

mors, both benign and malignant, in the high-dose and low-dose groups, there was in fact a significant increase in the number of *malignant* tumors found in the female rats fed the high dose. Gaylor's analysis, dated 31 December, became known to the press, a circumstance which led FDA Commissioner Schmidt to announce on 8 January that he would proceed with whatever action was warranted within 10 days. That launched a rushed reappraisal.

A working group of scientists from the Toxicology Advisory Committee, the FDA, and the National Cancer Institute met on 14 January to review Gaylor's analysis. They concluded, in essence, that Gaylor's statistical approach was valid, but that the strength of his conclusions would depend upon confirming the original pathology data "using a slight redefinition of tumor types." The significance of this is that some of the tumors counted as "benign" might conceivably be reclassified as "important" (benign now, but possibly heading for malignancy) or perhaps even "malignant." If a substantial number of the "benign" tumors in the low-dose group were reclassified, that might wipe out the difference between the low- and high-dose groups, perhaps indicating that Red 2 had no pronounced effect after all. Such, at least, is the speculation among those scientists at the Bureau of Foods who still are dubious that Red 2 is harmful.

The working group noted that the "botched" study was of such poor quality that it could never be used to demonstrate the safety of Red 2, but it suggested further evaluations of the data in an effort to determine whether Red 2 is carcinogenic. However, the FDA commissioner, who had recently been given a rough time on Red 2 by various senators and congressmen, the General Accounting Office, and reporters on a nationwide television interview show, was not about to wait for more evaluations. On 19 January, he announced that he would act immediately to terminate the approval for use of Red 2 in foods, drugs, and cosmetics. He did not claim that Red 2 is carcinogenic. Rather, he noted that Red 2 had only a "provisional" approval, a category that is meant to indicate that studies are under way that are expected to demonstrate safety and thus lead to "permanent" approval. Since the latest FDA study could not establish safety, he said, and since no other studies are known to be under way that could resolve the safety questions, the provisional approval had to be rescinded. The burden of proof, he added, lies with those who manufacture or use Red 2 to prove that it is safe and useful. Then, since he had not exactly ruled that Red 2 is unsafe, he explained that there would be no recall of existing

products containing Red 2 since there is "no evidence of a public health hazard."

Industry spokesmen were predictably outraged. The top color scientist at one company that makes Red 2 told *Science*: "I think it's a disgrace. It's a case where media pressure and consumer group pressure really took precedence over scientific judgment. The commissioner acted upon emotion and without a final opinion from the full Toxicology Advisory Committee. As far as I'm concerned, Red 2 is still safe." But consumer activists who believe that Red 2 should have been banned long ago on the basis of earlier suspicious test results were enthusiastic.

One potentially significant revelation to emerge from the confused proceedings is that the FDA's Bureau of Foods does not always perform a sophisticated statistical analysis of the results of its studies. The Bureau's report to the advisory committee last November—the one which found "no adverse effects"—was based on an examination by pathologists but not on a detailed statistical analysis of the pathological findings. Bureau officials have since offered two explanations for this. One is that they were so rushed to get a report together for the November meeting of the advisory committee that they didn't have time to do the statistics—an excuse that some participants find preposterous, since the Bureau was able to perform an analysis lickety-split after Gaylor's memorandum challenged their original conclusions. The other is that no analysis seemed necessary in this case. Thus Herbert Blumenthal, director of the division of toxicology in the Bureau of Foods, told the working group that the tumors observed in the study were typical of the particular colony of rats, and that the pathologists were not concerned about them. According to the minutes of the meeting, he said he "would not have requested a statistical analysis of this study." Blumenthal, whose division was in charge of the "botched" study, and who was obviously dispirited after a hectic week, declined to elaborate in an interview with *Science* on why he felt no statistical analysis was needed.

But one participant in the review process believes the Red 2 flap has uncovered a serious flaw in the FDA's system of evaluating tests. "In the past, they've just had people eyeballing the stuff," he said. "They look at the data and look for things that jump out at them. But in so doing, they could quite easily make a mistake. In this case they did. If this study had not been botched, there would have been no statistical analysis. How many things have they done in the past where they just eyeballed the data and said, 'It looks OK?'"

—PHILIP M. BOFFEY

## APPOINTMENTS

**Amoz I. Chernoff**, director, University of Tennessee Memorial Research Center, to medical and scientific director, Cystic Fibrosis Foundation, Atlanta. . . . **Edward C. Melby**, dean, New York State College of Veterinary Medicine, to chairman, Institute of Laboratory Animal Resources, National Research Council. . . . **William H. Knisely**, assistant chancellor for health affairs, University of Texas System, to vice president, academic affairs, and president-elect, Medical University of South Carolina. . . . **Byron S. Gottfried**, professor of industrial engineering, University of Pittsburgh, to director, School of Engineering's Energy Resources Program at the University. . . . **Louis Padulo**, associate professor of electrical engineering, Stanford University, to dean, College of Engineering, Boston University. . . . **Robert H. Walker**, acting dean, College of Natural Sciences and Mathematics, University of Houston, to dean of the college. . . . **Riley Schaeffer**, professor of chemistry, Indiana University, to dean of arts and sciences, University of Wyoming. . . . **H. Ray Hoops**, chairman, communicative disorders and sciences department, State University of New York, Buffalo, to dean, Graduate College, University of Northern Iowa. . . . **Joseph T. Durham**, dean, School of Education, Howard University, to dean, School of Education, Coppin State College. . . . **Edward I. Isibor**, associate professor of technology, Florida International University, to dean, School of Engineering and Technology, Tennessee State University.

**Erratum:** In the 9 January issue, page 51, the weight of the Trident I missile was incorrectly stated. The correct weight is 70,000 pounds.

**Erratum:** In the report "Chemical Fractionation of the Lunar Regolith by Impact Melting" by J. B. Adams, M. P. Charette, and J. M. Rhodes [190, 380 (1975)], the following should be added to the legend of Fig. 1: "Trace elements determined by instrumental neutron activation analysis were made by D. P. Blanchard, J. W. Jacobs, J. C. Brannon, and L. A. Haskin of the NASA Johnson Space Center. These results are discussed in more detail in J. M. Rhodes, J. B. Adams, D. P. Blanchard, M. P. Charette, K. V. Rogers, J. W. Jacobs, J. C. Brannon, L. A. Haskin, *Geochim. Cosmochim. Acta* 1 (Suppl. 6), in press."

**Erratum:** In "High speed scintillation autoradiography" by B. G. M. Durie and S. E. Salmon (12 Dec., p. 1093), in the third paragraph, the sentence beginning "The scintillator consists of 35 g . . ." the quantity is incorrectly printed. The sentence should read "The scintillator consists of 5 g of 2,5-diphenyl-oxazole (PPO) and 100 mg of 1,4-bis-2-(4-methyl-5-phenyloxazolyl)-benzene (dimethyl-POPOP) dissolved in 500 ml of dioxane." In the next-to-last sentence of reference (6), the formula for dioxane should read  $C_6H_{10}O_2$ .

**Erratum:** In the report "Transcontinental baselines and the rotation of the earth measured by radio interferometry" by I. I. Shapiro *et al.* [186, 920 (1974)], the heading for columns 5 and 6 of Table 1 should read "Atomic time-universal time (A.1-UT.1)" and the second entry of column 1 should be followed by a double dagger (‡).