DES Residues

In his criticisms of the analytical methods used by the Food and Drug Administration (FDA) to detect DES (diethylstilbestrol) residues in meat, (News and Comment, 28 July, p. 335), Nicholas Wade fails to evaluate the validity of other available methods. No mention is made of the Umberger mouse uterine test, which, until the recent development of the still unapproved gas-liquid chromatography analytical procedure, was considered the most sensitive test for estrogenic materials. The Umberger test measures the response of tissue to estrogenic activity and is generally recognized to be sensitive to at least 2 parts per billion for DES. Many qualified scientists equate the carcinogenicity of estrogens to their estrogenicity, and it would appear that this test might indicate that, below some finite point, DES is not producing an estrogen response and therefore is not a carcinogen at those dosage levels.

Wade makes a great deal of the plight of the young women who developed vaginal adenocarcinoma. He appears to have made up his mind that there is no possible explanation other than that of DES. He does not discuss the fact that the mothers of these young women were experiencing high-risk pregnancies, which would, in all probability, have been terminated without some supportive therapy. Is it not possible that some physiological malfunction in the mothers themselves during their pregnancies was the causative agent, and that any means which preserved the pregnancy would have resulted in an increased incidence of (female) children with a predisposition to the disorder in question?

Wade suggests that the failure to develop chemical methods for detection of potential residues, DES in this case, at levels in the range of fractional parts per billion is inexcusable. This sort of logic casts a shadow of poor ethics over all scientists who are not working on this problem.

That the FDA is charged with the responsibility to protect the health and well being of the public is not subject to argument; that is the law. There are, however, differences of opinion among scientists as to what constitutes a hazard.

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Nicholas Wade states that "The hormone is a regular ingredient of the American diet because the federal government permits its use as an additive in cattle feed." First of all, the feed containing DES is consumed by cattle, not by people. Second, unless the material is metabolized by the consuming animal, no beneficial effect is obtained.

Wade says that DES saves cattlemen $90 million per year. Does he have reason to believe that the benefit of this growth promoter accrues to the cattleman who uses it? Since cattle prices received by the cattle feeder are essentially at the same level as those of 20 years ago, it must be clear that any increase in efficiency has been passed on to the American consumer and has not been held in the pocket of the cattle feeder.

Wade also states that DES continues to be found in *beef.* He should know the difference between "beef" and "liver." To date, no DES residue has been reported except in liver, which is an internal organ and not a component of the carcass.

Wade speaks of "cows" feed, apparently unaware that a cow is a breeding female and is only rarely "fattened" or fed a high grain or finishing ration. Neither is DES fed routinely to heifers, which are young females of the bovine species. Ordinarily DES is fed only to "steers," which are young, castrated, male bovines and the major source of the delectable high-quality beefsteak which Wade and millions of other Americans may enjoy daily, and which can be purchased at a cost of fewer hours of labor income than at any other time in history.

Wade mentions that 22 other countries have taken steps "to ensure they do without DES in their food supply." His implication seems to be that carelessness prevails in the United States. I do not, however, believe that cattle feeders can justifiably be so labeled.

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Nicholas Wade's statement that the saving of grain through the use of DES is not necessary because of the huge surplus of wheat in the United States indicates his ignorance of agriculture. He ignores the fact that wheat is regarded as a poor cattle feed. He also uses the example of DES in chickens as an argument against its use in cattle. He neglects the fact that the same amount of DES was used in a bird weighing 2½ to 3 pounds as is used in a 1000-pound steer. Furthermore, he fails to mention that the poultry industry itself acted to ban DES when its dangers as a caponizing substance were discovered. His estimate of a rise of 3.85 cents per pound in the price of beef as a result of a ban on DES is a reference to price on the hoof. This actually represents an increase of at least 10 cents per pound to the consumer or a total addition of something over $400 million to the nation's food bill.

Wade writes as if the Delaney Amendment were the epitome of glorious protection to the consumer, when in fact it has resulted in such asininities as the banning of certain dyes in lipstick because rats developed tumors after consuming the dye at the rates of 2 and 4 percent of their diets. A woman would have to eat about 3600 lipsticks per month to obtain an equivalent amount.

Wade seems to feel that the farmer, food processor, and merchandiser are out to "get him." Perhaps he should explore both the quantity and quality of food in other countries. He might then realize (to paraphrase a famous statesman) "Never have so few fed so many so well and so cheaply."

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. . . By what right does Wade characterize the history of the attempt to control DES as a "record that includes negligence, deception, and suppression by the USDA and prevarication by the FDA?" Who is he to judge that "Any claim by the NAS food protection committee to be an independent, unbiased, and representative body of experts must be weighed against the fact that it is supported by grants from the food, chemical, and packaging industries, and five of the nine scientists who prepared the 1969 report were employed by food or chemical companies?" Just where would he find experts on foods and chemicals if he rejected all employees of food, chemical, and packaging companies, all employees of the government, and all those who have accepted grants from either? What right does he have to accuse those five employees of prostituting their scientific integrity for the sake of their employers? Were the other four members of the committee bought off, or were they stupid? What kind of scientific argument is this for rejecting any conclusion from the Na-

tional Academy of Sciences, with which Wade disagrees? Why does he mention the packaging industry? Is it because food and chemical companies buy their packages from packaging companies? Or does Wade simply object to companies? A careful examination of any one of Wade's outraged comments demonstrates that they contain much outrage but little substance.

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Nicholas Wade's fascinating report on DES contains a common statistical blunder that should be corrected. Wade writes, "Since some 30 million cattle are slaughtered each year, 1023 is not too healthy a sample from which to draw statistically valid conclusions."

This sentence is puzzling in two small ways: lack of distinction between a sample and its size, and a suggested difference between "valid" and "statistically valid." Its big problem is the assertion that sample size should depend upon population size. Unless sample size gets to be a sizable fraction of population size, the accuracy of inference from the sample hardly depends at all upon population size. A thousand-odd cattle provide for any earthly purpose exactly the same information when the population is 30 million as when it is 3 million or 60 million. What is important is how the sample is drawn from the population, and there Wade appears to be silent.

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I could find no substantiation for the headline of Nicholas Wade's report "FDA invents more tales about DES" (11 Aug., p. 503). The report, except for the end of the first paragraph, the third from the last paragraph, and the final paragraph, appears to be a straightforward account of the matter. However, the tone of the report was one of having prejudged the FDA as guilty. Is it expecting too much to look for objectivity in news reporting and headline writing in *Science*?

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I would like to express my warm appreciation and congratulations to *Science* for the scholarly, well-balanced, and most timely reports on DES and on the Delaney Amendment (18 Aug., p. 588). These are two areas of concern that are critical to the protection of large human populations from synthetic chemical carcinogens.

I am unaware of any professional oncologists or scientists competent in these areas, apart from those who have clear economic or other constraints, who would not strongly endorse both the facts and arguments so cogently presented in these two reports.

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The reports by Nicholas Wade dealing with the attempts of the regulatory agencies to cope with the Delaney Amendment are important and timely. Granted that there may be a threshold dose of a carcinogen for an animal, but no one knows how to determine it. This is why the Delaney Amendment should be retained. The use of very large numbers of laboratory animals, as has been proposed, will not solve the problem. Even if the carcinogens selected are appropriate, the results of testing one or several of them in rats or mice, which consume and react for 2 years or so, cannot with surety be extrapolated to man, who can consume and react for 50, 60, or 70 years. Indeed, man's exposure can start in the womb, with the disastrous consequences to some individuals demonstrated by the case of DES, as Wade points out.

The lack of knowledge of the cumulative effects of known carcinogens, let alone of the effect of other compounds and combinations of compounds about which we know little or nothing, is serious. Businessmen and industrial managers are wise in the ways of commerce, but they know little of toxicology, and no more of the even narrower field of carcinogenesis. To entrust to them the decision of whether a new food additive presents a carcinogenic hazard would be folly.

No one questions the use of a life-saving drug in an emergency situation, even though it might be carcinogenic. However, widespread use of a chemical additive of unproven safety should be discouraged. It is imperative, therefore, that the Delaney Amendment be sustained, subject to intelligent interpretation by the FDA, to minimize the possibility that large populations could be exposed to carcinogenic chemicals.

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