



and (d) that NuMED, Inc. caused the introduction of the CP Stent and the BIB Catheter into interstate commerce.

3. NuMED, Inc. knowingly, voluntarily, and intelligently admits the following facts: (a) the CP Stent and the BIB Catheter were devices as defined in the Federal Food, Drug and Cosmetic Act; (b) before introducing the CP Stent and the BIB Catheter into interstate commerce, NuMED, Inc. and Allen J. Tower were required to obtain pre-market approval and/or pre-market clearance from the FDA; (c) NuMED, Inc. and Allen J. Tower did not obtain pre-market approval and/or pre-market clearance from the FDA; (d) despite not having such clearance or approval from the FDA, NuMED, Inc. and Allen J. Tower knowingly manufactured and shipped in interstate commerce more than 2,800 CP Stents; (e) despite not having such clearance or approval from the FDA, NuMED, Inc. and Allen J. Tower knowingly manufactured and shipped in interstate commerce more than 5,200 BIB Catheters; and (f) there is evidence sufficient to prove that NuMED, Inc. and Allen J. Tower made a gross gain of \$2,261,777 from the sales of the CP Stents and BIB Catheters that were neither approved nor cleared by the FDA.

4. The United States and NuMED, Inc. hereby agree and stipulate pursuant to Fed.R.Crim.P. 11(c)(1)(C) that the following sentence is the appropriate disposition of the Information as to NuMED, Inc.:

- a. pursuant to 18 U.S.C. § 3571(d), NuMED, Inc. will be jointly and severally responsible with Allen J. Tower to pay a criminal fine in the amount of \$2,293,451 at sentencing;
- b. as detailed in ¶6 below, NuMED, Inc. will be jointly and severally responsible with Allen J. Tower, Sr. to perform a community service project in the form of a payment in the amount of \$2,230,103 to The Johns Hopkins University, which will be used to fund the clinical trial of the CP Stent for the indicated use of coarctation of the aorta;

- c. pursuant to 18 U.S.C. § 3013, NuMED, Inc. will pay a mandatory special assessment of \$250 at sentencing; and
- d. that NuMED, Inc. be placed on probation for a period of three years.

5. NuMED, Inc. expressly understands and agrees that it may not withdraw its plea of guilty unless the Court rejects this Memorandum of Plea Agreement under Fed.R.Crim.P. 11(c)(5).

6. NuMED, Inc. agrees to perform a community service project in the form of a payment in the amount of \$2,230,103 to The Johns Hopkins University, which will be used to fund an aorta coarctation clinical trial of the CP Stent - Bare and Covered - sponsored by Dr. Richard Ringel of The Johns Hopkins University School of Medicine. NuMED, Inc. further agrees to pay the \$2,230,103 in three separate installments as follows:

- a. \$785,526 to be paid on or before September 1, 2007;
- b. \$776,620 to be paid on or before September 1, 2008; and
- c. \$667,957 to be paid on or before July 29, 2009.
- d. the defendant will send these payments via wire transfer as instructed by The Johns Hopkins University and will send confirmation of each wire transfer to the United States Probation Office for the District of Delaware.

7. NuMED, Inc. agrees to provide to Dr. Richard Ringel the CP Stents - Bare and Covered - and the BIB Catheters required for the aorta coarctation clinical trial of the CP Stent free of charge.

8. If the FDA approves and/or clears the CP Stent for distribution in the United States, NuMED, Inc. agrees that, for the first five years following FDA approval of the CP Stent, it will provide the CP Stent at no cost to any health care provider in the United States who requests the device for treatment of coarctation of the aorta in accordance with the CP Stent's approved labeling.

9. NuMED, Inc. hereby understands and agrees that it will not claim a deduction on its 2007, 2008 or 2009 corporate tax returns for funding the clinical trial of the CP Stent.

10. NuMED, Inc. hereby agrees to forego, waive or otherwise concede the following rights regarding the aorta coarctation clinical trial of the CP Stent described above: pre-review rights to publications arising out of the clinical trial; approval rights to the clinical trial protocol or workscope; rights to the clinical trial data beyond FDA regulatory use; and rights to intellectual property developed by The Johns Hopkins University arising out of performing the clinical trial, beyond that dominated by NuMed's and/or Allen J. Tower, Sr.'s device claims and proprietary information existing prior to the clinical trial.

11. The United States and NuMED, Inc. agree that sentencing will be imposed immediately following entry and acceptance of the defendant's guilty plea.

12. The United States Attorney's Office for the District of Delaware, on its own behalf and on behalf of the FDA, agrees that, other than the charges contained in the Information, it will not further prosecute NuMED, Inc. for conduct concerning the delivery of CP Stents and BIB Catheters into interstate commerce known to the United States Attorney's Office for the District of Delaware and/or to the FDA prior to the entry of NuMED, Inc.'s guilty plea.

13. Prior to the execution of this Memorandum of Plea Agreement, NuMED, Inc. shall enter into a Corrective Action Plan with the FDA. The Corrective Action Plan is attached hereto as Exhibit A and hereby incorporated by reference.

14. If the United States determines that NuMED, Inc. has failed to comply with any material provision of this Memorandum of Plea Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in their entirety by notifying NuMED, Inc., through counsel, in writing. The United States may also pursue all remedies available to it under the law, irrespective of whether it elects to be released from its commitments under this Agreement. NuMED, Inc. recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea.

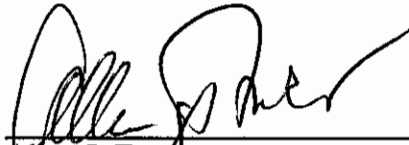
15. NuMED, Inc. shall provide to the United States and to the Court a copy of a Corporate Acknowledgment of Plea Agreement affirming that the Board of Directors of NuMED, Inc. has given the signatory authority to enter into the Memorandum of Plea Agreement on behalf of NuMED, Inc. and has done the following: (a) consulted with legal counsel in connection with this matter; (b) voted to authorize NuMED, Inc. to plead guilty to the charge specified in the Memorandum of Plea Agreement; and (c) voted to authorize Allen J. Tower to execute the Memorandum of Plea Agreement and any and all other documents necessary to carry out the provisions of the Memorandum of Plea Agreement. NuMED, Inc. further agrees that a duly authorized corporate officer will appear on behalf of NuMED, Inc. and will enter the guilty plea and will also appear for the imposition of sentencing.

16. It is further agreed by the undersigned parties that this Memorandum supersedes all prior promises, representations, and statements of the undersigned parties; that this Memorandum may be modified only in a written document signed by all the undersigned parties; and that any and all promises, representations, and statements made prior to or after this

/ / / / /

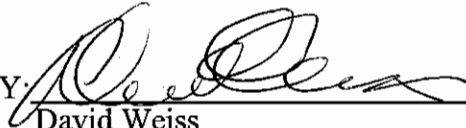
Memorandum are null and void and have no effect whatsoever, unless they comport with the subsequent written modification requirements of this paragraph.

COLM F. CONNOLLY  
United States Attorney



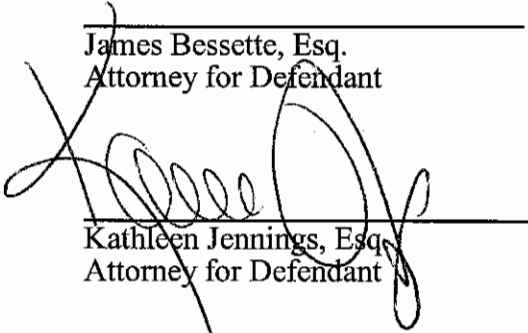
Allen J. Tower  
President  
NuMED, Inc.

BY:



David Weiss  
First Assistant United States Attorney  
Beth Moskow-Schnoll  
Assistant United States Attorney

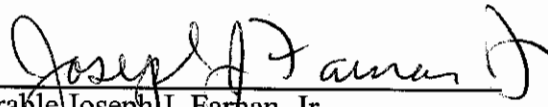
James Bessette, Esq.  
Attorney for Defendant



Kathleen Jennings, Esq.  
Attorney for Defendant

Dated: July 30, 2007

AND NOW this 30 day of July, 2007, the foregoing Memorandum of Plea Agreement is hereby (accepted) ~~(rejected)~~ by the Court.



Honorable Joseph J. Farhan, Jr.  
United States District Court Judge