financial support from the food, packaging, and chemical industries. It has long been dominated by scientists with close industry ties, some of whom openly deride concern for long term effects such as cancer, gene damage and birth defects. For example, Julius Coon, head of many Academy studies of FDA food matters, has stated, "There is not a shred of evidence or even a basis of reasonable suspicion that any such damaging effects [as cancer, birth deformities or genetic defects], have ever been caused by the additives or pesticides in food consumed in North America" (Industrial Medicine, vol. 39, no. 10, Oct. 1970, p. 31). Coon headed the Food Protection Committee "study" of Red #2. His bias on the subject glowed after an FDA scientist presented evidence that the dye caused birth defects in chicks. He said, "We all appreciate your coming over here and entertaining us this afternoon."

The Food Protection Committee issued a report that whitewashed Red #2 hazards. It discarded studies showing toxicity, without specifying any fault with them. It accepted instead, studies produced by the industry, all of whose summaries concluded that there were no adverse effects. In spite of the conclusions, the actual data of the tests, as analyzed by a Health Research Group biochemist, did show significant adverse effects.

Further, the NAS Report suggested that the results of FDA tests showing hazard be overlooked because the relationship between effects on animals and possible effects on human reproduction is "uncertain," and because of the "widespread use since the early days of this century" of red #2. This is grossly irresponsible.

We rely on animal toxicology data for food additives because human data is extremely difficult to obtain. It is almost impossible to get well-controlled human studies, as you can with animals -- because of the ever-expanding range of chemical substances to which humans are exposed. Even were such available, our society would not permit controlled tests on humans of substances found toxic in animals. Given the enormous use of Red #2 and the fact that effects could appear, if at all apparent, long after ingestion, it is unlikely that reliable human data will ever be available. Carefully planned and performed animal experiments are thus agreed upon by all competent scientists as a proper and sufficient indication of potentially harmful effects on human health. It is therefore ludicrous that the Food Protection Committee should ask for human data before recommending action, and that the committee rejected well-designed and executed FDA animal studies on that basis.

However, FDA embraced the Food Protection Committee report. We do not know whether the report ever reached agency scientists for scrutiny before the decision was made. Under the Freedom of Information Act I requested a look at scientific evaluations of the report, but FDA denied the request.

On the basis of the report, FDA abandoned its traditional 100-fold safety margin in setting permissible uses for the dye (37 F.R. 129, 13181).

FDA regulations call for a 100-fold safety factor for food additives.

> A safety factor in applying animal experimentation data to man of 100 to 1 will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals. 21 C.F.R. s. 121.5

The 100-fold safety factor is admittedly arbitrary, but it is used to compensate for the insensitivity of animals as indicators of human adverse effects and for widely varying consumer diets. FDA's regulation

gives the agency some discretion in choice of a safety margin from the no-effect dose in animals, but the choice of a safety margin 9/10 below the 100-fold prescription is utterly beyond discretionary bounds. And this is what FDA did. In an apparently unprecedented move, it used a 10-fold safety margin instead of a 100-fold.

Why did FDA adopt the 10-fold safety factor? Not because of the incompetent NAS report, although the report was used to justify the move.

The answer lies in a statement by Dr. Virgil Wodicka, head of FDA Bureau of Foods, reported in Medical World News, Sept. 8, 1972.

> We're stuck with Red 2; if we went to a 0.15 mg limit we'd wipe out its use.

The 0.15 limit is that dictated by the traditional 100-fold safety margin. A 110 lb. woman drinking one can of cherry soda a day would exceed the safe limit. Such a limit would prohibit the use of Red 2. Dr. Wodicka says, FDA used the meagre 10-fold margin because "we're stuck with Red 2." That is, FDA doesn't want to prohibit Red 2 because it is used by the food industry. Holding that value dear, FDA has invented a disarming new concept: find a "safety" factor that allows the industry to continue using its favorite additives, public be damned.

Dr. Wodicka continues:

> The only unfavorable evidence so far advanced is that under some conditions in some laboratories there is a diminution in litter size; all the fetotoxicity amounts to is that some fetuses are resorbed. In the rat pups that are born, there are no defects.

Thus, FDA states that fetal death is simply too unimportant to disturb the food industry about. The American public would rise up in terror if the Congress imposed a law requiring compulsory birth control. "Totalitarian," we would all cry. Yet the FDA in effect does exactly the same thing in allowing this dye on the market. In the name of retaining the "market profile" of fake red food products.

Further, FDA has ignored the indications of birth defects and of cancer that Red 2 has raised.

In short, in the case of Red 2, FDA has subscribed to the theory, sell now, test later. As tests later start rolling in, and they raise doubts of safety, FDA then subscribes to the theory, "we're stuck" with Red 2; and it therefore waives the safety margins its own regulations demand. In so doing, FDA waives its legal responsibility to protect consumer health.