[Ethical Guidelines for Statistical Practice: Report of the Ad Hoc Committee on Professional Ethics]: Comment

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used in statistical work. In my experience, equal or possibly even more importance should be given the data used in an inquiry. In clinical trials, one could perform analyses on one or all of the following groups of patients: all patients registered in the study; all patients registered who were eligible for the study; all registered and eligible patients who received the appropriate treatment and at least some adequate course(s) of the treatment; and all registered, eligible patients who received all of the appropriate courses of treatment as outlined in the protocol. In some clinical trials in which I have participated, the last-named subgroup of patients constituted less than 50 percent of the total patients registered. A scientific and ethical question arises when the relative merits of the treatments depend on which of the subgroups of patients received primary focus in the analysis. The most ethical approach is to analyze all of the various subgroups and, when conclusions differ among them, the study should be reported as inconclusive.

When writing up the results of some studies, a delicate problem arises in the emphasis to be given to reporting "known inaccuracies in the data." Giving too much detail about problems can supply critics with a basis for arguing that results must necessarily be invalid. Not divulging problems would be a cover-up. The only ethical approach is to report problems and inaccuracies, and to evaluate the effect that these might have had on the major conclusions of the study.

Any statement of guidelines developed within the ASA and approved by the Board of Directors could only apply to ASA members. However, the guidelines clearly should apply to all practicing statisticians and could be submitted to other statistical societies for their consideration. Legally, the guidelines can be used to delineate what is acceptable practice in the statistical profession. However, as written, the guidelines are more useful to a practitioner than if they had been written in the formal language of the law.

REFERENCES

LEVINE, R.J., and LEBACQZ, K. (1979), "Ethical Considerations in Clinical Trials," *Clinical Pharmacology and Therapeutics*, 25, 728–741.

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Comment

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I feel strongly that an officially recognized set of ethical guidelines for statistical practice is urgently needed; the American Statistical Association is to be commended for taking the initiative in developing and sponsoring the guidelines. The statement that has been prepared serves this purpose well. The guidelines apply appropriately to the practice of statistics generally; they are not and should not be limited in application to statisticians, however defined, or to members of the Association. And while some may consider these moral precepts clear and obvious, they are not necessarily so to everyone, and all statistical practitioners, but especially those first entering the field, need to be reminded of the ethical standards the profession expects of them.

No consideration should be given at this time to establishing sanctions for violators or setting up enforcement procedures, and the time may never come when we would want to do that. The guidelines will have their effect through moral suasion, and this should be enough. While I do not believe there would be any direct legal implications, surely the courts would take the Association's guidelines into account in considering any allegations of fraudulent statistical behavior.

There is one particular change I would urge be made in the document. The statistical practitioner does not need all the information about the charge to the Committee on Ethics. Such material detracts from the statement and should be deleted. All the practitioner needs to know in this regard is that there is a Committee on Ethics, that it will reconsider the guidelines for changes from time to time and after three years will determine whether to recommend that they be made permanent, and that any comments about the guidelines should be sent to the Committee on Professional Ethics by a specific date.

I hope the guidelines will get widespread distribution. Federal agencies such as ours will find the guidelines a valuable supplement to such publications as the *Statistical Policy Handbook* of the Office of Federal Statistical Policy and Standards. We shall see to it that all of our statisticians and analysts have a copy of the guidelines to use along with such sources as our *National Center for Health Statistics Staff Manual on Confidentiality*. The guidelines will also be invaluable in the universities and in the private sector.

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