formity in the listing of scientists in university catalogs, and such listings may bear little relation to the actual koza titles provided by the Ministry of Education. Assistants' names are not included in some university catalogs, and multiple appointments are difficult to assess.

Japan has effectively separated academic research from graduate education. Research opportunity for the professor is assured because financial support is automatic. The number of positions for graduate study in any area of science in the national universities is carefully controlled by the government. There is a limit of 14,394 entrants for the master's course and doctor's course in all areas of science, including medicine, in the national universities; this total rises to 24,654 entrants if one includes the local and private universities. The number of entrants into the doctoral course is limited to 4260 in the national universities, or 6793 if one includes the local and private universities. The actual enrollment in the doctoral course was only slightly over 50 percent of the maximum number allowed by the Ministry of Education, a fact that reveals the careful control of the productivity of the graduate schools.

In at least one major chemistry department at a national university, a graduate student's option to choose his major professor is based on his performance in the entrance examination. Those students who place highest on the examination may choose their area of study and research. Those further down the scale are assigned to kozas on the basis of their selection of priorities for area of study. The remainder are assigned to kozas in such a way that all professors have the same number of students. The rationale is that all professors are "equal." It is uncertain just how much recruiting for graduate students takes place. Usually, about twice as many candidates take the examination for entrance to graduate study as there are positions available. The automatic support in the Japanese system is not without its problems, since the professor may be subject to the whims of the Ministry of Education.

According to recent figures compiled by the Science Council of Japan, there are 37,136 research chemists in Japan, including 26,720 in industry, 3407 in research institutions, and 7000 in universities and colleges. The Japan Chemical Society, the oldest society for chemists in Japan, has 29,229 professional members, 6151 student members, and 1139 corporate members. Chemistry has the second largest group of researchers in Japan; it is surpassed only by the area of agriculture and forestry, which has 99,674.

The future directions of chemistry are not well defined. A change in Japan's economy is causing a tight job market, although supply and demand are carefully monitored by the government. There is now disagreement as to how academic research should be motivated. The Science Deliberation Council of the Ministry of Education recently stressed that academic research is a moving force for economic and industrial development. Emphasis on economy first contrasts with the viewpoint of the Science Council of Japan, which had released a report declaring that academic research should emphasize humanism and no longer be dominated by economic considerations. It is reasonable to assume that this controversy will not be resolved in the near future.

References and Notes

1. *Reviews of National Science Policy, Japan* (Organization for Economic Cooperation and Development, Paris, 1967).
2. *Reviews of National Policies for Education, Japan* (Organization for Economic Cooperation and Development, Paris, 1971).
3. All conversions reported in this paper are at the current rate of ¥308 = $1.00. It should be noted that, when the conversion rate was ¥360 = $1.00, the dollar equivalents were 16.88 percent lower. With the change in the value of the yen, a significant number of changes are taking place in Japan; these changes must be constantly reevaluated if one is to realistically convert to dollar equivalents.
4. *Official Gazette* (Printing Bureau of the Finance Ministry, Government of Japan, special issue No. 45, Tokyo, April 1971), pp. 1–63.
5. *Ministry of Education Notification No. 223* (Ministry of Education, Tokyo, 12 March 1971), pp. 1–5.

6. Opinions expressed herein are the author's and do not necessarily represent the views of the National Science Foundation. The author is indebted to the Ministry of Education of the Japanese Government for supplying the detailed statistics on doctoral production in Japan. Special thanks are due to Masanobu Miyahara of the National Science Foundation, Tokyo, who helped in collecting the material summarized in this article and in translating important items of information.

NEWS AND COMMENT

Delaney Anti-Cancer Clause: Scientists Debate on Article of Faith

When the carcinogenic beef additive diethylstilbestrol (DES) was banned earlier this month, there was little rejoicing in the halls of the Food and Drug Administration (FDA) that a threat to public health had been forestalled. On the contrary, FDA Commissioner Charles C. Edwards explained apologetically that he had "been left no choice" but to ban DES under what he implied were the unreasonable dictates of the law known as the Delaney anticancer clause. Edwards had good reason to be wary of invoking the Delaney amendment. The previous commissioner of the FDA lost his job when he used the Delaney clause to ban cyclamates in 1969. Almost from the moment it reached the statute books the clause has been the focus of vigorous debate, which is fanned into flames each time the clause is invoked. The DES ban is no exception. Representative William J. Scherle (D–Iowa) has introduced a bill to amend the Delaney clause, manufacturers have renewed their charge that the clause is unreasonable, and last month a senior government health official suggested in so many words that the clause should be scrapped. Why so much heat about a law which says only that cancer-causing substances shall not be allowed in people's food?

The distinctive feature of the Delaney clause is that, once operative, it cannot be bent. All other kinds of poison that manufacturers need to put in food, or find it inconvenient to exclude, are permitted in doses, known as tolerance levels, that the FDA deems small enough to be safe. Such would still be the case with carcinogens but for Representative James J. Delaney (D–N.Y.), who in 1958 devised a 50-word law that forbids any tolerance level being set for a carcinogen. The

law, an amendment to the Federal Food, Drug, and Cosmetic Act, stipulates:

> That no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

The main objection brought against the Delaney clause by those who don't like it is that it prevents the opportunity for scientific judgment to be exercised. The objection is usually couched in what may be called the "single rat" argument—that if a chemical causes one tumor in a single rat, even when fed in massive doses and by an unusual route (such as implantation), then the chemical must be banned, and maybe a whole industry wiped out, by application of the Delaney clause. A variant of the single egg argument is the "hard-boiled egg" argument in which, to demonstrate the absurdity of the Delaney clause if applied rigidly, the critic points to some staple food that in a certain experiment has apparently caused cancer. (Hard-boiled eggs, shown to cause cancer in mice, used to be a favorite example until it was suggested the eggs might contain DES.)

Of more recent vintage is the "universal toxin" argument, occasioned by the steady improvement of analytical techniques to the point where it is becoming possible to detect substances at concentrations approaching one part per trillion. Every animal probably contains in its body a few molecules of every stable chemical in the environment, toxins included. It would be intuitively unreasonable to ban these substances, or foods containing them, as and when they become detectable. Nature herself could not obey the Delaney clause, is another way this argument is sometimes put.

Behind the universal toxin argument lies the concept of a threshold or no-effect dose, which is the real scientific focus of controversy over the clause. The anti-Delaney position is that for every chemical, carcinogens included, there exists a dose small enough to be harmless. This view has been most positively expressed by Leo Friedman, director of the FDA's division of toxicology, who wrote in a recent letter to Representative L. H. Fountain (D–N.C.), "I am of the firm opinion that for every carcinogen that we know of, even the most potent, there is a finite level that will definitely not produce a cancer in a human being or in an experimental animal."

Supporters of the Delaney clause rest their case, in essence, not on a denial that threshold levels exist, although some deride the concept as an "article of faith," but on the practical contention that no one knows how to ascertain a threshold level for a carcinogen. The debate on this issue has not only divided the scientific community, but in an interesting way has become institutionalized, with the National Academy of Sciences (NAS) cast in the curiously partisan role of bandleader for the anti-Delaney forces and the National Cancer Institute (NCI) playing the somewhat more fitting part of chief defender of the clause. The NAS-NCI clash, together with a parallel schism within the FDA, was skillfully brought out at the hearings on DES before Fountain's intergovernmental relations subcommittee last December.

The dispute between the two institutions in fact stretches back at least to 1960, and its continued existence is an interesting instance of the scientific method, supposedly pure and impartial, failing to triumph over the particular perspectives of its practitioners. The NAS is involved in the issue through its Food Protection Committee, a branch of the NAS's operating subsidiary, the National Research Council. Critics of the Food Protection Committee allege that scientists who work or consult for industry are overrepresented on the committee, and those concerned with the environmental aspects of cancer are underrepresented. The chairman of the committee is William J. Darby of Vanderbilt University, an eminent nutritionist who is also well known for his criticism of Carson's *Silent Spring*.

The involvement of the cancer community with the Delaney clause can be traced to the 1954 meeting of the International Union Against Cancer, at which a distinction was drawn between reversible and irreversible actions of chemicals. For those that cause reversible actions, the conference said, threshold levels can be laid down, but for substances whose action is irreversible and maybe cumulative in effect, such as carcinogens, even small doses must be considered dangerous. At its Rome meeting in 1956, the International Conference Against Cancer codified this distinction in the recommendation that

> As a basis for active cancer prevention, the proper authorities of various countries promulgate and enact adequate rules and regulations prohibiting the addition to food of any substances having potential carcinogenicity.

It was this recommendation that Delaney, who had formerly chaired a House select committee on food chemicals, decided to make the basis of his eponymous clause. Enacted in 1958, the clause received its first full-dress investigation in 1960 in a hearing on food color additives before the House Committee on Interstate and Foreign Commerce. The battle lines formed then have not changed much since. Witnesses from the National Cancer Institute, including G. Burroughs Mider, testified in favor of the clause on the grounds that no one can say how much or how little of a carcinogen is required to produce cancer in humans. Darby, the chairman of the NAS Food Protection Committee, opined that "adequate protection would be afforded by the law without the inclusion of the Delaney clause." However, he was disputed by a member of his committee, Harold M. Stewart of the NCI. Stewart also criticized a report put out by the Food Protection Committee on the evaluation of carcinogens as containing "some misstatements and insecure conclusions." Thomas P. Carney, vice president for research of Eli Lilly, warned of "the danger of substituting *per se* decrees for careful exercise of scientific judgment," and as an example of the latter argued the safety of DES (of which his company was principal manufacturer) on the grounds that the previous year some 300,000 women had been treated with DES without coming to harm.* The single rat argument of which Carney's was an early variant, was countered by Arthur S. Flemming, then secretary of Health, Education, and Welfare (HEW), in an important statement before the House committee:

> The rallying point against [the Delaney clause] is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. . . . It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision has been made, the limits of

* Carney was ignoring the fact, well known at the time, that human cancers may have a latency period of 15 years or more. He would eat his words now. Last year, a rare type of vaginal cancer was observed in young women who, 20 years before, had been exposed to DES as fetuses when their mothers were treated with the chemical.

judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold for the established carcinogen.

After the 1960 hearings, the Delaney debate was more or less quiescent until the cyclamates affair of 1969, the first occasion on which the clause was invoked to rule a product off the market. Senior HEW officials decided the Delaney clause was somehow to blame for the debacle that resulted from their handling of cyclamates. They set afoot a legislative inquiry to see if the clause could be adulterated or otherwise rendered harmless, as well as a scientific inquiry to see if this course of action was justifiable. The scientific inquiry, known as the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, was entrusted to a group of NCI and university scientists chaired by Umberto Saffiotti, the NCI's associate scientific director of carcinogenesis.

The report of Saffiotti's committee was completed in April 1970 but has never been published in the scientific literature because of the objection of one of its members, Philip Shubik of the Eppley Institute for Research on Cancer. (Shubik told *Science* that his objections were confined to points of literary style, not principle. In the 1960 hearings, however, Shubik testified against the Delaney clause, which the Saffiotti report endorses.) Saffiotti, however, seems to have included the report in his testimony every time he visited Capitol Hill, a mode of publication that has given it quite wide circulation.

The distinctive features of the Saffiotti report are its definitive support of the Delaney clause and a full-throated attack on the NAS Food Protection Committee for espousing concepts that are "scientifically unacceptable," "of dubious merit in any life science," and of "absolutely no validity in the field of carcinogenesis." The target of these strictures was not the report that Stewart had criticized 10 years earlier, but a more recent study, *Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Foods*, prepared by a task force of the Food Protection Committee. The study appears to assert that certain chemicals can be considered safe in small doses without actually having been tested. For example, it recommends that, if a chemical has been in commercial production for 5 years or more without evidence of haz-

Roster of Top Science Committee Posts Filled

The Nixon Administration caught up with its appointments schedule in recent weeks and announced 21 new and reappointed members to the President's Science Advisory Committee (PSAC), the National Science Board (NSB), and the President's Committee on the National Medal of Science. There still seems to be some discussion about a possible altered role for PSAC (see *Science*, 23 July), and about new ways of presenting the National Medal of Science; but apparently these plans are not holding up the routine business of appointments. As usual, the selection of the additional members seeks to balance out academic disciplines, industry and university representation, and, in the case of the NSB, geographic distribution. Also, a fair number of the appointees, particularly to NSB, would appear to be new to the government science advisory scene.

On PSAC, replacing Herbert A. Simon, of Carnegie-Mellon University, and Harland G. Wood, of Case Western Reserve, will be *Luis W. Alvarez*, the Nobel prizewinning physicist of the University of California at Berkeley, and *James B. Wyngaarden*, chairman of the department of medicine at Duke University. *Gerald F. Tape*, president of Associated Universities, Inc., whose partial term had expired, is being reappointed for a full term. The most unusual addition to PSAC is *Howard S. Turner*, president of Turner Construction Company, New York. Turner is a chemist by training who has in the past held technical advisory posts with the National Aeronautics and Space Administration, the Department of Commerce, the Post Office Department, and the National Research Council. The last PSAC appointments were made in January 1971.

The new appointees to the NSB, which oversees the National Science Foundation, are from business administration, basic science, aerospace, and other fields. They are *Wesley G. Campbell*, director of the Hoover Institution on War, Revolution, and Peace; *T. Marshall Hahn, Jr.*, president of the Virginia Polytechnic Institute and State University, Blacksburg; *Anna Jane Harrison*, professor of chemistry at Mount Holyoke College; *Hubert Heffner*, of Stanford University, formerly deputy director, Office of Science and Technology; *William H. Meckling*, dean at the Graduate School of Management at the University of Rochester; *William A. Nierenberg*, director of the Scripps Institution of Oceanography, at La Jolla, California; *Russell D. O'Neal*, executive vice president for aerospace of the Bendix Corporation; and *Joseph M. Reynolds*, vice president for instruction and research of Louisiana State University, who is being reappointed.

The Administration still seems to be scratching its head over what to do about the National Medal of Science, the annual trophy passed out to distinguished scientists. The awards have been given every year since 1963—but this year there appears to be something extra in the works. Although ceremonies for the 1970 award took place in May 1971, a new committee to search for the 1971 medalists was not announced until a few weeks ago. The new group has already met once, and consideration is apparently being given to upgrading and glamourizing the award, which has in the past not exactly been front-page news. The new committee members are *William D. McElroy*, chancellor of the University of California at San Diego; *Thomas S. Smith*, president of Lawrence University; *James H. Boggs*, vice president for academic affairs and research coordinator at Oklahoma State University; *Howard O. McMahon*, former president of Arthur D. Little, Inc.; *Nathan M. Newmark*, head of the department of engineering at the University of Illinois, Urbana; *H. Guyford Stever*, director of the National Science Foundation; and *William P. Lear, Sr.*, chairman of the board of Lear Motors. *Edwin H. Land*, president of Polaroid Corporation, is being reappointed, as is *Charles P. Slichter*, professor of physics, University of Illinois, who is also being made chairman of the committee.—D.S.

ard, it is "consistent with sound toxicological judgment" to conclude that small amounts in the human diet are "toxicologically insignificant," an approach that the Saffiotti group describes as "practically inapplicable and potentially dangerous."

Asked by the surgeon general to comment on the Saffiotti report, Philip Handler, president of the NAS, replied in a letter of December 1970 that the *Guidelines* were meant only to set priorities for testing, not to suggest that any chemical should be permanently exempt from testing. Handler added that "we" —presumably the NAS—could not support the Saffiotti committee's unqualified acceptance of the Delaney clause because rigid interpretation of the law "removes every opportunity for bringing informed judgment to bear."

Handler also arranged for the Saffiotti and Darby committees to meet to iron out their differences. The peace treaty that resulted from this meeting repeats that the concept of toxicological insignificance is only meant to imply a low priority for testing. Saffiotti told *Science* that he regards this as a "good enough retraction" but adds that even for setting priorities the Food Protection Committee's guidelines are inapplicable to carcinogens. This was agreed at the meeting, Saffiotti says, but not spelled out in the peace treaty. Darby, who drew up the treaty, could not be reached this week for comment.

Saffiotti's disagreement with the Food Protection Committee extends to the composition of its members, who include several scientists employed by industry but none who can be regarded "primarily" as cancer experts. The Food Protection Committee is supported by grants from the food, chemical, and packaging industries, and, of the nine-man task force that authored the *Guidelines*, five are employed by industry and one by a commercial laboratory, giving nonacademic scientists a staggering 6 to 3 majority. "I am worried personally about the way the committees of the National Research Council are set up," Saffiotti told *Science*. "We all know that you can always set up a committee of scientists to reflect a certain trend. I have been concerned about the fact that in a number of advisory committees—and I don't think the Food Protection Committee is totally exempt—there have been people who represent certain sectorial interests. This is not to imply that people are put there to defend their products—I don't think this is the case—but the question is, what is the function of these groups? If the function of the Food Protection Committee is one of developing safer food supplies, they may very well give little emphasis to the problems of toxicology and food safety."

The Food Protection Committee itself does not always have a great deal of time for those who disagree with its views. In February 1970, in response to a request for advice from Senator Ralph W. Yarborough (D–Tex.), former chairman of the Senate health subcommittee, the Food Protection Committee not only urged its view that the Delaney clause be revised, but bypassed a decade of controversy by informing the Senator that "responsible scientists . . . have uniformly felt that the Delaney amendment unduly and unnecessarily restricts the application of . . . scientific judgment." The most charitable of several possible explanations is that the Food Protection Committee did not consider its NCI opponents responsible. Another example of the committee's eclectic approach to advising Congress was its statement that three other committees, the Mrak commission on pesticides and two panels of the White House Conference on Food, Nutrition, and Health, had "independently" recommended revision of the Delaney clause. The committee did not think it worth pointing out that all three "independent" committees have members of the Food Protection Committee as chairmen (in two instances) or vice chairman. In a covering letter to Yarborough, Handler stated that as president of the NAS he fully endorsed the Food Protection Committee's statement.

The strong affirmation of the Delaney clause by Saffiotti's committee was supported by another HEW committee, the Panel on Carcinogenesis of the FDA Advisory Committee on Protocols for Safety Evaluation, which reported in December 1969. The panel, chaired by Shubik, concluded that, although it is "possible in principle to estimate safe levels of a carcinogen," the uncertainties involved in downward extrapolation from test levels will "usually result in permissible levels which are the practical equivalent of zero." The panel noted that errors in extrapolation had contributed to the Salk vaccine scandal of 1955. Use of an appropriate safety factor "would lead to few conflicts with the results of applying the Delaney clause," the panel advised.

In the wake of the cyclamates episode of 1969, senior HEW officials drew up a strategy for watering down the Delaney clause. Since a direct move to repeal the clause might be misconstrued, the plan was to "strengthen" it by making it apply to mutagenic and teratogenic chemicals as well as carcinogens, while at the same time allowing the Secretary of HEW to set tolerance levels for all three types of chemicals. A proposed amendment was drafted along these lines but caused considerable anxiety at lower levels in HEW. "I am opposed to any attempt to water down the Delaney clause at this time, and particularly in the manner suggested by the draft bill," a senior FDA official wrote in an internal memo of December 1969.

Whether or not because of the two scientific reports supporting the Delaney clause, the prepared strategy was never put into action, and until recently FDA officials have been eminently ambivalent in their public utterances on the clause. "The Food and Drug Administration accepts and endorses the Delaney clause," Commissioner Edwards told the Fountain subcommittee last November. Yet the FDA does not accept the Saffiotti committee's recommendation that "no level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man." "Our scientists," Edwards told Fountain, "together with many others outside of FDA, do not accept the no-threshold approach to carcinogenic exposure as it applies to an environmental chemical carcinogen." The FDA agrees that "we cannot with confidence determine what a practical safe level would be of a carcinogen." "However," Edwards added, " we must be pragmatic."

The temptation to do away with the vexatious law seems once again to be stirring at higher levels in HEW. Early this month Merlin K. DuVal, assistant secretary of HEW for health and scientific affairs, aired in public the single rat argument that the law prevents the exercise of scientific judgment (*Science*, 4 August). But if the Administration is planning an assault of the Delaney clause, it has yet to produce any new scientific arguments for doing so. "So long as outstanding experts in the NCI and FDA tell us that they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anti-cancer clause is sound," said HEW Secretary Flemming in 1960. According to Saffiotti's committee, progress of knowledge in the last decade "has only strengthened" the points made in Flemming's testimony of 1960.

—NICHOLAS WADE