In Reply—Dr. Finkelstein and colleagues raise a number of important issues related to the intravenous administration of fluids and drugs. They indicate that glass particles may be found in ampoules, either before opening or after opening of the ampoule. A further search of the literature indicates that particulate matter or glass has been found in administration sets,1 plastic bags,2 iv solutions,3 drug solutions,4 syringes,5 glass containers,6 and powders for reconstitution.7 Clear drug solutions7 have been found to contain both macroscopic and microscopic particles upon opening of the ampoules. These microscopic particles can be aspirated, and many of them are too small to be visible under normal lighting conditions, even in clear drug solutions. Macroscopic fragments such as those identified by Dr. Finkelstein and co-workers would be too large to be aspirated through a needle.

Quality assurance is of the highest priority for Stuart Pharmaceuticals, and we are working with the ampoule manufacturer as an ongoing process to ensure that Diprivan® (propofol) is of the highest possible quality. Currently, every filled ampule of Diprivan® is inspected during production, consistent with our approved quality-assurance procedures. We have recently instituted an additional inspection prior to filling, for further assurance.

A thorough review of the safety data base for Diprivan, based on an estimated exposure of ten million patients worldwide and over 80 controlled clinical trials in North America, has not revealed any clinical events that appear to be related to the injection of particulate matter.

Should an anesthesiologist choose to filter intravenous agents, filters with a pore size of 0.22 μm are not appropriate for use with Diprivan®. Filters of less than 5 μm could restrict the flow of Diprivan® and may cause breakdown of the emulsion. Although we are currently conducting studies to determine the performance and compatibility of different filter types with Diprivan®, evidence has been presented that a 5 μm filter does not affect the integrity of a more concentrated emulsion.

In summary: review of the international safety database for Diprivan® has not revealed evidence of clinical events due to injection of particulate matter to date.

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References


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