tion of the study has to be considered. For example, while there was no statistically significant difference between treatment groups for the primary end point (respiratory-related death or life-threatening experience: risk ratio, 1.40; 95% confidence interval, 0.9 to 2.1), if the study had continued as planned, it is likely that this comparison would have reached statistical significance.

It is also unclear why certain analyses were included in the report; for instance, data are included from the 28-week treatment period combined with data spontaneously reported for a 6-month poststudy period (Table 6). The authors state that patients may have continued to take unused study medication after the study was completed. However, it is possible that placebo-treated patients could have initiated treatment with salmeterol following their participation in the study, which would obscure any treatment effect. Also, the authors included analyses based on an artificial division of the study into two ‘phases,’ based on different recruitment strategies. Whether this post hoc, exploratory analysis was initiated based on a scientific hypothesis or data dredging is unclear. Nonetheless, in both phases, there were more asthma-related deaths in the salmeterol group. Interested readers may review the proceedings of the Food and Drug Administration advisory committee convened to discuss SMART and the public statements issued by the Food and Drug Administration.3,4

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To the Editor:

The data collection and analysis of the Salmeterol Multicenter Asthma Research Trial were conducted with rigorous scientific integrity, and without known bias; our article was a transparent, peer-reviewed communication designed to inform health-care practitioners.

Dr. Seymour questions why data from the 28-week treatment period plus a 6-month follow-up period were included along with data from the 28-week treatment period. The protocol included a 6-month follow-up because patients received 6 months of therapy and underwent minimal procedures to retrieve unused medication. It is well-recognized that medication therapy compliance is poor; therefore, patients may have had study medication left and continued to take it beyond the 28-week period. Although it is possible that patients receiving placebo may have initiated salmeterol therapy after the study, the only planned analysis included the data from the 28-week treatment period plus the additional 6-month follow-up period, which were provided to an independent Data Safety Monitoring Board and subsequently to the US Food and Drug Administration (FDA). After study termination and the reporting on the interim analysis, further discussions with the US FDA led to an agreement to focus the analysis on the 28-week treatment period, although no substantial differences exist between the analysis of the 28-week treatment period and that of the 28-week treatment period plus the 6-month follow-up period.

Dr. Seymour further questions the data reported for the two distinct phases. These data were acknowledged in the article as being exploratory. It is well-recognized that study design and recruitment approaches can lead to confounding in studies. Switching from media-driven recruitment, yielding 13 asthma-related deaths in 15,342 patients (phase I), to investigator-driven recruitment, yielding 3 asthma-related deaths in 11,013 patients (phase II), suggests that the recruitment approach may have affected outcomes. Furthermore, the quality of care and the physician-patient relationship can affect outcomes and were likely different between the phases, providing the scientific basis for this analysis.

We agree that interested readers should review the breadth of the data and the proceedings of the US FDA advisory committee that was convened to discuss long-acting β-agonists.

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Dr. Nelson is a consultant, speaker, and recipient of research grants from GlaxoSmithKline, and was also a member of the Morbidity and Mortality Review Committee. Dr. Dorinsky is an employee of GlaxoSmithKline. Reproduction of this article is prohibited without written permission from the American College of Chest Physicians (www.chestjournal.org/misc/reprints.shtml).

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Disposable vs Reusable Bronchoscope Valves

To the Editor:

Mehta et al should be congratulated for developing a much-needed American College of Chest Physicians/American Association for Bronchology (ACCP/AAB) consensus statement on preventing infections associated with flexible bronchoscopy, which recently appeared in CHEST (September 2005).1 However, at issue are specific ACCP/AAB recommendations to use only bronchoscopes that have “disposable suction valves and biopsy valves” and that “nonimmersible bronchoscopes and those with a reusable valve should be replaced as soon as possible.”2 These well-intentioned recommendations essentially contraindicate the use of many existing scope/valve designs, and end users may feel compelled to discard their current equipment utilizing reusable valves and seek replacement instruments utilizing only
disposable valves. Pentax Medical Company believes these specific recommendations are unnecessary, financially imprudent, and without scientific basis or documented evidence.

In compliance with current regulations and guidance for reusable medical devices, manufacturers should provide microbiologically validated reprocessing instructions for cleaning and high-level disinfection (or sterilization) of the endoscope and reusable endoscope components (valves). Provided that manufacturer-validated instructions are supported by simulated-use studies and end users strictly adhere to these recommendations, reusable scope components (valves) should be an acceptable alternative to disposable components for semicritical devices, including bronchoscopes.

The reference to support the ACCP/AAB recommendation described a 1986 incident identifying one brand/design and involved a questionably inferior valve design unlike the valves of other manufacturers. Many years of experience has demonstrated that reusable valves, if reprocessed in strict accordance with the validated recommendations of the manufacturer, have not been reported to be vectors of infection.

While we recognize the potential for possible contamination of valves, we believe the same potential risks exist whenever any endoscopic instrument and/or scope component is not reprocessed in strict accordance with the validated instructions of the manufacturer. We hope that the ACCP/AAB can reconsider its current position and accept the use of reusable valves reprocessed by validated high-level disinfection or sterilization processes.

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To the Editor:

We thank Mr. Nelson for his interest in the consensus statement on the prevention of flexible bronchoscopy-associated infections (November 2005).1 We also appreciate Mr. Nelson’s concerns regarding the recommendation to replace flexible bronchoscopes equipped with reusable biopsy valves with flexible bronchoscopes equipped with the disposable valves.

A faulty valve design was deemed responsible for the outbreaks of “true” as well as “pseudo” infections related to flexible bronchoscope in a significant number of patients.2,3 These events prompted the development of the consensus. We recognize that several flexible bronchoscope manufacturers have introduced a number of flexible bronchoscope models, and that each of these models has suction and biopsy ports capped with valves of different designs. Therefore, it was beyond the scope of the consensus statement to review each of these valve designs and make specific comments. It was the decision of the committee to make the safest recommendation for using disposable valves. We agree with Mr. Nelson that if a manufacturer of the flexible bronchoscope can ensure the proper sterilization of a reusable valve each time, that should be acceptable.

The consensus statement “highly recommends” and does not mandate the practice or set a time limit. We believe that the financial burden of replacing expensive flexible bronchoscopes would strongly encourage strict adherence to the disinfection practices or the use of properly sterilized reusable valves. We once again stress that, due to the lack of adequate scientific evidence, this consensus statement was based on the opinions of experts.

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