

Pontikas, Jean (DPH)

From: Manning, Susan (DPH)
Sent: Monday, April 24, 2006 2:12 PM
To: Pontikas, Jean (DPH)
Cc: Young, Charles (DPH); Coffey, James D (DPH)
Subject: NECC Follow-Up

Attachments: 2 guilty of selling bad sterilizers to hospitals Chicago Tribune.html



2 guilty of selling
bad steril...

1 Jean - Note conclusion as reported in 4/14/06 news item.

On Chuck's return today, we reviewed the NECC communication dated 4/19/06 (I believe a copy was placed in your box last week). The very specific (tho not clearly major) items to be completed at this point appear to be recommended HVAC work scheduled for May 18; gowns and sleeves ordered are expected to be received this week; and new procedures re: sterilizing filter testing to commence with next lot ordered from Millipore (projected date not specified in response).

The NECC response comments re: Par. 2. re: one way flow in Clean Room 2 (not agreed to be "wise" by NECC - causing possibility of outside air flowing into clean room from continuous egress thru emergency exit) and re: Par. 3. re: retention of certain non-essential equipment in current location appears to not clearly present a risk to sterility since sterile prep is performed in the microenvironments in this room which is maintained as a clean room. These last items can be reviewed by the Board at the 5/9 meeting.

Let us know if you have any questions or direction - SM

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2 guilty of selling bad sterilizers to hospitals

By Michael Higgins
Tribune staff reporter
Published April 14, 2006

A federal jury found two medical-products executives guilty Thursday of charges that they sold millions of dollars in faulty sterilization equipment to hospitals in the 1990s.

Ross Caputo, former CEO of Mundelein-based Abtox Inc., and Robert Riley, the company's former vice president of regulatory affairs, falsely represented to hospitals that the U.S. Food and Drug Administration had approved their sterilization machines, prosecutors said.

The FDA had warned Abtox that the machines should not be sold, and the product's inability to properly sterilize medical instruments caused 18 patients to be blinded in one eye, prosecutors said.

Abtox sold 168 of the machines from about 1994 to 1998, earning about \$18 million in revenue, prosecutors said. Abtox later went bankrupt.

Caputo slumped back in his chair as a courtroom deputy read the jury's verdict. Riley dropped his head, covering his face with his arms.

Both Caputo and Riley were convicted on more than a dozen charges, including conspiracy to defraud the FDA and sale of a misbranded medical device.

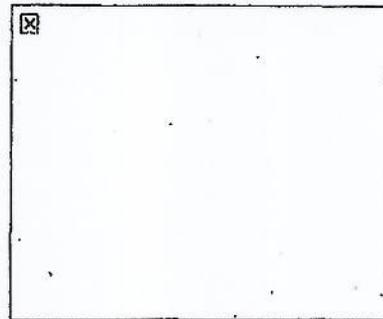
The trial took nine weeks. The jury returned its verdict in less than two days.

U.S. District Judge Ruben Castillo is scheduled to sentence both men on July 12. Under federal guidelines, they could face 10 years or more in prison, prosecutors said.

Riley's attorney Jonathan Feld said he expects his client to appeal, but he declined to comment further. An attorney for Caputo could not be reached.

The product at issue uses chemicals to sterilize medical instruments at low temperatures. Caputo and Riley said they had acted in good faith and believed they had the right to market the product.

But Assistant U.S. Atty. Michael Gurland argued that the FDA had approved a smaller version of the Abtox sterilizer for certain purposes.



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That product wouldn't sell, so Abtox, which was struggling financially, created a far larger, unapproved product and marketed it aggressively to hospitals, Gurland said.

"The defendants pulled a bait-and-switch on the FDA," Gurland said Thursday. He said that during the trial, an Abtox official testified that Caputo told him to sell as many of the sterilizers as he could "before the FDA catches on."

The injured people included three patients at Ravenswood Hospital in 1996, Gurland said.

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