To the Editor:

In the January 2009 issue of CHEST, Michael A. Jantz, MD, FCCP, reviewed the issue of sedation during bronchoscopy.1 I certainly agree with the gist of the editorial until the concluding paragraph. The last line of the editorial reads: “Based on the available data, fospropofol appears to be safe for moderate sedation and should not require anesthesia monitoring.” The clinical experiences described by Dr Jantz certainly give the impression of the appropriateness of his comment. However, the following is from the labeling for fospropofol (LUSEDRA) as approved by the US Food and Drug Administration (FDA) on December 12, 20082:

LUSEDRA should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the diagnostic or therapeutic procedure. Sedated patients should be continuously monitored, and facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available. Patients should be continuously monitored during sedation and through the recovery process for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.

As further clinical evidence is accumulated, the FDA may see fit to modify the labeling for fospropofol. Future clinical studies performed to establish the clinical safety of fospropofol will need to adhere to the FDA’s labeling as should clinicians performing bronchoscopy with sedation provided by fospropofol.

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REFERENCES

Caution Advised With Use of Fospropofol

To the Editor:

I appreciate the comments in response to my editorial1 provided by Dr. Fuhrman regarding the use of fospropofol during bronchoscopy.

I am in agreement with the US Food and Drug Administration labeling for fospropofol that “patients should be continuously monitored during sedation and through the recovery process for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.”2 I do not necessarily believe, however, that “LUSEDRA should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the diagnostic or therapeutic procedure.”2 Available data suggest that fospropofol can be used safely for moderate sedation without anesthesia monitoring. In addition to the study in CHEST by Silvestri and colleagues (January 2009)3 involving 252 patients undergoing bronchoscopy and demonstrating an acceptable safety profile, a study of 101 patients undergoing colonoscopy treated with fospropofol plus fentanyl for sedation showed a low incidence of hypoxemia.4

I do think that physicians who use fospropofol should be able to manage the airway in the event that the patient has a temporary state of deep sedation or general anesthesia. In my opinion, most pulmonologists have the skills to do this and most bronchoscopy suites have the capabilities for airway management and cardio-pulmonary resuscitation. I would encourage additional studies of fospropofol compared with standard medications for sedation during bronchoscopy. In the appropriate clinical setting and with institutional review approval, I do not feel that anesthesia monitoring is necessarily warranted for these studies. Whether the Food and Drug Administration will modify the labeling for fospropofol after completion of additional studies is certainly open to conjecture. I believe the data will ultimately show that fospropofol can be safely used for sedation during bronchoscopy by pulmonary and critical care physicians.

Response

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