Comment

Avital Cnaan

I have thoroughly enjoyed reading David Banks' paper "Is Industrial Statistics Out of Control?". I am currently in academia and have spent several years in industry, allowing me to have some perspective on the topic both from within and outside industry. Much of what Dr. Banks wrote was familiar to me; some of it was new to me. What surprised me was the implication that this article represents the entire role which statisticians play in industry. Dr. Banks looked solely at industry as manufacturing processes, and he reviewed most aspects of statistics as they relate to manufacturing. He reviewed issues of experimental design, control charts, the popular Taguchi methods and so on. I could not agree more with him about the overpopularity of these methods. I myself was surprised when I first understood what they were about, how simple and straightforward they were and the fact that they stemmed from such elementary statistics. However, they have an aura of something fantastically new. Therefore, regarding most of his presentation, other than minor points, I could not but agree. There are some statements that Dr. Banks made that probably could not have been truer. For example, his statement about the Japanese being committed to continual improvement as opposed to the U.S. "home run" corporate strategies. Unfortunately, it is still true now, if not even more true, because corporations feel financial pressures even more so than in previous years. I agree with Dr. Banks that the Japanese success can be attributed to their policy approaches more than their use of one statistical technique or another.

There is a big role of statisticians in industry that Dr. Banks ignored. There is a tremendous role for statistics in the research and development components of industry. It appears that Dr. Banks, and there must be many others like him, perceives that the primary role that statisticians serve in the industry relates to manufacturing. My experience has been that, at least in some industries, statisticians play a much stronger and larger role in the research and development part of the industry than in the manufacturing part. These statisticians, including myself, would definitely define themselves as "industry statisticians" and their primary professional agenda as dealing with "industrial statistics." My personal experience has been primarily with the biopharmaceutical industry in the research and development part. At Merck & Co., which is one of the largest pharmaceutical companies worldwide, there are roughly 70 statisticians. More than 60 of those are in the research and development part, and fewer than 10 of them are in either manufacturing or marketing. I think that the distribution, if not the magnitude, reflects the rest of the pharmaceutical industry. In addition, there are statisticians working at various clinical research organizations who are not formally part of the industry but support this industry also on its research part and not on its manufacturing part. I devote this commentary to describing the work that industrial statisticians involved in research and development do and the areas to which they make contributions.

Statisticians are involved in all phases of the research that occurs in their company. In the pharmaceutical industry, the first step is to come up with a viable compound. Then, that compound goes through laboratory testing, animal testing and finally human testing. The statisticians are involved in all of those phases, and statisticians both in academia and industry have been responding to needs over time to develop new methodologies. Recent examples are a paper on estimation of relative potency (Racine-Poon, Weihs and Smith, 1991) and a paper on simultaneous evaluation of benefits and risks in clinical trials (Chuang-Stein, Mohberg and Sinkula, 1991). In the preclinical or laboratory setting, statisticians are also frequently asked for help in a consulting role that does not necessarily translate into publications, but certainly often involves innovative and thoughtful approaches. These approaches are valued by their colleagues, be they biologists, chemists, pathologists or other professionals. In the clinical phase of drug development, the role of the statistician is very important and the drug cannot be licensed without very heavy input from statisticians. The statisticians support the experimental design of these studies, also known as clinical trials, they monitor their progress from the statistical viewpoint and finally they are responsible for data analysis. Of course, many of these analyses are straightforward and involve only t tests, χ-squares or analysis of variance. But many of them are not and as time marches along, the industrial statisticians develop a variety of new and better ways to deal with analyzing more complex data, more complex phenomena and increasing demands of

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