JUN 03 2008

CLERK, U.S. DISTRICT COURT MINNEAPOLIS, MINNESOTA

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA.

Plaintiff.

V.

NO.CR 08-112 JMR

AGA MEDICAL CORPORATION,

DEFERRED PROSECUTION

**AGREEMENT** 

Defendant.

Defendant AGA Medical Corporation ("AGA"), a Minnesota corporation, by its undersigned attorneys, pursuant to authority granted by AGA's Board of Directors, and the United States Department of Justice, Criminal Division, Fraud Section (the "Department of Justice" or "the Department") enter into this Deferred Prosecution Agreement ("the Agreement"). The terms and conditions of this Agreement are as follows:

## Criminal Information and Acceptance of Responsibility

1. AGA accepts and acknowledges that the United States will file a two-count criminal Information in the United States District Court for the District of Minnesota charging AGA with conspiracy to committen offense against the United States, in violation of 18 U.S.C. § 371, that is, to violate the Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, 15 U.S.C. § 78dd-2(a)(1) (Count One); and violating the FCPA, 15 U.S.C. § 78dd-2(a)(1) and 18 U.S.C. § 2 (Count Two). In so doing, AGA knowingly waives its right to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United

SCANNED

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U.S. DISTRICT COURT MPLS

States Constitution, Title 18, United States Code Section 3161, and Federal Rule of Criminal Procedure 48(b). In addition, AGA consents to the filing of the Information and the Agreement in the United States District Court for the District of Minnesota.

2. AGA admits, accepts and acknowledges that it is responsible for the acts of its officers, employees and agents, as set forth in the Statement of Facts attached hereto as "Attachment A," and incorporated by reference into this Agreement, and that the facts described in Attachment A are true and accurate. Should the Department initiate the prosecution that is deferred by this Agreement, AGA agrees that it will neither contest the admissibility of, nor contradict, in any such proceeding, the Statement of Facts.

## Term of the Agreement

3. This Agreement is effective for a period beginning on the latest date on which any party signs it and ending three (3) years and seven (7) calendar days from that date (the "Term"). However, AGA agrees that, in the event that the Department determines, in its sole discretion, that AGA has knowingly violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by Department, in its sole discretion, for up to a total additional time period of one-year. Any extension of the Agreement extends all terms of this Agreement for an equivalent period. Conversely, in the event the Department finds, in its sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the Monitor, and the other provisions of this Agreement have been satisfied, the Term of the Agreement may be terminated early.

## **Voluntary Cooperation**

- 4. The Department enters into this Agreement based on the individual facts and circumstances presented by this case and AGA. Among the facts considered were: (a) AGA voluntarily and timely disclosed the misconduct described in the Information and Statement of Facts; (b) AGA conducted a thorough internal investigation of that misconduct; (c) AGA reported all of its findings to the Department; (d) AGA cooperated in the Department's investigation of this matter; (e) AGA has undertaken remedial measures as contemplated by this Agreement; and (f) AGA has agreed to continue to cooperate with the Department in any investigation of the conduct of AGA and its directors, officers, employees, agents, consultants, contractors and subcontractors relating to violations of the FCPA.
- 5. During the Term of this Agreement, AGA agrees to cooperate fully with the Department, and any other authority or agency, domestic or foreign, designated by the Department investigating AGA, or any of its present and former directors, officers, employees, agents, consultants, contractors and subcontractors, or any other party, in any and all matters relating to corrupt payments. AGA agrees that its cooperation shall include, but is not limited to, the following:
- a. AGA shall truthfully disclose all information with respect to its activities and those of its present and former directors, officers, employees, agents, consultants, contractors and subcontractors, concerning all matters relating to corrupt payments, related false books and records, and inadequate internal controls about which AGA has any knowledge or

about which the Department may inquire. This obligation of truthful disclosure includes the obligation of AGA to provide to the Department, upon request, any document, record or other tangible evidence relating to such corrupt payments, books and records, and internal controls about which the Department may inquire of AGA.

- i. The Department specifically reserves the right to request that AGA provide the Department with access to information, documents, records, facilities and/or employees that may be subject to a claim of attorney-client privilege and/or the attorney work-product doctrine.
- ii. Upon written notice to the Department, AGA specifically reserves the right to withhold access to information, documents, records, facilities and/or employees based upon an assertion of a valid claim of attorney-client privilege or application of the attorney work-product doctrine. Such notice shall include a general description of the nature of the information, documents, records, facilities and/or employees that are being withheld, as well as the basis for the claim.
- iii. In the event that AGA withholds access to the information, documents, records, facilities and/or employees of AGA, the Department may consider this fact in determining whether AGA has fully cooperated with the Department.
- iv. Except as provided in this paragraph, AGA shall not withhold from the Department any information, documents, records, facilities and/or employees on the basis of an attorney-client privilege or work product claim.

- b. Upon request of the Department, with respect to any issue relevant to its investigation of corrupt payments in connection with the operations of AGA, related books and records and inadequate internal controls, AGA shall designate knowledgeable employees, agents or attorneys to provide to the Department the information and materials described in Paragraph 5(a) above, on behalf of AGA. It is further understood that AGA must at all times provide complete, truthful and accurate information.
- c. With respect to any issue relevant to the Department's investigation of corrupt payments in connection with the operations of AGA, or any of its present or former subsidiaries or affiliates, AGA shall use its best efforts to make available for interviews or testimony, as requested by the Department, present or former directors, officers, employees, agents and consultants of AGA as well as the directors, officers, employees, agents and consultants of contractors and subcontractors. This obligation includes, but is not limited to, swom testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities. Cooperation under this paragraph will include identification of witnesses who, to the knowledge of AGA, may have material information regarding the matters under investigation.
- d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Department pursuant to this Agreement, AGA consents to any and all disclosures to other governmental authorities, whether United States authorities or those of a foreign government, of such materials as the Department, in its sole discretion, shall deem appropriate.

## **Payment of Monetary Penalty**

6. AGA agrees to pay a monetary penalty in the amount of \$2,000,000 to the United States Treasury within ten days of the execution of this Agreement. The \$2,000,000 penalty is final and shall not be refunded: (a) if the Department moves to dismiss the Information pursuant to this Agreement; or (b) should the Department later determine that AGA has breached this Agreement and bring a prosecution against AGA. Furthermore, nothing in this Agreement shall be deemed an agreement by the Department that the \$2,000,000 amount is the maximum penalty that may be imposed in any such prosecution, and the Department is not precluded from arguing that the Court should impose a higher fine, although the Department agrees that under those circumstances, it will recommend to the Court that the amount paid under this Agreement should be offset against any fine the Court imposes as part of a judgment.

## Conditional Release from Criminal Liability

7. In return for the full and truthful cooperation of AGA, and compliance with the terms and conditions of this Agreement, the Department agrees not to use any information related to the conduct described in the attached Statement of Facts against AGA in any criminal or civil case, except: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (o) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code. In addition, the Department agrees, except as provided herein, that it will not bring any criminal or civil case against AGA related to the conduct of present and former directors, officers, employees, agents, consultants, contractors and

subcontractors, as described in the attached Statement of Facts, or relating to information AGA disclosed to the Department prior to the date on which this Agreement was signed.

- a. This paragraph does not provide any protection against prosecution for any corrupt payments or false accounting, if any, made in the future by AGA, or any of its directors, officers, employees, agents, consultants, contractors and subcontractors irrespective of whether disclosed by AGA, pursuant to the terms of this Agreement.
- b. This paragraph also does not provide any protection against prosecution for any corrupt payments made in the past which are not described in the attached Statement of Facts or were not disclosed to the Department prior to the date on which this Agreement was signed. In addition, this paragraph does not provide any protection against eximinal prosecution of any present or former director, officer, employee, shareholder, agent or consultant of AGA for any violations committed by them.

# Corporate Compliance Program

8. AGA represents that it has implemented and will continue to implement a compliance and ethics program designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws throughout its operations, including those of its affiliates, joint ventures, and those of its contractors and subcontractors, with responsibilities that include interactions with foreign officials. Implementation of these policies and procedures shall not be construed in any future enforcement proceeding as providing immunity or amnesty for any crimes not disclosed to the Department as of the date of signing of this Agreement for which AGA would otherwise be responsible.

9. In order to address deficiencies in its internal controls, policies and procedures regarding compliance with the FCPA and other applicable anti-corruption laws, AGA represents that it has undertaken, or will undertake in the near-future, in a manner consistent with all of its obligations under this Agreement, a review of the existing internal controls, policies and procedures within AGA. Where necessary and appropriate, AGA will adopt new or modify existing internal controls, policies and procedures in order to ensure that AGA maintains: (a) a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records and accounts; and (b) a rigorous anti-corruption compliance code designed to detect and deter violations of the FCPA and other applicable anti-corruption laws. The internal controls system and compliance code will include, but not be limited to, the minimum elements set forth in Attachment C, which is incorporated by reference into this Agreement.

#### Independent Corporate Monitor

- 10. AGA agrees to engage an independent corporate monitor ("the Monitor") within sixty (60) calendar days of signing this Agreement. Within thirty (30) calendar days after the signing of this Agreement, and after consultation with the Department, AGA will propose to the Department a candidate to serve as the Monitor. The Monitor shall have, at a minimum, the following qualifications:
- a. demonstrated expertise with respect to the FCPA, including experience counseling on FCPA issues;

- b. experience designing and/or reviewing corporate compliance policies,
   procedures and internal controls, including FCPA-specific policies, procedures and internal controls;
- c. the ability to access and deploy resources as necessary to discharge the Monitor's duties as described in the Agreement; and
- d. sufficient independence from AGA to ensure effective and impartial performance of the Monitor's duties as described in the Agreement.
- Monitor proposed by AGA pursuant to the Agreement. In the event the Department rejects a proposed monitor, AGA shall propose another candidate within ten (10) calendar days after receiving notice of the rejection. This process shall continue until a Monitor acceptable to all parties is chosen. The Monitor's term shall be three (3) years from the date on which this Agreement was signed, subject to extension or early termination as described in paragraph 3. The Monitor's duties and authority, and the obligations of AGA with respect to the Monitor and the Department, are set forth in Attachment D, which is incorporated by reference into this Agreement.

## Deferred Prosecution

12. In consideration of: (a) the past and future cooperation of AGA described in Paragraphs 4 and 5 above; (b) AGA's payment of a monetary penalty of \$2,000,000; and (c) AGA's adoption and maintenance of remedial measures, and independent review and sudit of

such measures, including the compliance code and review by the Monitor described in Paragraphs 8 through 11 above, the Department agrees that any prosecution of AGA for the conduct set forth in the attached Statement of Facts, and for the conduct relating to information that AGA disclosed to the Department, prior to the signing of this Agreement, be and hereby is deferred for the Term of this Agreement.

13. The Department further agrees that if AGA fully complies with all of its obligations under this Agreement, the Department will not continue the criminal prosecution against AGA described in Paragraph 1 and, after the Term, this Agreement shall expire and the Department will move to dismiss the criminal Information pending against AGA.

## Breach of the Agreement

discretion, that AGA has committed any felony under federal law subsequent to the signing of this Agreement, has, at any time, provided deliberately false, incomplete or misleading information, or has otherwise breached the Agreement, AGA shall thereafter be subject to prosecution for any federal criminal violation of which the Department has knowledge. Any such prosecutions may be premised on information provided by AGA. Any such prosecution that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against AGA notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, AGA agrees that the statute of limitations with respect to any prosecution that is not time-barred on the date of this Agreement shall be tolled for the Term plus one year.

- Agreement: (a) all statements made by or on behalf of AGA to the Department or to the Court, including the attached Statement of Facts, and any testimony given by AGA before a grand jury or any tribunal, at any legislative hearings whether prior or subsequent to this Agreement, or any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Department against AGA; and (b) AGA shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal. Procedure, Rule 410 of the Federal Rules of Evidence or any other federal rule, that statements made by or on behalf of AGA prior or subsequent to this Agreement, and any leads derived therefrom, should be suppressed. The decision whether conduct or statements of any individual will be imputed to AGA for the purpose of determining whether AGA has violated any provision of this Agreement shall be in the sole discretion of the Department.
- AGA acknowledges that the Department has made no representations, assurances or promises concerning what sentence may be imposed by the Court if AGA breaches this Agreement and this matter proceeds to judgment. AGA further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

## Sale or Merger of AGA

17. AGA agrees that in the event it sells, merges, or transfers all or substantially all of its business operations as they exist as of the date of this Agreement, whether such sale is

structured as a stock or asset sale, merger or transfer, it shall include in any contract for sale, merger or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement.

#### · Public Statements by AGA

18. AGA expressly agrees that it shall not, through present or future attorneys, directors, officers, employees, agents or any other person authorized to speak for AGA make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by AGA set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of AGA described below, constitute a breach of this Agreement and AGA thereafter shall be subject to prosecution as set forth in Paragraphs 13 and 14 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to AGA for the purpose of determining whether they have breached this Agreement shall be at the sole discretion of the Department. If the Department determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Department shall so notify AGA, and AGA may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Consistent with the obligations of AGA as set forth above, AGA shall be permitted to raise defenses and to assert affirmative claims in civil and regulatory proceedings relating to the matters set forth in the Statement of Facts. This paragraph does not apply to any statement made by any present or former employee of AGA in the course of any criminal, regulatory or civil case initiated against such individual, unless such individual is speaking on behalf of AGA.

19. In connection with this Agreement, AGA shall not issue a press release unless it first determines that the text of the release is acceptable to the Department.

## Limitations on Binding Effect of Agreement

20. This Agreement is binding on AGA and the Department but specifically does not bind any other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, although the Department will bring the cooperation of AGA and its compliance with its other obligations under this Agreement, to the attention of such agencies and authorities if requested to do so by AGA.

## Complete Agreement

21. This Agreement sets forth all the terms of the Deferred Prosecution Agreement between AGA and the Department. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Department, the attorneys for AGA and a duly authorized representative of AGA.

### Notice

22. Any notice to the Department under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service or registered or certified mail, in each case, for the Department, addressed to Mark F. Mendelsohn (or his successor), Deputy Chief, Fraud Section, Criminal Division, U.S. Department of Justice, fourth floor, 1400 New

York Avenue, N.W., Washington, D.C. 20005 and, for AGA, addressed to Ronald B. Lund, General Counsel, AGA Medical Corporation. Notice shall be effective upon actual receipt by AGA.

AGREED:

FOR AGA MEDICAL CORPORATION:

Jackson Kelly, LLP

Counsel for AGA Medical Corporation

## FOR THE DEPARTMENT OF JUSTICE:

STEVEN A. TYRRELL Chief, Fraud Section

David Bybee

Trial Attorney, Fraud Section

William B. Jacobson Assistant Chief

United States Department of Justice Fraud Section, Criminal Division 10<sup>th</sup> & Constitution Avenue, NW Washington, D.C. 20530 (202) 514-7023

Filed at Minneapolis, Minnesota, on this \_\_\_\_\_ day of June, 2008.

## OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with counsel for AGA Medical Corporation ("AGA"). I understand the terms of this Agreement and voluntarily agree, on behalf of AGA, to each of its terms. Before signing this Agreement, I consulted with the attorney for AGA. The attorney fully advised me of the rights of AGA, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed this Agreement with the Board of Directors of AGA. I have advised, and caused outside counsel for AGA to advise, that Board fully of the rights of AGA, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of AGA, in any way to enter into this Agreement. I am also satisfied with the attorney's representation in this matter. I certify that I am an officer of AGA and that I have been duly authorized by AGA to execute this Agreement on behalf of AGA.

Date: June 2 , 2008

**AGA Medical Corporation** 

Bv:

ald E. Lund, General Counsel

### CERTIFICATE OF COUNSEL

I am counsel for AGA Medical Corporation ("AGA") in the matter covered by this
Agreement. In connection with such representation, I have examined relevant AGA documents
and have discussed this Agreement with the AGA Board of Directors. Based on my review of
the foregoing materials and discussions, I am of the opinion that: the representative of AGA has
been duly authorized to enter into this Agreement on behalf of AGA and that this Agreement has
been duly and validly authorized, executed, and delivered on behalf of AGA and is a valid and
binding obligation of AGA. Further, I have carefully reviewed this Agreement with the Board of
Directors and General Counsel of AGA. I have fully advised them of the rights of AGA, of
possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering
into this Agreement. To my knowledge, the decision of AGA to enter into this Agreement is an
informed and voluntary one.

Date: 2, 2008

Stanley Styn

Counsel for AGA Medical Corporation

## ATTACHMENT A

#### STATEMENT OF FACTS

The following Statement of Facts is incorporated by this reference as part of the Deferred Prosecution Agreement ("the Agreement") between the United States Department of Justice, Criminal Division, Fraud Section ("the Department") and AGA Medical Corporation ("AGA") and the parties hereby agree and stipulate that the following information is true and accurate. As set forth in Paragraph 2 of the Agreement, AGA accepts and acknowledges that it is responsible for the acts of its efficers, employees and agents as set forth below.

Should the Department initiate the prosecution that is deferred by this Agreement, AGA agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding.

If this matter were to proceed to trial, the United States would prove beyond a reasonable doubt, by admissible evidence, the facts alleged in the Criminal Information filed contemporaneously with this Agreement. This syldence would establish the following:

- 1. AGA MHDICAL CORPORATION ("AGA") was incorporated in
  1995 in Minnesota, had its principal place of business in Golden Valley, Minnesota, and was a
  "domestic concern" as that term is used in the FCPA, 15 U.S.C.§ 78dd-2(b)(1)(B).
- 2.. AGA manufactured and sold medical devices for the minimally invasive treatment of congenital heart defects. AGA marketed and sold its products in over 90 countries, including the People's Republic of China ("China"), through a network of local distributors and direct sales.
- AGA maintained small servers at its Golden Valley, Minnesota, headquarters
  and all small directed to AGA employees was sent to these email servers.

- 4. From at least March 2000, through in or about late 2002, AGA applied to the State Intellectual Property Office of the People's Republic of China ("the Chinese Patent Office"), an agency of the Chinese government, for patents on several of its products.
- 5. From in or about 1995 to the present, "Officer A," a U.S. citizen, was a high-ranking officer and part owner of AGA, who had authority to set company policy, contract with distributors, hire and fire employees, set sales prices, and approve sales practices in foreign countries.
- From in or about 1997, through in or about November 2001, "Employee B," a
   U.S. citizen, was the head of international sales for AGA.
- 7. From in or about December 2001, through in or about early-2007, "Employee C," a U.S. citizen, was the head of international sales for AGA.
- 8. In or about December 1998, AGA entered into an agreement with a Chinese company to be the sole distributor of AGA products in China. An employee of that company, "the Chinese Distributor," a Chinese citizen, was responsible for the AGA account at that company and was the main point of contact for AGA. In or about 1999, the Chinese Distributor left his employer to form his own company. AGA moved its business from the initial company to the Chinese Distributor's new company and AGA maintained a business relationship with the Chinese Distributor and his company until AGA suspended the shipment of products to the Chinese Distributor in June 2005. On or about April 12, 2006, AGA terminated its agreement with the Chinese Distributor.

- 9. The Chinese Distributor was authorized to sell AGA products, negotiate prices, and employ salespeople. The Chinese Distributor's primary customers were hospitals owned and operated by the government of China and government-employee physicians working at those hospitals.
- 10. Government-owned and controlled hospitals in China are "instrumentalities" of the Chinese government and physicians employed by such hospitals are "foreign officials," as those terms are used in the FCPA, 15 U.S.C. § 78dd-2(h)(2)(A).
- 11. In or about December 1997, Officer A, on behalf of AGA, signed and executed a distributorship agreement with the company that then employed the Chinese Distributor.
- 12. On or about December 20, 1997, the Chinese Distributor sent an email from China to Officer A in Minnesota informing Officer A that hospitals in China were asking for a 10% "discount" and physicians were asking for a 10% "commission" on products sold. The Chinese Distributor further informed Officer A that if AGA did not accept those terms, the hospitals and physicians would not purchase AGA's products.
- 13. In or about January 1998, the Chinese Distributor traveled from China to Minnesota to discuss with Officer A, among other things, the prices that the Chinese Distributor would charge for AGA's products and the kickbacks that the Chinese Distributor would pay to physicians in China in order to induce them to purchase AGA's products.
- 14. On or about July 16, 1998, Officer A sent an e-mail to the Chinese Distributor stating: "I understand that the fee you must pay each physician was to be included in your selling price. It should therefore not be an issue."

- 15. In or about December 1998, Officer A, on behalf of AGA, signed and executed a second distributorship agreement with the company that then employed the Chinese Distributor.
- 16. In or about 1999, after the Chinese Distributor left his original employer to start his own company, Officer A, on behalf of AGA, entered into a distributorship agreement with the Chinese Distributor's new company.
- 17. On or about February 1, 2000, the Chinese Distributor again traveled from China to Minnesota to discuss with Officer A, among other things, the prices that the Chinese.

  Distributor would charge in China for AGA's products and the kickbacks that the Chinese Distributor would pay to physicians in China to induce them to purchase AGA's products.
- 18. On or about March 19, 2001, the Chinese Distributor sent an email from China to Employee B in Minnesota stating that the Chinese Distributor had, to that point, paid \$460,000 in "commissions" to physicians in China and had also contacted a Chinese patent official to whom he would have to pay money. The Chinese Distributor wrote, "This week I have maken [sic] an appointment with one key person in China knowledge and Patent Protection Burean. Any action in China I must pay money to do."
- 19. On or about May 11, 2001, the Chinese Distributor sent an email from China to Officer A in Minnesota stating that the Chinese Distributor had met with a Chinese patent official regarding AGA's patent application and that the official had agreed to speed up the review of AGA's application and to "solve some problems in different departments in her bureaut" related to the application. The Chinese Distributor explained in the email that he would

have to "sponsor" the patent official for this work and asked Officer A if AGA would agree to cover that cost. By return email on or about that same day, Officer A agreed, on behalf of AGA, to cover the fee to be paid to the Chinese patent official by the Chinese Distributor, stating, "I am still in agreement with our prior discussions and will cover her fee as long as we can get the [sic] patent issued in a timely manner."

- Officer A in Minnesota stating: "Very good news that your patents have been taken out from the stock and begun to check by the observation people. My friends told me that if there are any news, they will tell me. I think we will win this war if we can get the patent approvement [sic]. I contacted with two officials working in different departments. They will help us from different ways. They don't know each other and don't know I asked two people to help us . . . About your new product, my friend told me that you should ask your agent to apply the invent and practical patents sametime [sic]. I can ask my friend to help to approve the practical patent in one year and get 10 years protection."
- 21. On or about February 6, 2002, the Chinese Distributor sent an email from China to Employee C in Minnesota stating: "Please inform [Officer A] don't give up the application for the first three patents in China. I will contact with the officials of China patent bureau again after Chinese new year. Maybe money will help us."
- 22. On or about March 20, 2002, the Chinese Distributor sent an small from China informing Officer A that the Chinese Distributor had paid \$20,000 to the patent official to

approve patents for AGA products and that: "I just need the results of patents approved no matter what way he do."

- 23. On or about April 17, 2002, the Chinese Distributor sent an email from China to Officer A stating: "Today my friend tells me that one of your last two patents have been approved and the other one will be approved soon."
- 24. On or about October 18, 2002, the Chinese Distributor sent an email from China to Officer A stating that the Chinese Distributor was currently paying a "reward" to each physician who purchased an AGA product in an amount ranging from \$300 to \$1,000 per product purchased.
- 25. On or about October 31, 2002, Employee C sent a memo to Officer A listing the then-current prices for various AGA products in China and including a column entified "Reward to Physicians," with dollar amounts listed for each product. On or about this same date, Employee C hand-wrote a notation reading, "OK, effective immediately," at the top of this memo.
- 26. On or about October 21, 2003, Employee C-wrote a memorandum to Officer A and other AGA employees reporting on his recent trip to China. The memorandum contained a chart of then-current prices being charged for various AGA products in China and contained a notation reflecting the amount of the "rebates" given by the Chinese Distributor to physicians.
- 27. On or about December 2, 2003, the Chinese Distributor sent an email to Employee C regarding pricing for AGA products in China which stated: "My company also need to provide 20% kickback for physicians and sometimes 10% discount to hospitals."

- 28. On about December 5, 2003, the Chinese Distributer sent an email from China to Employee C, explaining how physicians at hospitals in China selected products for purchase:

  "The physicians suggest the patient to use which device according [to] the petient's family economic ability and the kickback."
- 29. On or about February 26, 2005, the Chinese Distributor sent an email from China to Employee C providing Employee C with a list of then-current prices being charged for various AGA products in China and informing Employee C that the Chinese Distributor was paying physicians kickbacks of 15% to 25% of the purchase price.
- 30. Between 1997 and 2005, AGA regularly shipped its products from Minnesota to the Chinese Distributor in China, via interstate and international freight carriers, for sale by the Chinese Distributor at the prices, and pursuant to the terms, discussed and agreed to by AGA, Officer A, Employee B, Employee C, the Chinese Distributor and others.
- Between 1997 and 2005, AGA sales in China totaled approximately \$13.5
   million.

#### ATTACHMENT B

## CERTIFICATE OF CORPORATE RESOLUTION

WHEREAS, AGA MEDICAL CORPORATION ("AGA" or, "the Company") has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section ("the Department") in connection with issues arising in relation to certain corrupt payments to foreign officials to facilitate the award of contracts and obtaining business for the Company; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Department; and

WHEREAS the Company's General Counsel, together with investigative and outside counsel for the Company, have advised the Board of Directors of the Company's rights, possible defenses, the Scatteneing Guidelines' provisions, and the consequences of entering into such agreement with the Department;

Therefore, this Board hereby RESOLVES that:

1. The Company (i) consents to the filing in the United States District Court for the District of Minnesota of a two-count Information charging AGA with conspiracy to commit an offense against the United States, namely, to violate the Foreign Corrupt Practices Act ("FCPA") (15 U.S.C. § 78dd-2(a)(1), in violation of 18 U.S.C. § 371 (Count One); and the payment of bribes, in violation of 15 U.S.C. § 78dd-2 and 18 U.S.C. § 2 (Count Two); (ii) waives indictment on such charges and enters into a Defecred Prosecution Agreement with the Department; and (iii) agrees to accept a monetary penalty against AGA of \$2,000,000, and to pay \$2,000,000 to the United States Treasury with respect to the conduct described in the Information.

- 2. The General Counsel, or his delegate, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Deferred Prosecution Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the General Counsel, or his delegate, may approve;
- 3. The General Counsel, or his delegate, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate, and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and
- 4. All of the actions of the General Counsel, which actions would have been suthorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved and adopted as actions on behalf of the Company.

Date: 12008

Ronald B. Lund, Socretai

Board of Directors

**AGA Medical Corporation** 

### ATTACHMENT C

# CORPORATE COMPLIANCE PROGRAM

In order to address deficiencies in its internal controls, policies and procedures regarding compliance with the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78dd-1, et seq., and other applicable anti-corruption laws, AGA Medical Corporation ("AGA") agrees to conduct, in a manner consistent with this Agreement, a review of its existing internal controls, policies and procedures.

Where necessary and appropriate, AGA further agrees to adopt new or to modify existing internal controls, policies and procedures in order to ensure that it maintains: (a) a system of internal accounting controls designed to ensure that AGA makes and keeps fair and accurate books, records and accounts; and (b) a rigorous anti-corruption compliance code, standards and procedures designed to detect and deter violations of the FCPA and other applicable anti-corruption laws. At a minimum, this should include, but ought not be limited to, the following elements:

- A clearly articulated corporate policy against violations of the FCPA and other applicable anti-corruption laws.
- A system of financial and accounting procedures, including a system of internal
  accounting controls, designed to ensure the maintenance of fair and accounts books, records and
  accounts.
- 3. Promulgation of compliance standards and procedures designed to reduce the prospect of violations of the FCPA, other applicable anti-contuption laws and AGA's compliance code. These standards and procedures should apply to all directors, officers and employees and, where necessary and appropriate, outside parties acting on behalf of AGA in foreign

jurisdictions, including agents, consultants, representatives, distributors, teaming partners and joint venture partners (collectively referred to as "agents and business partners").

- 4. The assignment of responsibility to one or more senior corporate officials of AGA for the implementation and oversight of compliance with policies, standards and procedures regarding the FCPA and other applicable anti-corruption laws. Such corporate official(s) shall have the authority to report matters directly to AGA's Board of Directors.
- 5. Mechanisms designed to ensure that the policies, standards and procedures of AGA regarding the FCPA and other applicable anti-corruption laws are effectively communicated to all directors, officers, employees and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (A) periodic training for all such directors, officers, employees, agents and business partners; and (B) annual certifications by all such directors, officers, employees, agents and business partners, certifying compliance with the training requirements.
- 6. An effective system for reporting suspected criminal conduct and/or violations of the compliance policies, standards and procedures regarding the FCPA and other applicable anticorruption laws for directors, officers, employees, agents and business partners.
- 7. Appropriate disciplinary procedures to address, among other things, violations of the FCPA, other applicable anti-corruption laws or AGA's compliance code by directors, officers, employees, agents and business partners.
- Appropriate due diligence requirements pertaining to the retention and oversight
  of agents and business partners.

9. Standard provisions in agreements, contracts, and renewals thereof with all agents and business partners which are designed to prevent violations of the FCPA and other applicable anti-corruption laws, which provisions may, depending upon the circumstances, include: (A) anti-corruption representations and undertakings relating to compliance with the FCPA and other applicable anti-corruption laws; (B) rights to conduct audits of the books and records of the agent or business partner to ensure compliance with the foregoing; and (C) rights to terminate an agent or business partner as a result of any breach of anti-corruption laws, and regulations or representations and undertakings related to such matters.

#### ATTACHMENT D

#### INDEPENDENT CORPORATE MONITOR

- 1. Within sixty (60) calendar days of the execution of this Agreement, AGA
  MEDICAL CORPORATION ("AGA" or "the Company") agrees to engage an independent
  corporate monitor (the "Monitor") for a period of three (3) years. The Monitor's primary
  responsibility is to assess and monitor the Company's compliance with the terms of this
  Agreement so as to specifically address and reduce the risk of any recurrence of the Company's
  misconduct, including evaluating the Company's corporate compliance program with respect to
  the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78dd-1, et seq., and other relevant
  anti-corruption laws. Within thirty (30) calendar days after the signing of this Agreement, and
  after consultation with the Department, AGA will propose to the Department a candidate to
  serve as the Monitor. The Monitor shall have, at a minimum, the following qualifications:
- a. demonstrated expertise with respect to the FCPA, including experience counseling on FCPA issues;
- b. experience designing and/or reviewing corporate compliance policies,
   procedures and internal controls, including FCPA-specific policies, procedures and controls;
- c. the ability to access and deploy resources as necessary to discharge the Monitor's duties as described in the Agreement; and
- d. sufficient independence from AGA to ensure effective and impartial performance of the Monitor's duties as described in the Agreement.
- 2. The Department retains the right, in its sole discretion, to accept or reject the Monitor proposed by AGA pursuant to the Agreement. In the event the Department rejects a proposed monitor, AGA shall propose another candidate within ten (10) calendar days after

receiving notice of the rejection. This process shall continue until a Monitor acceptable to all parties is chosen. The Monitor's term shall be three (3) years from the date on which this Agreement was signed, subject to extension or early termination as described in Paragraph 3 of the Agreement. The Monitor's duties and authority, and the obligations of AGA with respect to the Monitor and the Department, are set forth below.

- 3. AGA agrees that it will not employ or be affiliated with the Monitor for a period of not less than one year from the date the Monitor's work has ended.
- 4. The Monitor will review and evaluate the effectiveness of AGA's internal controls, record-keeping, and financial reporting policies and procedures as they relate to AGA's compliance with the books and records, internal accounting controls and anti-bribery provisions of the FCPA, and other applicable anti-corruption laws. This review and evaluation shall include an assessment of those policies and procedures as actually implemented. The retention agreement between AGA and the Monitor will reference this Agreement and include this Agreement as an attachment so the Monitor is fully apprised of his or her duties and responsibilities.
- 5. AGA shall cooperate fully with the Monitor and the Monitor shall have the authority to take such reasonable steps as, in his or her view, may be necessary to be fully informed about the compliance program of AGA within the scope of his or her responsibilities under this Agreement. To that end, AGA shall provide the Monitor with access to all information, documents, records, facilities and/or employees that fall within the scope of responsibilities of the Monitor under this Agreement. Any such disclosure by AGA to the

Monitor concerning corrupt payments, related books and records and related internal controls shall not relieve AGA of its obligation truthfully to disclose such matters to the Department.

- a. The parties agree that the Monitor is an independent third-party, not an employee or agent of AGA or the Department, and that no attorney-client relationship shall be formed between AGA and the Monitor.
- b. In the event that AGA seeks to withhold from the Monitor access to information, documents, records, facilities and/or employees of AGA on grounds that the information, documents, records, facilities and/or employees are protected from disclosure by the attorney-client privilege or the attorney work-product doctrine, AGA shall promptly provide written notice of this determination to the Monitor and the Department. Such notice shall include a general description of the nature of the information, documents, records, facilities and/or employees that are being withheld, as well as the basis for the claim. The Department may then consider whether to make a further request for access to such information, documents, records, facilities and/or employees, as provided in Paragraph 5(a) of the Agreement.
- c. Except as provided in this paragraph, AGA shall not withhold from the Monitor any information, documents, records, facilities and/or employees on the basis of an attorney-client privilege or work product claim.

## 6. AGA agrees that:

a. The Monitor shall assess whether AGA's existing policies and procedures are reasonably designed to detect and prevent violations of the FCPA and other applicable anticorruption laws.

- b. The Monitor shall evaluate AGA's compliance with this Agreement.
- c. The Monitor shall oversee AGA's implementation of and adherence to all existing, modified or new policies and procedures relating to FCPA compliance (the "Policies and Procedures"), including the minimum policies and procedures set forth in Attachment C.
- d. The Monitor shall ensure that the Policies and Procedures are appropriately designed to accomplish their goals.
- e. During the three (3) year term, the Monitor shall conduct an initial review and prepare an initial report, followed by two follow-up reviews and reports as described below:
- (i) With respect to each of the three (3) reviews, after initial consultations with AGA and the Department, the Monitor shall prepare a written work plan for each review, which shall be submitted in advance to AGA and the Department for comment. In order to conduct an effective initial review and to understand fully any existing deficiencies in controls, policies and procedures related to the FCPA and other applicable anti-corruption laws, the Monitor's initial work plan shall include such steps as are reasonably necessary to develop an understanding of the facts and circumstances surrounding any violations that may have occurred, but the parties do not intend that the Monitor will conduct his or her own inquiry into those historical events. Any disputes between AGA and the Monitor with respect to the work plan shall be decided by the Department in its sole discretion.
- (ii) In connection with the initial review, the Monitor shall issue a written report within one hundred twenty (120) calendar days of his or her retention setting forth the Monitor's assessment and, if appropriate and necessary, making recommendations reasonably designed to improve the policies and procedures of AGA for ensuring compliance

with the FCPA and other applicable anti-corruption laws. The Monitor shall provide the report to the Board of Directors of AGA and contemporaneously transmit copies to Mark F.

Mendelsohn (or his successor), Deputy Chief, Frand Section, Criminal Division, U.S.

Department of Justice, 10<sup>th</sup> and Constitution Ave., N.W., Bond Building, Fourth Floor,

Washington, DC 20530. The Monitor may extend the time period for issuance of the report with prior written approval of the Department.

- the Monitor's report, AGA shall adopt the recommendations set fortis in the report; provided, however, that within sixty (60) calendar days after receiving the report, AGA shall advise the Monitor and the Department in writing of any recommendations that AGA considers unduly burdensome, impractical, costly or otherwise inadvisable. With respect to any recommendation that AGA considers unduly burdensome, impractical, costly or otherwise inadvisable, AGA need not adopt that recommendation; instead, AGA may propose in writing an alternative policy, procedure or system designed to achieve the same objective or purpose. As to any recommendation on which AGA and the Monitor ultimately do not agree, the views of AGA and the Monitor shall promptly be brought to the attention of the Department. The Department may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether AGA has fully complied with its obligations under this Agreement.
- (iv) The Monitor shall undertake two follow-up reviews to further monitor and assess whether the policies and procedures of AGA are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws.

- (v) Within sixty (60) calendar days of initiating each follow-up review, the Monitor shall: (A) complete the review; (B) certify whether the anti-bribery compliance program of AGA, including its policies and procedures, is appropriately designed and implemented to ensure compliance with the FCPA and other applicable anti-corruption laws; and (C) report on the Monitor's findings in the same fashion as with respect to the initial review.
- (vi) The first follow-up review and report shall be completed by one year after the initial review. The second follow-up review and report shall be completed by one year after the completion of the first follow-up review.
- (vii) The Monitor may extend the time period for submission of the follow-up reports with prior written approval of the Department.
- 7. In undertaking the assessments and reviews described above, the Momitor shall formulate conclusions based on, among other things: (a) inspection of relevant documents, including all the policies and procedures relating to AGA's anti-corruption compliance program; (b) onsite observation of AGA's systems and procedures, including its internal controls, record-keeping and internal audit procedures; (c) meetings with, and interviews of, relevant employees, officers, directors and other persons at mutually convenient times and places; and (d) analyses, studies and testing of AGA's anti-corruption compliance program.
- 8. Should the Monitor, during the course of his or her engagement, discover credible evidence that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid or authorized by any AGA entity or person, or any entity or person working directly or indirectly for AGA, or that related false books and records have been maintained, the Monitor shall promptly report such conduct to

AGA's General Counsel, its Board of Directors, and its outside counsel for further investigation, unless the Monitor believes, in the exercise of his or her discretion, that such disclosure should be made directly to the Department. If the Monitor refers the matter only to AGA's General Counsel, its Board of Directors, and its outside counsel, AGA shall promptly report the same to the Department and contemporaneously notify the Monitor that such report has been made. If AGA fails to make disclosure to the Department within ten (10) calendar days of the Monitor's report of such conduct to AGA, the Monitor shall independently disclose his or her findings to the Department at the address listed in Paragraph 6(e)(ii) above. Further, in the event that AGA, or any entity or person working directly or indirectly for AGA, refuses to provide information necessary for the performance of the Monitor's responsibilities, the Monitor shall promptly disclose that fact to the Department. AGA shall not take any action to retaliate against the Monitor for any such disclosures or for any other reason. The Monitor may report other criminal or regulatory violations discovered in the course of performing his or her duties, in the same manner as described above.