PRESS RELEASES

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Clinical Trial Fraud Detected by Independent Review Board, Reported to Federal and State Authorities

Washington, D.C.: On Friday, March 6, 2009, Coast Independent Review Board, an independent review board that has protected human subjects in thousands of clinical trials, discovered that a protocol submitted to it for review of a medical device called Adhesiabloc by a Device Med Systems of Clifton, Virginia, was in fact fraudulent in violation of federal and state law. Upon receipt of proof of the fraud, Coast IRB and its CEO, Daniel Dueber, ordered the immediate termination of the clinical trial, referred evidence to federal and state authorities for investigation and prosecution, and instituted measures to prevent a recurrence.

Coast IRB notified the Criminal Fraud unit of the U.S. Department of Justice, the Federal Bureau of Investigation, the Food and Drug Administration, and the Commonwealth of Virginia Department of Health Professions of the fraud. Coast IRB has urged authorities to investigate and prosecute the perpetrators whose actual identities remain unknown. Several felony fraud violations and potential RICO may have been committed.

"We are informing the media in the hopes of alerting those who might otherwise become study subjects that this appears to be a fraudulent trial," said Coast IRB CEO Daniel Dueber. "We are also doing so because we want other institutional review boards to learn of our experience and avoid review of this trial pending the result of federal and state investigations," he said.

Coast IRB discovered evidence of the fraud in a routine audit of the trial. In particular, Coast IRB discovered that credentials for the principal investigator for the trial were forged and that neither the principal investigator nor the medical director were licensed in the Commonwealth of Virginia. The Department of Health Professions of the Commonwealth of Virginia from whence the forged license was allegedly issued reported no record of ever granting a license to the person involved, no record of the license number listed on the forged credentials, and no issuance of licenses in the history of the Commonwealth in the format presented by the study sponsor. Coast IRB further discovered through an on-site visit that the address for the clinical trial organization where testing was presumably taking place, 5746 Union Mill Road, Clifton, Virginia 20124, was in fact a strip mall (The Colonnade) in Clifton, Virginia. Finally, a 510(k) FDA number given for the medical device did not exist in FDA's records.

Coast IRB has supplied information concerning the fraud to the House Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee, which is now investigating FDA regulation of human clinical trials. "We are shocked and dismayed by these developments," said Coast IRB CEO Daniel Dueber. "We are pleased, however, that we uncovered the apparent

fraud and alerted federal authorities. I hope those responsible are identified, investigated, and, if guilty of federal and state crimes, prosecuted to the full extent of the law," he said. "We are cooperating with the FDA and law enforcement on the federal and state levels to ensure that those responsible account for their wrong-doing."

Coast IRB is one of the largest independently owned IRB's and was founded in 2002. Its mission is to protect the rights and welfare of subjects in clinical trials by providing an ethical and thorough review in a timely and efficient manner. Coast IRB is proud of its history of providing ethical services with high integrity. It is located in Colorado Springs, Colorado.

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