

Summary of today's conference call with FDA and ASA regarding anesthesia drug shortages

The FDA has allowed the importation of Propovan from Europe during the current emergency. Propovan is made by APP and is similar to propofol except for a few medium chain triglycerides in the emulsion. Clinically, it should be similar to propofol. Some clinicians have reported a slower onset when compared with propofol.

The package insert for Propovan says that allergy to soy and nut products contra-indicates the use of Propovan. Propovan contains soy and there is a presumed cross-over with other nut products. The FDA has no official position regarding the contra-indication to nut products. Propofol preparations are also made with soy and the FDA is not currently aware of problems that have occurred when propofol has been used in patients with other nut allergies.

All three firms (Hospira, APP and Teva) have reported that propofol is back in production. They will begin shipping to wholesalers immediately. However, they will not be able to fill the current demand for several weeks and the shortage is expected to remain until late January.

Hospira has resumed production of thiopental but the shortage of that drug is expected to continue until the end of January. The shortage was not due to an FDA related issue but by a company decision to temporarily halt its production of the drug.

Amidate, brexvatil and ketamine are reported to be in good supply.

Several of the neuromuscular blocking agents are also in short supply. Chief among these are vecuronium and cisatracurium. These shortages are not due to FDA related issues but to internal problems with the manufacturers. Cisatracurium and vecuronium are currently being released and demand should be met by January.

Responses to questions from callers.

The FDA does not know when Fospropofol will be released for sale. That is a decision of the manufacturer.

There may be price gouging by the wholesalers. Incidents of that should be reported to: drugshortages@FDA.hhs.gov

Hospira is considering ending its production of thiopental. The FDA would like to collect data regarding its use. This data collection will be co-ordinated by the ASA. The method of data collection will be announced later.

The FDA strongly opposes drawing propofol into multiple syringes for use on more than one patient. This would violate current regulations. The exception would be syringes that are drawn under a uniflow hood by a pharmacist in a sterile environment, for immediate use (defined as within one hour of preparation). It should be noted that Propovan contains no preservatives

whatsoever and like propofol, it can support bacterial growth. As with propofol, Propovan in the operating room should be drawn for immediate use on one patient and should be discarded after six hours. The FDA reminded participants that there have been reports of sepsis and death following the use of both propofol and Propovan which have not been used in a timely fashion.

Amidate had been reported to be in short supply, but Hospira has informed the FDA that it is now able to meet demand.