Elliott Reports Available for Distribution

The following publications have been issued by the House Select Committee on Government Research. Copies may be ordered from the U.S. Government Printing Office, Washington, D.C. 20402.

Study No. 1: "The Administration of Research and Development Grants," is out of print.

Study No. 2: "Manpower for Research and Development," 25¢.

Study No. 3: "Federal Facilities for Research and Development," 60¢.

Study No. 4: "Documentation and Dissemination of Research and Development Results," 60¢.

Study No. 5: "Federal Student Assistance in Higher Education," 30¢.

Study No. 6: "Impact of Federal Research and Development Programs," 65¢.

Study No. 7: "Contract Policies and Procedures for Research and Development," 45¢.

Study No. 8: "Interagency Coordination in Research and Development," 25¢.

Study No. 9: "Statistical Review of Research and Development," 60¢.

Study No. 10: "National Goals and Policies," 25¢.

Hearings: "Federal Research and Development Programs": Part 1, $2.50; Part 2, $1.00; Part 3, 60¢. Committee print: "Federal Research and Development Programs," 15¢.

fluence simply by being very competent.

As Elliott's committee sees it, the Joint Committee on Research Policy would not supersede the committees that now have scientific and technical jurisdictions: rather, it would attempt to obtain the sort of overall view that now has little or no place in the thinking of committees responsible for specific programs or agencies. It would have no weapons to employ outside of reports and studies, but, hopefully, these could go a long way if they were well done.

It is far too early in the session to tell whether any influential support can be obtained for this proposal. But at this stage there is a great deal working against it. In response to the creation of Elliott's committee, subcommittees on research were set up by Miller's own space committee and by the Joint Committee on Atomic Energy and the Armed Services Committee. Thus, the way is far from clear for a new standing committee to step into the field of science and technology.

Furthermore, Congress seems to be tending toward less agitation about federal support for research and development. A few years ago it found that funds in this area were growing by a couple of billion dollars a year, and it became quite excited. But it now seems to be accustomed to R & D as a 15-percent slice of the budget, and rather than gaping at this figure, the members are concentrating on getting fair slices for their districts. Finally, the hearings held by Elliott and other committees have reinforced the sense of mystery that many laymen feel about science. One witness after another told these committees that you never know what might come out of the most nonsensical-sounding research project, and, in the absence of any solid argument to the contrary, the general congressional attitude seems to be that we don't understand it too well, or at all, but it's good for the country. If the new and large Democratic majority starts a wave of general congressional reform, it is possible that a Joint Committee on Research Policy might win approval, but in the absence of any large-scale revision of the committee structure, it seems unlikely that the Elliott committee will leave behind anything but an impressive pile of reports.—D. S. GREENBERG

Food: NAS–NRC Report Cites Microbiological Hazards in New Types of Processing

Serious outbreaks of food- and water-borne diseases are fortunately rare in this country. Despite the triumphs of public health and sanitation services, however, flare-ups of botulism caused by contaminated smoked fish and canned tuna and of infectious hepatitis traced to shellfish from polluted waters have served as reminders in recent years that constant vigilance is necessary. And Americans continue to suffer in substantial numbers from various forms of gastroenteritis, mainly food-borne.

Because these latter illnesses are usually relatively mild in their effects and of short duration, most of those affected suffer in statistical silence. But it is estimated that these diseases rank second only to respiratory infections among short-term illnesses suffered by members of middle-class families in the United States.

About 2 years ago an *ad hoc* subcommittee on food microbiology was formed by the National Academy of Sciences–National Research Council food protection committee, and the result was the recently published report *An Evaluation of Public Health Hazards from Microbiological Contamination of Foods.**

In the past, the NAS food protection committee has concentrated on problems related to chemicals in food production, processing, packaging, and storage. But the subcommittee was asked to take a hard look at the hazards associated with microbiological contamination of food.

In the words of the report, "Food scientists in industry and government are concerned about the increasing disparity between the rate of technological change in certain segments of the food industry and the level of efforts being made to evaluate and control health hazards associated with new products and processes. They recognize that radical departures from the time-honored practices in production, processing, preservation, distribution and serving of foods have raised new questions concerning the microbiological contamination of products now reaching large segments of the public

* Available from the Printing and Publishing Office of the National Academy of Sciences, 2101 Constitution Avenue, Washington, D.C. 20418; 64 pages; price, $2.

in partially or completely prepared form."

The subcommittee was commissioned to (i) review the incidence of food-borne illness, (ii) discuss microbiological hazards associated with new technologies, and (iii) formulate principles on which microbiological criteria for foods might be based.

The subcommittee makes clear that assessment of the microbiological hazard to health is difficult from a statistical standpoint, since reporting is incomplete and insufficiently detailed. The records for 1951 through 1960 show 2300 outbreaks and 100,000 cases of water-, milk-, and food-borne diseases. Authorities say that figures ten times greater would be much more accurate. What is revealing in these figures, however, is that, of the reported cases, some 93 percent were associated with food and only 3 percent with water and 4 percent with milk or milk products.

In recent years the Public Health Service has stopped issuing annual reports on outbreaks connected with food, milk, and water, but the information continues to appear in weekly reports. Responsibility for reporting these statistics has been given the new PHS Communicable Disease Center at Atlanta. Beginning in 1962 the center began publishing a regular "Salmonella Surveillance Report," which observers regard as a useful start toward gathering information on a national basis on one group of food-borne diseases.

The subcommittee in its report included a number of suggestions for improving the reporting of gastrointestinal illnesses. These suggestions stressed measures to encourage greater interest on the part of practicing physicians and health department personnel, and centralization of responsibility for these diseases in one component of the PHS environmental health structure.

The illnesses with which the subcommittee was concerned are described this way in the report.

"The case fatality rate for all reported outbreaks is less than six per thousand, and the very large majority of illness can be described as short-term, non-fatal gastroenteritis. The most common types of illness are staphylococcal food poisoning and salmonellosis. Among the less frequently reported causes of food-borne illness are *Clostridium botulinum, Clostridium perfringens, Bacillus cereus,* Shigella and paracolon organisms, streptococci, *Trichinella spiralis*, the virus of infectious hepatitis and various poisoning chemicals."

Since the effects of these afflictions are usually temporary indisposition, such as many people would place in the category of nuisances rather than serious hazards, it may seem surprising that an NAS–NRC committee should single them out for a full-scale study.

Radical advances in food technology and changes in patterns of food distribution and preparation apparently explain the concern of the food scientists.

As any veteran housewife knows, in the years since World War II American food-buying and eating habits have been markedly altered, particularly by the availability of frozen and precooked foods. Coin-operated food-dispensing machines and the growing popularity of "carry out" foods have contributed to the changing of patterns.

The report points out that the safety of food in traditional forms—pasteurized milk and canned goods, for example—was reasonably well assured by processing which met accepted standards. With many of the new techniques now being used, potential hazards along the chain of production, processing, storage, distribution, and final preparation have greatly increased.

From Home to Factory

The main impact of the new food technology has been to shift preparation of food from the home to the factory. The mass market for factory-prepared foods can, of course, mean the mass distribution of contaminated food.

In a factory a conflict may possibly arise between production efficiency and sanitary control. Around-the-clock operation of machinery, for instance, may allow the buildup of microbial contamination. In general, however, according to the report, food canners and major frozen-food processors maintain good sanitary control.

Contamination in frozen foods apparently is likeliest to occur through mishandling or delays during storage or transportation, during display in stores, or after purchase by consumers.

The report expresses concern about so-called "mildly processed" foods, in which "microbial populations have been reduced in number by some mild bactericidal treatment—usually heat." The report goes on to say that "the final product is most commonly packaged in a metal can or a plastic bag, often under vacuum, and should be stored under refrigeration [above freezing]. Since these are not sterile products, there is an obvious danger associated with bad handling of the food either before or after processing. A few retailers handle *all* canned goods as though they are sterile; consequently it is possible to see canned nonsterile products such as hams and bacon stored out of the refrigerated area."

Ironically, in some ways untreated food is safer than the mildly processed variety. "In untreated food," says the report, "the normal flora serves two functions that concern the consumer: it quickly renders the food undesirable when storage conditions are poor, and in some cases it competitively represses the growth of food poisoning organisms. . . . The former serves to warn the consumer of a potential danger, and the latter may actually eliminate the danger. In pasteurized foods the balance is upset; the organisms that normally grow most vigorously on the stored food are eliminated, and conditions are probably made more favorable for growth and, perhaps, toxin production by potentially pathogenic organisms."

The report notes that outbreaks of botulism traced to smoked fish in 1960 and 1963 are instances of the hazard of a mishandling of mildly processed food.

A number of new techniques for processing "convenience" foods are in the development stage or are being used for foods already on the market. The freeze-drying process (in which a product is frozen under vacuum, assumes a crystalline structure, and can be stored on a pantry shelf until required) has been the object of considerable hoopla. Among other new processes on the horizon are vacuum packaging, infrared irradiation, microwave heating, and radiation sterilization.

The report makes the point that "little time now elapses between a successful market trial of a product and its almost universal appearance throughout the very large American market."

The Food and Drug Administration's authority is limited to products where the presence of poisonous, toxic, or deleterious substances can be demonstrated. With many of the new products it appears that the full microbio-

logical implications are not understood. And, according to the report, "despite renewed interest in microbial contamination of foods, current efforts are inadequate to cope with problems associated with rapid changes and new developments in the food supply."

The subcommittee report culminates in a discussion of the development and use of microbiological criteria for food. It is a very circumspect treatment. The report notes that it is premature to set legal microbiological standards for food, other than milk, and water. The latter are homogeneous liquids which may be readily subjected to heat and filtration or chemical treatment in closed systems. "On the other hand," the report says, "solid foods cannot be filtered, vary widely in formulation and in the kind of processing to which they are subjected, and are handled in closed systems with difficulty. In addition, their production facilities are widely dispersed, so that control is difficult."

Other practical difficulties intrude. There is really no consensus on what specific criteria should be applied (which organisms should be included, and in what number, which methods should be used for sampling and analysis). If microbiological standards were written into law, the report says, an enforcing agency might be hard put "to prove that a bacterial level in excess of the standard was dangerous to health or was indicative of decomposition or filth."

Case For Uniformity

Industry, which has been concerned about the hazards implied in the new processes and, in fact, is largely responsible for initiation of the subcommittee study, is concerned that new microbiological standards be reasonably uniform across the country, so that "trade barriers" are not erected. Efforts by the leading national organization of food and drug officers to promote a model law in states considering such legislation appears to be having some success.

It is widely recognized, incidentally, that most state and local health authorities are ill prepared to enforce a microbiological code, and that money for trained personnel and new facilities would have to be found.

From all of this it is clear that the trail being blazed in food technology needs some tidying up, by public health officials, microbiologists, and other food scientists.—JOHN WALSH

Patents: Industry, Universities Renew Debate on Who Gets Rights to U.S.-Sponsored Medical Research

After more than a year of relative quiet, the question of government patent policies is again receiving concentrated attention, as government agencies and other interested parties move toward a clarification of the policy memorandum issued by President Kennedy in October 1963.

The Kennedy memorandum was the first attempt to cope on a government-wide basis with a major problem growing out of the skyrocketing federal investment in scientific research: Who should have the patent rights to inventions discovered on government grants and contracts? Although this was a topic on which ideologues on all sides were vociferous (some calling anything less than full government retention a "giveaway," others regarding government holdings as an attack on free enterprise), Kennedy took a middle ground. The memorandum rejected a "single presumption of ownership" on behalf of the government and provided that in certain cases patent rights could be acquired by the contractor. In one area, however, that of "exploration into fields which directly concern the public health," the memorandum was definitely weighted in favor of government retention. In this it followed a long-standing policy of the Department of Health, Education and Welfare (parent agency of the Public Health Service and the National Institutes of Health) under which the government generally took title to medical discoveries made by researchers on agency funds.

Now the pharmaceutical industry, supported to a certain extent by some university representatives, has begun to protest this policy and is seeking a change. The industry contends that this policy has produced (i) "an accelerating decline of medical research cosponsored by industry and government" and (ii) "an increased strain on the traditional university-industry bonds which have been such an important segment of this country's efforts in medical research." The first of these, according to a document recently made available by the Pharmaceutical Manufacturer's Association (PMA), the industry's trade association and Washington lobby, is largely the result of HEW's "confiscatory policies" and its reluctance to recognize that "the contribution of industry in providing private financing and know-how to develop and market a drug deserves a compensatory degree of market exclusivity." The second, the statement claims, is caused by "unrealistic government patent policies toward academic grantees, its refusal to recognize the right to appropriate financial return for them, and the inability of the industry to compete with the government financially for university research facilities." These policies, the PMA statement asserts, are "rapidly erecting a 'Berlin Wall' between the pharmaceutical industry and a heavily financed governmental research program."

What the industry seems to be saying, in short, is that if the government always takes the patent regardless of industry's contributions to the same research (either in the form of outright grants to researchers or in the actual development of a product first discovered on a government grant), industry's incentive to continue such cooperation will—and by implication, the productivity of medical research—decline.

The only trouble with the industry's position is that there does not seem to be much solid evidence for it. It is true that in the past 2 years the number of new drugs placed on the market has declined, but this is thought by most observers to be related chiefly to the effects of more stringent marketing requirements of the Kefauver-Harris drug laws of 1962. The link between the decline and any asserted breakdown in university-industry relations seems remote. Evidence of a "breakdown" is itself lacking, since the pharmaceutical industry appears to have spent over $2 million more in R&D expenditures at academic institutions, medical schools, hospitals, and nonprofit institutions in 1964 than it did in 1963. (The industry-wide total for such expenditures in 1964 is estimated to be $15.2 million.) In addition, the industry is able to supply no statistical evidence of a deteriorating relationship, and when asked for specific examples, PMA could contribute only a handful of anonymous illustrations which it recently solicited from its member firms. These offer several statements of the case but tell nothing at all about the potential seriousness of the events described. (There is, as yet, no reason to think that industry anxiety over patent rights has ever deprived the public of a valuable drug.) One company, for instance, said, "There have been dozens of cases in which we have had to give up any idea of cooperation with university people and others because they have had govern-