

Prison time handed out in AM2PAT, Sierra Pre-Filled syringe scandal

Triangle Business Journal - by Jeff Drew Associate Editor

February 24, 2009

Two former employees of AM2PAT Inc. were sentenced Monday in Raleigh to 54 months in prison for their roles in sending out improperly labeled syringes linked to hundreds of bacterial infections and some deaths, according to a statement issued by U.S. Attorney George E.B. Holding.

U.S. District Judge Terrence Boyle handed down the sentences against Ravindra Kumar Sharma, 54, of Richmond, Va., Quality Control Director, and Aniruddha Patel, 43, of Carpentersville, Ill., Plant Manager. The two men pleaded guilty to a number of federal charges, among them mail fraud and knowingly sending misbranded medical devices into interstate commerce with the intent to defraud.

Sharma and Patel made the guilty pleas as part of an agreement with the U.S. attorney in which they pledged their cooperation to the ongoing investigation into AM2PAT, a Chicago-based company whose Angier office operated under the name Sierra Pre-Filled until it was shuttered last year.

The news release from Holding's office says that the charges stem from Sharma's work as quality control director and Patel's job as plant manager at the Angier facility, where AM2PAT manufactured syringes pre-filled with saline and heparin, a commonly used anti-coagulant.

Holding alleges that "members of the conspiracy" sent out syringes containing saline and heparin that were mislabeled as sterile when, in fact, the required sterility tests had yet to be performed. After the syringes were shipped, dates on records were changed to give the false impression that the tests had been done, according to Holding's press release.

The U.S. attorney's office alleges that "this scheme" led to between 200 and 300 cases of bacterial infections in patients injected with AM2PAT syringes. Some of those infections resulted in spinal meningitis and permanent brain damage, Holding says. Other infections led to death, though the release does not give a specific number.

In a related development, a federal grand jury in the Raleigh-based Eastern District of North Carolina indicted AM2PAT and its former president, Dushyant Patel, on 10 charges including conspiracy, mail fraud, the release of misbranded and adulterated medical devices into interstate commerce, and making materially false statements about the syringes to the U.S. Food and Drug Administration. Dushyant Patel may have fled to his home in India. Interpol is reportedly assisting in the international search for Patel.

“The crimes committed by Mr. Sharma and Mr. Anu Patel, and the related crimes alleged in the indictment against AM2PAT and Dushyant Patel constitute the most fundamental breach of the public’s trust,” Holding was quoted as saying in the news release. “Citizens in this country trust that producers of medical devices aren’t lying when they say that (they) have adequately tested a given product. As we’ve seen in this case, such lies can literally mean the difference between life and death.”