by Bond have been raised in the review process or in a subsequent issue in response to the publication? Bond is not listed on the editorial board of *Infection Control and Hospital Epidemiology*. Whom do his comments represent? Should not scientific concerns be addressed by appropriate test data gathered in a scientific way and in a scientific forum?

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The author replies.

Opinions may differ based on a number of factors. However, there must be some degree of misunderstanding in Malchesky's response to my editorial. The use of biologic indicators designed for steam or ethylene oxide to monitor a liquid chemical sterilizer process has no precedent in the literature, and as such, the concept is open to question and concern. Further, Malchesky calls for specific data to justify my editorial position. The only such data are in corporate handout material or from other sources linked with vested commercial interests. The product-specific references listed in Kralovic's paper, in my editorial, and in Malchesky's reply to the editorial attest to this fact. Also, Malchesky should know that testing and evaluation of medical devices, other than in instances of ongoing disease outbreak investigations, is not in the mission function of the Centers for Disease Control and Prevention.

Malchesky mentions "much development work in the industry" toward resolution of current difficulties in instrument reprocessing. Apparently, details and results of such efforts are neither published nor distributed widely in the field. Herein is part of a major problem for medical device users. Until truly independent, unbiased data are forthcoming and are published in peer-reviewed journals, manufacturers' claims clearly will remain just that-claims. Appropriate studies in a number of areas could be made possible by, for instance, arrangement of carefully granted funds and supplies to a qualified and totally impartial academic institution. It is difficult to understand why this has not been done to date, especially for a product incorporating concepts as novel as the one represented by Malchesky.

In the interim, it is important to know that data submitted to federal regulatory agencies prior to marketing of a medical device do not necessarily reflect whether the device will work as expected in an in-use setting. With regard to my editorial questions about the unique methodologies allowed by regulatory federal agencies during pre-market testing of the medical instrument reprocessing system, it is also important to know that others recently have examined and questioned the entire process for federal registration, marketing clearance, and regulation of chemical germicides and related medical devices.[1,2] Interested readers may obtain single copies of these documents at no charge from the U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20884-6015; telephone (202) 512-6000. At present, the user community will have little choice but to gather existing information and make individual decisions.

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The Editor replies.

In his final paragraph, Malchesky poses a series of questions that suggest an unfamiliarity with the traditions of this journal and, indeed, most medical journals. He states that publication of a "negative" editorial is "unusual." However, the editorials in four of the first eight issues of 1993 have criticized or taken issue with the related manuscript. As Malchesky notes, Bond is not on our Editorial Board; but then, neither has been any other editorialist this year.

Malchesky appears to be offended that the editorial contains opinion; but that is precisely its role. For each issue, we select the manuscript (even, rarely, a

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