# *NEWS RELEASE*

## *OFFICE OF THE UNITED STATES ATTORNEY*
## *SOUTHERN DISTRICT OF CALIFORNIA*
***San Diego, California***

***United States Attorney***
***Laura E. Duffy***

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*For Immediate Release*

# LOCAL BIOTECH FIRM AND EMPLOYEES ADMIT CONCEALING TOXIC NATURE OF PRODUCT FROM THE FDA

**NEWS RELEASE SUMMARY - January 30, 2014**

San Diego biomedical device manufacturer Valor Medical, Inc, ("Valor") and four of its employees admitted today that they failed to provide the Food and Drug Administration ("FDA") with required information that would have cast doubt on the safety of Neucrylate, a product intended to treat aneurysms.

According to court documents, in 2007, Valor commissioned two preclinical tests on Neucrylate, a mouse lymphoma assay (MLA) and a chromosomal assay (CAA), both of which contained unfavorable results. Although Valor acknowledged receiving the reports, the company failed to include the results of the MLA and CAA testing when it submitted an application to the FDA for an investigational device exemption in September 2010. This failure represents a violation of the federal criminal statutes as all defendants admitted that the report was required to have been included with Valor's application under the Food, Drug and Cosmetic ACT ("FDCA").

According to court records, Valor created two separate products, one intended for use in blood vessels in the brain (Neucrylate AN) and one intended for use in blood vessels near the heart (Neucrylate AVM).

Because both products are considered to be Class III medical devices under the FDCA, premarket approval from the FDA is required before they can be sold in the United States. In order to perform clinical trials on humans to obtain the data needed to support an application for premarket approval, Valor needed to first obtain an investigational device exemption ("IDE") from the FDA. The regulations relating to such exemptions require applicants to submit "reports of all prior clinical, animal and laboratory testing of the device."

As the Valor devices are intended to be permanently implanted in the body, biocompatibility is very important. The FDA evaluates the biocompatibility of medical devices pursuant to ISO-10993, an international standard, which requires a series of at least three tests. Two of the three tests typically performed to satisfy these requirements are the MLA and CAA tests.

According to sentencing documents, after Valor sent the samples of Neucrylate to be tested, the lab reported to Alan Donald, a consultant hired by Valor, that all the chromosomes in the CAA test had been destroyed by initial contact with the Neucrylate. The lab asked if Valor wanted the lab to follow the standard protocol, which called for diluting the samples of Neucrylate and retesting. Rather than follow the standard protocol, Donald told the lab that no further testing should be performed. The lab's final report indicated that "no chromosomes were present to be scored" – indicating that the Neucrylate was cytotoxic (*i.e.*, toxic to cells). The official conclusion to the report indicated that the testing had not been completed pursuant to the testing protocol.[1]

At about the same time, the laboratory sent an email to Valor's Chief Scientist, Peter Friedman, attaching the preliminary results of the MLA test, which advised Valor that "all testing has been completed and the test article is considered to be mutagenic" (*i.e.*, an agent that changes the genetic material of a cell, usually DNA, thereby increasing the frequency of mutations). Friedman forwarded the email later that same day, with the attached preliminary results, to Valor's then-CEO Charles Kerber, Board Member H. Clark Adams, and Alan Donald. Adams replied to all, saying, "Let's huddle and determine how we overcome this obstacle. I have confidence that we can find an answer."

Following this huddle, the company provided neither the CAA test results nor the MLA test results to the FDA, even though they filed two separate IDE applications and responded to several additional requests for information (virtually all of which specifically requested that the CAA and/or MLA tests be performed).

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1 The lab's internal Quality Event Details Form noted that the samples for the CAA test were "cytotoxic," and the results were valid, but the sponsor was "choosing to cancel the study rather than perform dilutions" so a "full conclusion as to the genotoxicity of the sample will not be made."

At the time that defendant Cathy Bacquet, Clinical Affairs Manager, compiled and submitted the IDE application to the FDA, the CAA test report was filed as Test Report #27 in the Valor Medical Technical Report Log. According to a Valor employee, Adams, Kerber, and Bacquet made the decision not to provide the CAA test to the FDA.

The MLA report was not in the Technical Report Log at the time Valor's IDE was submitted in 2010 because Adams specifically prohibited its inclusion. However, a copy of the MLA test report was found on both Friedman's and Bacquet's computers during the execution of a search warrant. The file, created in 2007 on Friedman's computer and in 2009 on Bacquet's computer, was identified as "mouse lymphoma-failed." In an email two months after the submission of the IDE, Bacquet wrote, "We have already done Mouse Lymphoma and do not want to repeat it." Fortunately, the FDA rejected all of Valor's IDEs for Neucrylate despite not having the failed test results.

After a December 2010 inspection of Valor uncovered the CAA test, the FDA sent a Warning Letter to Adams at Valor. The letter referenced Valor's failure to disclose as a violation of the regulations requiring an applicant to submit all preclinical testing to the FDA. Bacquet, responding on behalf of Valor, claimed that Valor "inadvertently" left out the CAA and MLA tests in the application for the IDE. Valor blamed this "unintentional violation" on Alan Donald, who had separated from the company nearly a year before that IDE was filed. Bacquet falsely wrote in the letter, "Prior to February 10, 2011, the existence of this report [the MLA] was not known to VM management or Quality/Regulatory staff," which is clearly contradicted by the series of emails between Friedman, Kerber, Adams, and Donald when the MLA results were received by Valor in 2007, and the presence of copies of the MLA report on the computers of Friedman and Bacquet.

The American people depend on the FDA to determine that there is sufficient scientific basis to believe that a proffered medical device is safe and effective before permitting clinical trials on human beings. The FDA, in turn, depends on the full and truthful disclosure of all pre-clinical testing by device manufacturers to make an educated determination. When information is withheld from the FDA, the decision-making process is corrupted. Here, the FDA did not approve the proffered medical device for clinical trials on humans, so no Americans were endangered by the defendants' failure to provide the testing data to the FDA.

"Our nation's system of evaluating medical device safety and effectiveness depends upon the submission of truthful data to the FDA," said U.S. Attorney Laura Duffy. "When manufacturers like these defendants place their profits above their duty to honestly report the results of product testing, they place the

American public's health and safety in jeopardy. This office will continue to vigorously enforce laws designed to protect the health and safety of our citizens through cases like this."

The company pled guilty to Failure to Provide Required Information in violation of Title 21, United States Code, Section 331(q)(1)(B) and 333(a)(1) (a felony). Former Valor CEO and current member of the Board of Directors H. Clark Adams, and Valor Regulatory and Clinical Affairs Manager Cathy Bacquet also pled guilty to the same crime but as misdemeanor. Valor founder Dr. Charles Kerber and Chief Scientist Peter Friedman entered into Deferred Prosecution Agreements in which they admitted that they knew the required information was omitted in the FDA Application. Finally, former Valor consultant, Alan Donald, pled guilty in a related criminal case for his role in failing to submit the CAA and MLA test results to the FDA with the 2008 IDE application. At the time, Donald was a member of the Board of Directors of Valor Medical, and was paid as a regulatory consultant.

"The FDA's regulatory decisions must be based on sound and truthful scientific evidence," said Lisa Malinowski, Special Agent in Charge, Office of Criminal Investigations, Los Angeles Field Office. "We will continue to protect the Agency's public health mission against this type of deliberate deception and aggressively pursue the prosecution of those who may endanger the public's health. We commend the U.S. Attorney's Office for their diligence in pursuing this investigation."

United States Magistrate Judge David H. Bartick sentenced former Valor CEO H. Clark Adams to one year of probation, and a $5,000 fine, and sentenced Regulatory and Clinical Manager Cathy Bacquet to one year of probation and a $2500 fine. The sentencing for Valor Medical, Inc. is scheduled for February 19, 2014, at 9:30 a.m. before U.S. District Judge Dana Sabraw. A status hearing has been set for February 3, 2015, at 1:30 p.m. with respect to defendants Kerber and Friedman.

| **DEFENDANT** | **Criminal Case No. 14cr0196-DMS** |
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| Valor Medical, Inc.<br>San Diego, California | Date of Incorporation: 2007 |
| H. Clark Adams<br>San Diego, California | |
| Cathy Bacquet<br>San Diego, California | |
| Charles Kerber | |

San Diego, California Age: 77

Peter Friedman
San Diego, California Age: 49

**SUMMARY OF CHARGES**

Count 1 (Defendant Valor Medical)

Failure to Provide Required Information, a felony, in violation of Title 21, United States Code, Section 331(q)(1)(B) and 333(a)(2)

Maximum Penalty for a corporation: 5 years probation, a $500,000 fine, $400 special assessment

Count 2 (remaining defendants)

Failure to Provide Required Information, a misdemeanor, in violation of Title 21, United States Code, Section 331(q)(1)(B) and 333(a)(1)

Maximum Penalty: 1 year in custody and/or $100,000 fine, $25 special assessment.

**AGENCY**

U.S Food and Drug Administration, Office of Criminal Investigations