THE ROLE OF STATISTICIANS IN HELPING FORMULATE NATIONAL HEALTH POLICY

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1. Introduction

The main theme of my talk is to discuss how and why I expect Statisticians or those with strong quantitative training to be increasingly drawn in to the orbit of policy making in the Federal Government. This will be an evolutionary process in recognition of the need to rely on individuals who can synthesize large, multi-dimensional data sets.

In the next 20 years, I fully expect that all Management Information Systems directed towards administering governmental programs will be designed and administered by individuals having strong statistical training. (By a management information system, I mean the use of computers for storing and retrieving large amounts of timely data which are used for making decisions). Although we have many such systems in existence today, they have been regarded as an End in itself, rather than an instrument to be used in making decisions.

In my opinion, one of the main reasons for the breakdown and dissatisfaction with many large government programs is the failure to provide for continuous evaluation of the program so that it can be continually modified on an ongoing basis. Every program should have a fixed proportion of funds for continual evaluation. -- A figure of 5% seems about the right figure to me.

Often, long after a program has started, a crisis erupts, a hurried evaluation is made, and critical decisions are taken. We have all seen how bad programs can be started. Although many such Programs are well intentioned, often the program is not realistic. There has been an inability to synthesize known information into decision models which can be readily applied. Often the data is much too complex to be interpreted by inexperienced or untrained individuals.

An example of poorly framed legislation is the Delaney Amendment. As you know, this legislation is supposed to protect the public against having carcinogens (or co-carcinogens) in products normally purchased in the open market. Essentially, as the legislation is written, any substance causing cancer in animals, cannot be used in foods and cosmetics. Neglecting for the moment that animal carcinogens are not necessarily carcinogenic in humans, we have the serious problem of relating the legislation to the "safe" dose of a substance. After the legislation was passed it quickly became apparent that many substances may be carcinogenic when given at high enough doses. Hence the legislation was interpreted in relation to "low-risk" of the substance inducing cancer. Some people have regarded a low-risk as one in which the dose of the carcinogen is so low that the risk of getting cancer is one in 100 million.

The difficulty with this interpretation is that the establishment of such a threshold level is impossible by direct experimentation. The problem is a statistical one as one is attempting to estimate the probability of a response at the low end of a dose-response curve. In order to directly establish a risk level of 10^{-8}, it is necessary to run 10^{10} tests without observing a single response. Alternatively one could model the situation by having a dose-response relationship, extrapolating to low values of the potential carcinogen and then adding on an additional margin of safety.

Last May at the Cancer meetings, someone calculated that the safe dose for cigarette smoking would be 1/10 of a puff in a person's lifetime if one applies some of the currently advocated statistical procedures for calculating a safe dose.

2. Indirect and Direct Policy Making

One must distinguish between two general types of contributions of statistics and statisticians in helping formulate government policy. These are characterized by indirect and direct input to policy making.

The contributions of statistics at an indirect level of policy making has been going on within the government for a very long time. For example, the data produced by the Census Bureau, the National Center for Health Statistics, and the Bureau of Labor Statistics have long been used as an indirect aid to policy making. One would expect that such data collection activities will be continually improved and extended to non-traditional areas.

However, I expect the increased impact of statisticians in the remaining part of this century to be more in the area of direct policy making. They tell the story that during W. W. I,

President Wilson appointed a scientific advisory group, chaired by Thomas Edison to make suggestions on new weapons. At that time the widespread perception of a scientist was the model generated by Edison or the Wright Brothers. That of an individual working in the basement or barn inventing something. So the advisory group was composed of so-called inventors. At the last minute, it was decided to appoint a physicist to the advisory group -- just in case some "figurin" had to be done.

We are now seeing a similar situation evolving with regard to statisticians. Much of government is conducted by thousands of advisory committees continually being appointed to aid both the executive and legislative arms of government. The number of advisory committees having statisticians as members is increasing. This is a reflection that such advisory groups may need a specialist in data analysis. Someone who can synthesize complicated data sets -- separate the fundamental phenomenon from the "noise" -- and explain the interpretation to the advisory group -- usually made up of individuals with diverse backgrounds.

Nowhere is this tendency more pronounced than in the health area. The number of advisory health groups in which statisticians are participating is one of the interesting characteristics of the applications of statistics to biomedical problems.

3. Personal Experiences

During the remainder of my talk I will tell you about one of my recent experiences dealing with advisory committees. During the recent past I have served on the Panel studying Bioequivalency for the Office of Technological Assessment; the FDA's Biometry and Epidemiology Committee, I was one of approximately 40 chairmen who helped draw up the National Cancer Plan, and have served on many ad-hoc committees assembled to recommend policy for a particular situation.

Whenever a committee is composed entirely of statisticians, it has been my experience that it is completely ineffectual with regard to having its recommendations carried out. There may be many reasons for this, but in general the committee is at too low a level to be taken seriously. Sometimes such Committees are set up to guard an administration from potential criticism on the statistical aspects of a problem.

By far the most successful committees are those in which the statistician is involved as an interdisciplinary member. The OTA Committee on Drug Bioequivalency is an interesting example of a rather successful committee.

About two years ago, new legislation was passed setting up the Office of Technological Assessment for the Congress. The idea was that Congressmen would suggest studies which the OTA would carry out. These studies were to serve as the basis for generating new legislation. The first study organized was one on Drug Bioequivalency. The Panel was chaired by Bob Berliner, Dean, School of Medicine, Yale University. In addition to Dr. Berliner, there were two other Deans, three Chairman of medicine or pharmacology, and two Professors. -- I was one of the Professors. All the individuals were internists or pharmacologists. I was the house statistician. Membership on the Panel came about from lists supplied by the PMA (Pharmac. Manuf. Assoc.) AMA and FDA. All members had to be acceptable to these groups.

This panel was particularly important, aside from the problem it dealt with, because since it was the first OTA panel, it was likely to set a precedent as to how it operated.

The way the panel functioned was kind of interesting. It was formed in April 1974 and delivered a final printed report on July 15, 1974. In-between, there were 4 Panel meetings, all in Washington where we were literally working 12 hours/day. Finally, a few panel members put the entire report together.

The problem of Drug Bioequivalence was to examine the relationships between the chemical and therapeutic equivalence of drug products. That is, do products with the same physical and chemical composition produce comparable therapeutic effects?

During the course of the study, it became apparent that the drug bioequivalence problem was not as serious as the quality control and acceptance sampling methodology used to insure acceptable drug quality. By law drug products must pass tests adopted by the U. S. Pharmacopea. In my view and in the eyes of the Panel these were entirely inadequate. The Panel's recommendations and findings are summarized in Drug Bioequivalence, A Report of the Office of Technological Assessment, Drug Bioequivalence Study, GPO. 1974.

Finally in closing, I have the personal impression that as a country we are on the doorstep of having some kind of National Health Insurance Plan. This will involve many statisticians in both an indirect and direct policy level. The evaluation of the coming National Health Insurance Plan will probably be one of tha major biometric challenges of the next decade in this country.