THE FOOD AND DRUG ADMINISTRATION'S NATIONAL TESTING CENTERS

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The Food and Drug Administration is currently engaged in an experiment to determine the feasibility of operating a centralized laboratory for microbiological analyses on a large scale. Because of rising concern in recent years about the level of contamination of foods, drugs, and cosmetics by microorganisms, it has become apparent that FDA must expand its programs for bacteriological surveillance manyfold. Two courses were open to us: To enlarge the microbiological staff and facilities in each of the District laboratories; or to institute a centralized microbiological laboratory or laboratories. We chose the latter course.

The FDA field laboratories have been staffed with bacteriologists for less than a decade. Our building program in this field has been sharply accelerated within the last two years, and we now have between 70 and 80 professional bacteriologists reporting to the District Chief Chemists, or an average of less than five per District. These bacteriologists, in addition to their pursuits at the bench, accompany inspectors in their visits to plants and warehouses, and, of course, the newer recruits require training and indoctrination in regulatory bacteriological analyses. Much of this training is provided by experienced research bacteriologists in our headquarters Division of Microbiology.

For more than forty years, the Division of Microbiology has conducted investigations on the contamination of foods, drugs, and cosmetics by microorganisms, has developed methods for the detection, identification, and isolation of such microbiological contaminants, and has applied these methods to limited numbers of selected commodities in planned surveys. A notable example of such applied research has been our twenty-year project on the classification of toxic staphylococci and our development of ultra-sensitive serological tests for the detection and identification of staphylococcal enterotoxins. Other investigations have dealt with salmonellae, *Clostridium botulinum*, and E. coli contaminations. Our objective now is to increase the scope of such research and surveillance programs and to examine large numbers of different articles in an attempt to define the dimensions of the microbiological contamination problem. If this task could be assigned to the Division of Microbiology, where we already have a cadre of trained bacteriologists, we could proceed to activate the program at once. But we would thereby cut off the source of research talent for future activities. We concluded that our best recourse would be to gather bacteriological resources in a centralized field laboratory under the direction and guidance of experts in the Division of Microbiology, train them in one phase of microbiological analysis after another, as needed, and funnel samples into that central point for rapid analysis. The collection and flow of samples could be controlled to suit the capabilities of the analysts, and large numbers of similarly constituted articles could be examined simultaneously, thus increasing the efficiency of the operation. Furthermore, by collecting samples throughout the country, it should be possible to accumulate information about the condition of the food and drug supply nationally, as well as that of imported commodities, instead of integrating the meager data derived from sporadic local sampling over a long period of time.

With these potential advantages in mind, we propose to launch a feasibility study for a National Center for Microbiological Analysis this autumn. A suitable model for a national surveillance project might well be the detection and determination of *Salmonella* contaminants in baby food, or the incidence of deleterious staphylococci in cheese. Samples of these commodities will be collected by our inspectors in the 17 field District offices. The samples will then be sent to the Center for examination. In the meantime, bacteriologists detailed for this duty will have been indoctrinated in the techniques for isolating and identifying salmonellae by our experienced research bacteriologists in the Division of Microbiology. These experts will also participate in the analytical program and will preside over the interpretation of the results.

Before completion of the salmonellae project, we would proceed to train staff intensively in the isolation and identification of staphylococci. We could then collect domestic and imported cheeses at points throughout. the United States and send them to the central laboratory for examination. In this manner, we could ascertain the bacterial load of samples throughout the country and determine whether a national or international problem exists, or if there are local problem areas which require further attention. If this approach succeeds, we shall recommend to the Secretary that a National Center for Microbiological Analysis be established officially.
In the scientific aspects of this process, we expect to follow the pattern we have previously evolved in setting up a National Center for Drug Analysis at St. Louis. In the drug area, as in the microbiological area, we wished to intensify our surveillance of articles moving in interstate commerce. We therefore decided to test the feasibility of a National Center for Drug Analysis, and in March 1967 we selected the St. Louis District laboratory for this experiment. Two categories of drugs were collected for examination-anticoagulants and mild tranquilizers. The chemists in the St. Louis District were given intensive training in the analysis of these drugs by experienced scientists in the Division of Pharmaceutical Chemistry. The normal laboratory workload of the District office was diverted to the surrounding Districts--namely, Chicago, Kansas City, Dallas, and New Orleans. After several months and about a thousand sample analyses, it became apparent that the experiment was successful. Samples were examined expeditiously, the pattern of violative samples was readily discerned, and the home Districts were promptly notified where corrective action seemed appropriate. For example, the large volume of anticoagulant drugs analyzed in a short period of time indicated faulty batch-to-batch control, and several lots of these drugs produced by a manufacturer in the Chicago District and one in the New York District had to be recalled. Such disclosures probably would not have been brought to light if we had relied on the previous sampling and analytical programs in which small clusters of samples were examined by, the District laboratories over a long period of time. On the other hand, results obtained in the systematic examination of minor tranquilizers showed few violative batches, and we were able to conclude that only occasional regulatory attention is necessary for this category of drugs.

On the basis of this feasibility study, the Food and Drug Administration recommended to the Secretary of HEW that a National Center for Drug Analysis be established at St. Louis. The St. Louis District office subsequently was abolished and its administrative and inspection functions, as well as its laboratory responsibilities, were distributed to the neighboring Districts.

In the past year, the National Center for Drug Analysis has handled two different types of programs. One of them involves sampling at hospital and retail drug stores for the collection of categories of drugs similar to those examined in the feasibility study. In the second type, the so-called "saturation program," samples of one particular type of product from all manufacturers are collected from whatever source available, including warehouses and manufacturing plants. We are still uncertain as to which approach is preferable, and our evaluation of our findings continues.

In concentrating surveillance drug samples and bacteriological samples in national or regional laboratories, to do not intend to curtail analytical work of that nature in the District laboratories. On the contrary, we expect that our District drug chemists and microbiologists, freed from responsibility for such surveillance work, will be able to accompany our inspectors in their examination of plants and warehouses and thus help to disclose and correct local problems in manufacturing practices. They will also be ready to analyze the samples collected in these problem plants as corroborative evidence of a poor manufacturing environment.

Although the concept of a national or regional laboratory in the field is a new departure for FDA, such specialized laboratories have been operated in headquarters for at least 25 years. The National Center for Antibiotics and Insulin Assay was officially designated as such only this year. But its predecessor, the Division of Antibiotics, specialized in the examination of antibiotic products ever since FDA was given responsibility for the certification of penicillin and other antibiotics; beginning in 1945. All analyses involving antibiotics-whether automated or manual chemical or microbiological assays for potency, of biological tests for sterility or toxicity, or the determination of drug concentrations in blood or urine, or the detection of antibiotic residues in meat, fish, milk, and eggs-are performed in the National Center for Antibiotics and Insulin Assay. Upwards of 25,000 samples are analyzed in this laboratory annually. We have been able to meet our program requirements adequately with a staff of less than 100 chemists, microbiologists, and biologists because the steady flow of similar samples can be handled efficiently by specialists trained in the requisite techniques using modern instrumental systems. At the same time, we have been able to engage in research on problems arising in the course of analyzing antibiotic samples, to aid in the promulgation of standards and specifications for antibiotic drugs, and to advise the industry or improving its manufacturing and analytical processes.

Similarly, our Division of Color and Cosmetics has operated for many years as a centralized laboratory for the analysis and certification of color additives for use in foods, drugs, and cosmetics, and we have also centralized the examination of cosmetic samples in that Division and in the Division of Pharmacology and Toxicology. Bioassay methods for drugs such as ACTH, digitalis, and chorionic gonadotropins have also been centralized in the headquarters laboratory because it would have been uneconomical to set up small animal colonies in each of the District laboratories for this purpose. For the same reason our program of vitamin analyses traditionally has been concentrated it our Division of Nutrition.

In summary, we believe that centralized national or regional laboratories are advantageous chiefly because of their efficiency. With such a laboratory, it is possible to train specialists to analyze large numbers of similar samples by continuous use of complicated equipment, to obtain uniformly

reliable results, and to gain expert interpretation of these results. With modern automated and computerized systems of analysis, we hope to increase our effectiveness significantly.

Because food products are highly perishable, in contrast to drugs and preserved microbiological samples, it has been difficult to apply automated techniques in centralized laboratories to analyses for pesticides and food additives. However, given modern advances in food preservation and transportation, even food samples may be amenable to analytical treatment in centralized laboratories. If the proposed National Center for Microbiological Analysis is successful, we intend to explore the feasibility of national and regional laboratories for the analysis of pesticides and food additives.

Thank you.