

## PRESS RELEASES

PRESS RELEASE FOR IMMEDIATE RELEASE: 3/11/2009  
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### **Clinical Trial Fraud Detected by Independent Review Board, part of a congressional “sting” operation**

Washington, D.C.: In a press release issued on March 10, 2009, Coast Independent Review Board informed the public that it had discovered what appeared to be a fraudulent clinical trial submitted to that Independent review board for evaluation. Coast IRB has since learned that the fraudulent trial was apparently commenced as part of a congressional “sting” operation. Apparently at the behest of the U.S. House Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce agents submitted false credentials and clinical trial data to Coast IRB and possibly other IRBs to induce them to perform reviews. Evidence of the progress of the trials could then form the basis for arguments critical of FDA and in favor of greater regulatory oversight. Unless pursuant to a court order or under the auspices of the Department of Justice, the sting could be illegal, violating wire fraud, mail fraud, and state laws against fraud and false credentialing.

Coast IRB CEO Daniel Dueber had been asked by subcommittee staff to submit to an informal interview prior to giving testimony before the committee on March 19. Following notice from Coast IRB that the fraud had been detected, committee staff informed Coast that the hearing would be post-poned until March 26, 2009 and that the chairman of Coast IRB and possibly another Coast official would now have to appear for a “transcribed interview” with committee staff. “We are doing our level best to ensure protection for subjects of clinical trials under our review, an objective we share with the Food and Drug Administration,” said Daniel Dueber, CEO of Coast IRB. “We are legally and morally obliged to report any unlawful conduct we find occurring in a clinical trial and, so, fulfilled that responsibility in this case.”

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 Fairfax, Virginia district office of 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.

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

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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 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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FOR IMMEDIATE RELEASE: 3/10/2009

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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."

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