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Will Clinical Trials Survive?

by Carl G. Kardinal, M.D.

When I assumed the presidency of ACCC on March 25, 1994, the major issue regarding the future of clinical trials in the United States evolved around the issue of third-party reimbursement for the patient care costs incurred in scientifically based, peer-reviewed protocols. With larger and larger segments of the patient care base being controlled by managed care plans that limited access to subspecialty care, accrual to clinical trials would be expected to decline. What could be worse than third-party payers refusing to pay for investigational treatments? Well, worse was about to happen.

On March 28, 1994, Bernard Fisher was forced to resign as NSABP chairman. By April 1, all currently active NSABP protocols were suspended. This issue has been extensively reported in medical journals as well as the popular press. It is not my purpose to rehash a series of issues that have been previously discussed *ad nauseam*, but to postulate on the impact of the NSABP events on the future of clinical trials.

A series of articles appeared in the *Chicago Tribune*, the *New York Times*, and the *Wall Street Journal*, as well as the local press, which described the issue of fraudulent data submitted by Dr. Roger Poisson of the St. Luc Hospital in Montreal on patients enrolled in the NSABP lumpectomy trial. These reports precipitated Congressional hearings and led to public and professional reactions of outrage, betrayal, and loss of trust in the clinical trials' mechanism.

A second destructive blow to cancer clinical trials occurred almost simultaneously with the reporting of the Roger Poisson incident. It was revealed that four deaths had occurred due to endometrial cancer in women taking tamoxifen for Stage I breast cancer. Questions were raised as to when the deaths from endometrial cancer were known, and if the NSABP was withholding information. This angered women's groups and precipitated further Congressional inquiry.

It may take years before the public trust in clinical trials can be reestablished. This may be particularly true in the African-American population. Only recently, through considerable hard work, has the public trust in this group of individuals been reestablished following the great abuse of the black population during the Tuskegee syphilis trials.

What are the implications for health care professionals? Clinical research has never been self-supporting and is becoming perceived as a nonrevenue-generating cost burden by many administrators. If the reputation of clinical trials is tarnished and if it is a luxury item, many institutions will cease to conduct this vital activity. Since half of all patients entering cancer clinical trials are enrolled by non-university community oncologists, what is their reward for clinical trials' participation? It is definitely not monetary, but rather their ability to offer their patients cutting-edge therapy. Also, community oncologists can become involved in protocol design and have direct interaction with other physician investigators. Many new regulations for clinical trials are proposed that will greatly increase the hassle factor and may make clinical trials' participation much more difficult and less rewarding.

The most important lesson to be learned from the recent NSABP events is that fraud and scientific misconduct are unacceptable, even when the study outcome is unchanged. Also, if fraud or other scientific misconduct occurs, there is a need for immediate and accurate reporting so that the public, the media, and Congress can be reassured. Certainly, the NSABP did not tolerate fraud or misconduct, but the events that followed the *Chicago Tribune* publication precipitated a crisis that may take years from which to recover. Hopefully, the public trust can be rapidly regained, and few clinical investigators and clinical trial participants will be lost. Hopefully, ACCC will continue to devote its efforts to the still unsolved issue of third-party reimbursement for the patient care costs of clinical trials. ■