

## NON-PROSECUTION AGREEMENT

1. On the understandings specified below, the United States Attorney's Office for the Eastern District of North Carolina and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, "the Government"), will not criminally prosecute B. Braun Medical Inc. ("B. Braun"), a Pennsylvania corporation, or any of its present or former affiliates, directors, officers, employees, agents, or representatives for any crimes, including but not limited to violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), in relation to B. Braun's business relationship with AM2PAT, Inc., as described in Attachment A attached hereto, which is incorporated herein by reference.

2. B. Braun expressly understands that this Agreement does not provide any protection against prosecution for any crimes except as set forth above, and applies only to B. Braun and its present or former affiliates, directors, officers, employees, agents, or representatives.

3. The Government enters into this Agreement based, in part, on the following factors: (1) B. Braun's acknowledgement of its particular conduct set forth in Attachment A and B. Braun's acceptance of responsibility for that conduct; (2) B. Braun's commitment to the enhanced compliance measures set

forth in Attachments B and C, which are designed to ensure compliance with the FDCA and which are incorporated herein by reference; (3) B. Braun's payment of the monetary penalty described in Paragraphs 12-13 below; (4) B. Braun's forfeiture of the amount described in Paragraphs 14-15 below; (5) B. Braun's commitment to make restitution in accordance with the Restitution section set forth in Paragraphs 16-25 below; and (6) B. Braun's commitment to fulfill all of the terms of this Agreement.

#### Acceptance of Responsibility

4. It is understood that B. Braun admits, accepts, and acknowledges responsibility for the conduct of its employees, directors, and officers as set forth in Attachment A. It is further understood that B. Braun admits, accepts, and acknowledges that the facts described in Attachment A are true and accurate and agrees it will neither contest the admissibility of the facts described in Attachment A nor contradict those facts in any prosecution brought under Paragraph 26, including any guilty plea or sentencing proceeding.

5. It is further understood that B. Braun expressly agrees that it will not make any public statement contradicting

the acceptance of responsibility by B. Braun set forth above or the facts described in Attachment A.

6. In any prosecution of B. Braun pursuant to this Agreement, B. Braun can assert defenses it may have and raise additional facts which support such defenses as long as those defenses and facts are consistent with Paragraphs 4 and 5 above.

#### Term of the Agreement

7. B. Braun's obligations under this Agreement will have a term of thirty (30) months from the date that all parties have signed the Agreement (the "Effective Date").

8. It is understood that, in the event the Government determines, in its sole discretion, that B. Braun has knowingly and materially violated any provision of this Agreement, an extension or extensions of the term of this Agreement may be imposed by the Government, in its sole discretion, for up to a total additional period of one year, without prejudice to the Government's right to proceed as provided in Paragraphs 26-32 below. Any extension of the Agreement extends all terms of this Agreement, including the terms described in Attachments B and C, for an equivalent period.

9. Notwithstanding anything to the contrary in this Agreement, it is understood that after one year, B. Braun may periodically petition the Government for an early termination of

the Agreement of up to one year. The Government agrees to evaluate in good faith any request for early termination, taking into account B. Braun's compliance with this Agreement and any other factors that the Government deems relevant. B. Braun acknowledges that the Government is under no obligation to grant an early termination or to explain its reasoning denying a request for early termination.

#### Compliance and Cooperation

10. It is understood that B. Braun will comply in a timely manner with all of the terms of this Agreement, including the maintenance, or as necessary, the establishment, of the Enhanced Compliance Provisions as described in Attachment B, which are designed to prevent violations of the FDCA. If B. Braun sells, merges, or transfers all or substantially all of its business operations, B. Braun will maintain its existence and its ability to fulfill all of its obligations under this Agreement, or include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest, to fulfill all of B. Braun's obligations under this Agreement.

11. Until the date upon which all investigations and any prosecution arising out of the conduct described in this Agreement are concluded, whether or not they are concluded within the term of this Agreement, it is understood that

B. Braun will: (1) cooperate fully with the Government and any law enforcement agency designated by the Government regarding matters arising out of the conduct covered by this Agreement; (2) use its best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of B. Braun at any meeting or interview or before the grand jury or at any trial or other court proceeding regarding matters arising out of the conduct covered by this Agreement; and (3) truthfully disclose to the Government all factual information, documents, records, or other tangible evidence not protected by a valid claim of privilege or work product regarding matters arising out of the conduct covered by this Agreement about which the Government or any designated law enforcement agency inquires. This paragraph does not apply to any investigation or prosecution of B. Braun.

#### Payment of Monetary Penalty

12. It is understood that B. Braun has agreed to pay a monetary penalty of \$1,000,000 to the United States within twenty-one (21) days following the Effective Date of this Agreement. This penalty is final and will not be refunded. B. Braun will pay the monetary penalty by wire transfer according to the wire instructions provided by the Government.

13. It is understood that nothing in this Agreement constitutes an agreement by the Government that the monetary penalty in Paragraph 12 is the maximum fine that may be imposed in any future prosecution in the event of a breach of this Agreement, and that the Government is not precluded from then arguing or presenting evidence in any future prosecution that the Court should impose a higher fine. However, it is further understood that in the event of a future prosecution due to a breach of this Agreement, the Government agrees that it will recommend to the Court that any amount paid by B. Braun under this Agreement should be offset against any fine that the Court might impose as part of a future judgment and conviction.

#### Forfeiture

14. It is understood that B. Braun has agreed to forfeit the amount of \$3,800,000 to the United States within twenty-one (21) days following the Effective Date of this Agreement. This forfeiture is final and will not be refunded. B. Braun will pay the money to be forfeited by wire transfer according to the wire instructions provided by the Government. Upon payment of the money to be forfeited, B. Braun will release any and all claims it may have to the money and execute such documents as necessary to accomplish the forfeiture of the money. B. Braun will not file any claim to the money to be forfeited or otherwise contest

the forfeiture of the money, and will not assist anyone in asserting a claim to the money. B. Braun agrees to an uncontested administrative forfeiture by the U.S. Postal Inspection Service and waives its rights to notice.

15. It is understood that nothing in this Agreement constitutes an agreement by the Government that the forfeiture amount in Paragraph 14 is the maximum forfeiture that may be imposed in any future prosecution in the event of a breach of this Agreement, and that the Government is not precluded from then arguing or presenting evidence in any future prosecution that the Court should impose a higher forfeiture amount. However, it is further understood that in the event of a future prosecution due to a breach of this Agreement, the Government agrees that it will recommend to the Court that any amount forfeited by B. Braun under this Agreement should be offset against any forfeiture or fine that the Court might impose as part of a future judgment and conviction.

#### Restitution to Victims

16. Within twenty-one (21) days following the Effective Date of this Agreement, B. Braun will pay as restitution the amounts listed in Attachment E to the Restitution Administrator for distribution by the Restitution Administrator to the persons as listed in Attachment E.

17. In accordance with the procedures, requirements, and limitations set forth in Paragraphs 16-25 of this Agreement, B. Braun also agrees to pay restitution to persons who were directly and proximately harmed as a result of an adulterated B. Braun pre-filled saline flush syringe manufactured by AM2PAT that was contaminated with *Serratia marcescens* ("Eligible Claimants"). Those persons listed in Attachment E are not eligible for restitution under this Agreement to the extent that they have already been compensated by B. Braun for their harm through the payments made pursuant to Attachment E. Eligible Claimants do not include persons who have previously received compensation from B. Braun.

18. B. Braun agrees to the appointment of a Restitution Administrator for the purpose of collecting, assessing, and paying restitution claims submitted by any Eligible Claimant claiming to have been directly and proximately harmed as a result of an adulterated B. Braun pre-filled saline flush syringe manufactured by AM2PAT that was contaminated with *Serratia marcescens*. B. Braun and the Government have jointly selected Judge Frank W. Bullock, Jr., as the Restitution Administrator. B. Braun has separately agreed to pay the Restitution Administrator a reasonable fee and costs for his work under this Agreement.



19. For one hundred and eighty (180) days after the Effective Date of this Agreement, the Restitution Administrator will collect restitution claims from Eligible Claimants. The Restitution Administrator will determine the validity of each restitution claim. Restitution claims submitted to the Restitution Administrator later than one hundred eighty (180) days after the Effective Date of this Agreement are not eligible for restitution from B. Braun.

20. All decisions conferred upon the Restitution Administrator in this Agreement will be vested in the Restitution Administrator's discretion and, if contested, will be reviewed under the arbitrary-and-capricious standard set forth in 5 U.S.C. § 706(2)(A). Review of any decision by the Restitution Administrator made under this Agreement will be based exclusively on the written record before the Restitution Administrator at the time of the decision. No discovery will be taken in a challenge to the Restitution Administrator's decision.

21. If the Restitution Administrator decides to award any Eligible Claimant restitution, B. Braun will pay that claim within ten days after the Restitution Administrator's decision becomes final. The Restitution Administrator's decision becomes final thirty-one (31) days after notice to B. Braun of the decision. B. Braun may appeal in a court of competent

jurisdiction any restitution award greater than \$10,000.

B. Braun will pay any restitution award of \$10,000 or less ten days after the Restitution Administrator's decision becomes final. If B. Braun appeals or challenges the Restitution Administrator's decision within thirty (30) days after notice of the decision, the Restitution Administrator's decision does not become final until all of B. Braun's appeals have been exhausted.

22. B. Braun agrees to pay restitution under this Agreement up to a total of \$3,000,000, which includes amounts paid pursuant to Attachment E in Paragraph 16 above. Once B. Braun has paid \$3,000,000 in restitution, including the restitution paid pursuant to Attachment E in Paragraph 16 above, it will not be obligated to pay any additional restitution awards from the Restitution Administrator, even if the claim was outstanding when B. Braun paid restitution up to the \$3,000,000 limit.

23. The Restitution Administrator will promptly notify B. Braun and the Government of all claims received.

24. B. Braun will have a reasonable opportunity to investigate and challenge any claim before the Restitution Administrator makes a decision. B. Braun's reasonable opportunity to investigate and challenge a claim will not exceed six months from the notification to B. Braun of the claim,

unless the Restitution Administrator decides to extend the time for B. Braun to investigate and challenge a claim. In no event will B. Braun's opportunity to investigate and challenge a claim exceed twelve months.

25. The United States acknowledges that as of the Effective Date of this Agreement, it is not aware of any person who would be entitled to receive restitution outside of those persons listed on Attachment E.

#### Breach of the Agreement

26. It is understood that, if the Government in its sole discretion determines that, during the term of this Agreement, B. Braun has (1) committed any material violation of 21 U.S.C. § 331 relating to the adulteration or misbranding of its products after the Effective Date of this Agreement; (2) committed any felony under United States federal law after the Effective Date of this Agreement; (3) provided deliberately false, deliberately incomplete, or deliberately misleading information at any time in connection with this Agreement; (4) materially failed to perform any of the obligations set forth in Attachments B or C to this Agreement; or (5) otherwise materially violated any provision of this Agreement, B. Braun will thereafter be subject to prosecution for any violation of

federal law about which the Government has knowledge, including perjury and obstruction of justice.

27. It is understood that any such prosecution that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement, including time protected as the result of existing agreements between B. Braun and the Government to toll the applicable statute of limitations, may be commenced against B. Braun, notwithstanding the expiration of the statute of limitations during the term of this Agreement plus six months. Thus, B. Braun agrees that the statute of limitations with respect to any prosecution that is not time-barred as of the Effective Date of this Agreement will be tolled for the term of this Agreement plus six months.

28. It is further understood that the facts in Attachment A, and any testimony given by or on behalf of B. Braun before a grand jury, any court or tribunal, whether before or after this Agreement, and any leads derived from such statements, will be admissible in evidence in any and all criminal proceedings brought by the Government pursuant to Paragraph 26 of this Agreement against B. Braun; and B. Braun and its counsel will stipulate that the facts in Attachment A may be read to the jury or other finder of fact in whole or in part, as elected by the Government, as a stipulation to which B. Braun has agreed.

29. In the event that the Government determines that B. Braun has materially breached this Agreement, the Government agrees to provide B. Braun with written notice of such breach prior to instituting any prosecution resulting from such breach. B. Braun will, within thirty (30) days of receipt of such notice, have the opportunity to respond to the Government in writing to explain the nature and circumstances of the purported breach, as well as the actions B. Braun has taken to address and remediate the situation, if any, including whether B. Braun believes a breach occurred, whether such breach was material, and whether such breach was knowing or willful. The Government agrees to consider B. Braun's explanation in determining whether to institute a prosecution.

30. Whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of B. Braun will be imputed to B. Braun for the purposes of determining whether B. Braun has violated any provision of this Agreement, will be at the sole discretion of the Government, applying standards consistent with applicable law.

31. If the Government determines that B. Braun has breached this Agreement, it is understood that, as a contractual remedy, the Government may, at its sole discretion, impose a monetary payment of up to \$5,000 per day for each day B. Braun

is in breach of the Agreement ("Stipulated Penalties"). The imposition of such Stipulated Penalties will be in the alternative to instituting a prosecution due to a breach of this Agreement. The Government will notify B. Braun in writing of B. Braun's failure to comply and the Government's exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter will set forth: (a) the provision breached; (b) the date of the breach; (c) a description of the breach sufficient to permit B. Braun to cure (as described below); and (d) the amount of Stipulated Penalties claimed by the Government as of the date of the Demand Letter.

32. It is further understood that within thirty (30) days after receiving the Demand Letter, or such longer period as the United States may agree in writing, B. Braun will cure the breach to the Government's reasonable satisfaction ("Cure Period"). If B. Braun cures the breach within the Cure Period, no Stipulated Penalties will be due. If B. Braun fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment will be immediately payable to the United States. The Stipulated Penalties will be paid by electronic fund transfer according to wire instructions that will be provided by the Government. The U.S. Attorney's Office for the Eastern District of North

Carolina and the Department of Justice's Consumer Protection Branch will make a joint reasonable determination regarding B. Braun's failure to comply with any of the obligations described in this Agreement, and that decision will be final and non-appealable. It is understood that the United States District Court for the Eastern District of North Carolina will have jurisdiction over any action to collect a Stipulated Penalty.

#### Disclosure of the Agreement

33. It is understood that within ten (10) business days of the Effective Date of this Agreement, B. Braun will communicate to all B. Braun employees that B. Braun has entered into this Agreement and make available this Agreement, including all Attachments except Attachment E, to all such employees. However, B. Braun will not disclose to its employees Attachment E listing restitution amounts for victims.

34. It is further understood that B. Braun and the Government may disclose this Agreement, including all Attachments except Attachment E, to the public. B. Braun and the Government will not disclose Attachment E listing restitution amounts for victims.

### Limitations on Binding Effect of Agreement

35. It is understood that this Agreement is binding on B. Braun, the Office of the United States Attorney for the Eastern District of North Carolina, the Consumer Protection Branch of the Department of Justice, and the United States Attorney's Offices for each of the other ninety-three judicial districts of the United States. This Agreement specifically does not bind any other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. A copy of the letter from the Office of the Assistant Attorney General, Criminal Division, Department of Justice authorizing this Agreement is attached hereto as Attachment D.

### Notice

36. Any notice to the Government under this Agreement will be given by personal delivery, or overnight delivery by a recognized delivery service addressed to the following:

Chief, Criminal Division  
U.S. Attorney's Office,  
Eastern District of North Carolina  
310 New Bern Avenue  
Federal Building, Suite 800  
Raleigh, North Carolina 27601



Director, Consumer Protection Branch  
U.S. Department of Justice  
450 5th St NW Room 6400 South  
Washington, DC 20001

37. Any notice to B. Braun under this Agreement will be addressed to the following:

General Counsel  
B. Braun Medical Inc.  
824 Twelfth Avenue  
Bethlehem, Pennsylvania 18018-027

Mark T. Calloway  
Alston & Bird LLP  
101 South Tryon St., Suite 4000  
Charlotte, NC 28280-4000 USA

Complete Agreement

38. This Agreement, including all Attachments, sets forth all the terms of the Agreement between B. Braun and the Government. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the Government, the attorneys for B. Braun, and a duly authorized representative of B. Braun.

SIGNATURES FOR B. BRAUN MEDICAL INC.



CATHY L. CODREA  
General Counsel  
B. Braun Medical Inc.  
824 Twelfth Avenue  
Bethlehem, PA 18018

DATED: May 13, 2016



BRUCE A. HEUGEL  
Chief Financial Officer  
B. Braun Medical Inc.  
824 Twelfth Avenue  
Bethlehem, PA 18018

DATED: May 13, 2016

SIGNATURE OF B. BRAUN'S ATTORNEY



MARK T. CALLOWAY  
Alston & Bird LLP  
101 South Tryon Street  
Suite 4000  
Charlotte, NC 28280

DATED: May 13, 2016


**SIGNATURES FOR THE UNITED STATES**


BENJAMIN C. MIZER  
Principal Deputy Assistant  
Attorney General  
Civil Division  
U.S. Department of Justice

JOHN STUART BRUCE  
Acting U.S. Attorney  
U.S. Attorney's Office  
For the Eastern District  
of North Carolina

MICHAEL S. BLUME  
Director  
Consumer Protection Branch  
U.S. Department of Justice

FELICE M. CORPENING  
Deputy Criminal Chief  
Assistant U.S. Attorney  
U.S. Attorney's Office  
For the Eastern District  
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ALLAN GORDUS  
SHANNON L. PEDERSEN  
Trial Attorneys  
Consumer Protection Branch  
U.S. Department of Justice

  
EVAN RIKHYE  
Assistant U.S. Attorney  
U.S. Attorney's Office  
For the Eastern District  
of North Carolina

DATED: May 18, 2016

# Attachment A

## Statement of Facts

ATTACHMENT A

STATEMENT OF FACTS

This Statement of Facts is incorporated by reference as part of the Non-Prosecution Agreement, dated May 18, 2016, between the United States Department of Justice, by and through the United States Attorney's Office for the Eastern District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, the "Government") and B. Braun Medical Inc. ("B. Braun"). The Government and B. Braun agree that the following facts are true and correct:

Relevant Parties

1. During the relevant time period, from September 2004 through January 2008, B. Braun was a Pennsylvania corporation. B. Braun designed, manufactured and sold drugs and medical devices in the United States. B. Braun's Corporate Headquarters was in Bethlehem, Pennsylvania. The company had manufacturing plants in Allentown, Pennsylvania; Irvine, California; and Carrollton, Texas.

2. AM2PAT, Inc. ("AM2PAT") was an Illinois corporation. From September 2004 to May 2007, AM2PAT's principal place of business was 9400 Ransdell Road, Suite 10, Raleigh, North

Carolina. From May 2007 to April 2008, AM2PAT's principal place of business was 455 West Depot Street, Angier, North Carolina.

3. From September 2004 to September 2005, AM2PAT did business using the name Salient Healthcare Technologies. From September 2005 to April 2008, AM2PAT did business using the name Sierra Pre-Filled.

4. From September 2004 to January 2008, Dushyant Patel was AM2PAT's president and CEO.

5. AM2PAT manufactured pre-filled saline flush syringes. Pre-filled saline flush syringes were used to flush out or clean medical devices that provided access to a patient's veins, such as central lines, ports, and short peripheral catheters.

#### AM2PAT's Manufacturing Practices

6. At certain times from September 2004 to January 2008, AM2PAT and its employees failed to follow good manufacturing practices.

7. AM2PAT's bad manufacturing practices included, among other things, failing to properly clean its manufacturing facility and equipment, failing to properly train its employees, failing to test its equipment to ensure that it is working properly, and using dirty and filthy equipment to manufacture sterile saline syringes.

8. In 2007, AM2PAT's bad manufacturing practices resulted in flush syringes that were contaminated with bacteria and dangerous to patients.

9. AM2PAT also falsified records related to its manufacturing processes and intentionally hid that falsification from B. Braun and the FDA.

B. Braun Entered into an Agreement with AM2PAT to Make B. Braun  
Saline Syringes

10. In September 2004, B. Braun began to consider using AM2PAT to manufacture pre-filled saline flush syringes for B. Braun with a B. Braun label ("B. Braun saline syringes"). A Type II PFG is a finished product designed and manufactured by third parties unrelated to B. Braun without further processing and which bears the B. Braun name or logo. B. Braun followed a process for qualifying AM2PAT as a supplier. During this process B. Braun obtained from AM2PAT, among other things, product samples, information about sterilization processes and tests, confirmation that the United States Food and Drug Administration ("FDA") had cleared AM2PAT's pre-filled saline flush syringes for marketing, and proposed labeling stating that B. Braun is the product's distributor. In October 2004 B. Braun also audited AM2PAT's facility as part of the supplier qualification process.

11. After B. Braun decided to qualify AM2PAT to make B. Braun saline syringes, it held weekly teleconferences with AM2PAT in the summer of 2005 to plan for the launch of B. Braun's new saline syringes.

12. B. Braun approved AM2PAT to make B. Braun saline syringes without conducting independent analytical testing, such as sterility testing, to confirm that the representations AM2PAT made on its Certificates of Analysis were accurate. At that time B. Braun did not have, as part of its Type II PFG new supplier qualification process, a policy that required sterility testing of a sample of a Type II PFG solution product to corroborate any sterility test results reported to B. Braun by the PFG supplier through a Certificate of Analysis or similar representation before B. Braun first offered for sale that Type II PFG.

13. On August 30, 2005, B. Braun signed a quality agreement with AM2PAT. The quality agreement stated that B. Braun would "perform testing to supplement or confirm" AM2PAT's product test data and that B. Braun was "responsible for final release of [the syringes] for commercial distribution" to B. Braun's customers. The quality agreement also gave B. Braun the right to review and approve any changes by AM2PAT to its manufacturing processes that might "affect the safety or quality" of the B. Braun saline syringes made by AM2PAT.



14. On or about September 2, 2005, B. Braun approved AM2PAT to manufacture B. Braun saline syringes.

15. From September 2004 to January 2008, AM2PAT offered B. Braun the lowest price for making B. Braun saline syringes compared to other syringe suppliers.

#### FDA Regulation of Saline Syringes

16. Saline syringes were medical devices that the FDA regulated under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"). The FDCA prohibited the shipment in interstate commerce of an adulterated or misbranded medical device, 21 U.S.C. § 331(a).

17. The FDA promulgated the Quality System Regulations which governed the manufacture of medical devices including saline syringes. A medical device was adulterated within the meaning of the FDCA, 21 U.S.C. § 351(h), if it was not manufactured according to FDA's Quality System Regulations, 21 C.F.R. Part 820.

18. A medical device was also adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(A), if it was prepared, packed, or held under insanitary conditions whereby it may have been rendered dangerous to a patient's health.

FDA's Warning Letter to AM2PAT

19. In June 2005, FDA inspected AM2PAT and found numerous and significant quality problems with AM2PAT's operations.

20. In August 2005, FDA sent AM2PAT a Warning Letter describing the problems that FDA found during its inspection. FDA's Warning Letter stated that AM2PAT had nine problems, which included failing to properly train its employees who made the saline syringes and failing to properly test its manufacturing processes to ensure that all of the saline syringes that AM2PAT was making were sterile.

21. AM2PAT did not notify B. Braun of FDA's inspection or Warning Letter. Instead, on September 14, 2005, after B. Braun had already approved AM2PAT to manufacture saline syringes for B. Braun but before it had purchased any syringes, B. Braun found out about the Warning Letter on its own. AM2PAT admitted it was in violation of the quality agreement by failing to notify B. Braun, but claimed it had not received the Warning Letter until after Labor Day, which was after B. Braun's September 2 approval of AM2PAT. However, in November 2005, AM2PAT provided B. Braun with a letter from FDA that included information demonstrating that AM2PAT's representation was false.

22. After B. Braun learned that FDA had sent AM2PAT a Warning Letter, B. Braun suspended plans to purchase syringes from AM2PAT. Specifically, B. Braun's Quality-Management team decided to "maintain the current SAP 'Block' until such time that the FDA has accepted [AM2PAT's] course of action and that B. Braun receives a copy of that acceptance letter." In addition, B. Braun decided to do its own audit of AM2PAT's manufacturing operations.

#### B. Braun's Audit of AM2PAT

23. On November 8, 2005, B. Braun began its three-day audit of AM2PAT and found more problems than FDA listed in its Warning Letter.

24. On November 16, 2005, a major B. Braun customer expressed concern to B. Braun about AM2PAT's Warning Letter, noting that the quality violations seemed serious. B. Braun responded to the customer explaining that it would not stock the product until all issues were resolved to the FDA's satisfaction.

25. In a November 22, 2005 letter, FDA notified AM2PAT that the corrective actions in its responses to the Warning Letter, if appropriately performed and implemented, appeared to address the majority of concerns raised during FDA's inspection.

26. After B. Braun's November 2005 audit, B. Braun employees in Regulatory Compliance and Quality Assurance recommended that B. Braun (i) conduct another audit and/or verification of AM2PAT to ensure that AM2PAT completed B. Braun's requested corrective actions and (ii) receive confirmation that the FDA closed out AM2PAT's Warning Letter, before B. Braun began selling saline syringes made by AM2PAT.

27. Despite these recommendations of its employees and the concerns of a major customer, B. Braun began buying syringes from AM2PAT without conducting another on-site audit or verifying that AM2PAT had effectively implemented the corrective actions it had promised in response to B. Braun's own audit. B. Braun did wait until FDA had closed out its Warning Letter before it began buying syringes from AM2PAT.

28. B. Braun's sales and marketing employees emphasized repeatedly to B. Braun's quality employees the need to receive and ship B. Braun syringes from AM2PAT in order to fill long overdue B. Braun customer orders for those syringes.

#### B. Braun Began Selling Saline Syringes from AM2PAT

29. In January 2006, FDA inspected AM2PAT and found that AM2PAT had made sufficient progress in correcting the problems identified in FDA's Warning Letter. At the conclusion of the inspection FDA did not issue a Form FDA-483, which is the form

where any significant objectionable conditions would have been listed, and the inspection was classified as VAI (Voluntary Action Indicated).

30. Immediately after FDA's inspection, Dushyant Patel told B. Braun that FDA had concluded that AM2PAT had made sufficient progress in correcting the problems identified in FDA's Warning Letter.

31. In March 2006, after B. Braun learned of the results of FDA's January 2006 inspection, B. Braun agreed to accept and sell B. Braun saline syringes made by AM2PAT. The syringes bore the B. Braun logo and listed B. Braun as the distributor but did not list AM2PAT as the manufacturer.

32. On or about April 3, 2006, B. Braun sold the first shipment of B. Braun saline syringes made by AM2PAT.

33. In September 2006, B. Braun sales employees reported to B. Braun marketing employees that some of B. Braun's customers were concerned about purchasing saline syringes made by AM2PAT because those customers were aware of AM2PAT's history of quality and supply problems when AM2PAT did business as Salient. One of those same customers indicated its assumption that with the B. Braun name on the label, B. Braun must have done its due diligence in inspecting AM2PAT's manufacturing facility and processes. At that time, however, B. Braun still had not re-inspected AM2PAT to verify that AM2PAT had

effectively implemented the corrective actions it had promised in response to B. Braun's November 2005 audit and FDA's Warning Letter.

34. In December 2006, following B. Braun's decision to move more of its saline syringe business to AM2PAT, B. Braun conducted an on-site audit to assess AM2PAT's quality systems. The B. Braun auditor talked with AM2PAT personnel and reviewed documents, but did not perform a walk-through of AM2PAT's facility to observe its manufacturing operations. The auditor concluded that AM2PAT's quality systems were acceptable.

B. Braun Received Complaints of Orange, Brown, and Black  
Particles in its Saline Syringes

35. After B. Braun began selling its AM2PAT-made saline syringes, B. Braun received a small number of complaints of orange, brown, and black particles floating inside the syringes. B. Braun received these complaints from its customers and the people who were actually using the syringes with patients.

36. In August 2006, a B. Braun marketing employee discussed a "rusting issue" in syringes from AM2PAT with Dushyant Patel.

37. In December 2006, Dushyant Patel told B. Braun marketing employees that he was piloting a metal detector to

solve the problem with rust particles in B. Braun saline syringes.

38. In March 2007, AM2PAT assured B. Braun that it had taken steps to ensure that the rusting problem would not occur again. At various times thereafter, B. Braun received complaints suggesting the presence of rust. B. Braun did not investigate whether AM2PAT's claimed rusting solution was effective.

B. Braun Asked AM2PAT to Make More B. Braun Saline Syringes

39. Even though B. Braun found many problems at AM2PAT during its November 2005 audit and received complaints of orange, brown, and black particles in its saline syringes from AM2PAT, B. Braun continued selling AM2PAT-made syringes and asked AM2PAT to increase its production of B. Braun saline syringes. B. Braun had trouble filling all of the orders from its customers for its saline syringes.

40. A B. Braun purchasing executive recommended that B. Braun buy more AM2PAT-made saline syringes so B. Braun could increase its sales of these syringes.

41. Over the course of its relationship with B. Braun, AM2PAT lowered the price it charged to make B. Braun saline syringes.

### AM2PAT Made Major Changes to Its Operations

42. In April 2007, B. Braun approved a change whereby AM2PAT would use gamma radiation to sterilize the outside of the aseptically filled saline syringes that it made for B. Braun.

43. The new radiation sterilization process was meant to sterilize the outside of the syringes, making it possible to use the syringes in sterile environments, like surgical operating rooms. Because these saline syringes were meant for use in sterile environments, they were called "Sterile Field Ready" or "SFR" syringes.

44. B. Braun's April 2007 approval was based on a validation report from the gamma sterilizer establishing the minimum sterilization dose of radiation, including sterility tests on the actual B. Braun syringes made by AM2PAT, and a separate validation report from AM2PAT. AM2PAT's validation report concluded that the syringes manufactured for B. Braun and sterilized by the gamma sterilizer remained a bluish-silver color and did not show any yellowing or "inelegant" coloring.

45. In early May 2007, AM2PAT moved from its manufacturing plant at 9400 Ransdell Road in Raleigh, North Carolina, to a new plant at 455 West Depot Street in Angier, North Carolina.

46. Prior to AM2PAT's move, in March 2007, a senior B. Braun marketing executive expressed concern about AM2PAT's



move and stated that a move to a new manufacturing plant was "often more complicated than [it] seem[s]" and asked whether B. Braun's quality department was "OK with AM2PAT's performance."

47. Although various B. Braun employees were aware that AM2PAT planned to move to a new facility months before the move, B. Braun waited to start its evaluation and approval of the move in advance as required by the quality agreement until AM2PAT gave its "official" notice of the move. AM2PAT assured B. Braun that its new filler and packaging line would be fully installed and validated at its new facility.

48. B. Braun waited until AM2PAT gave "official" notice of its impending move on May 4, 2007, to begin its work to approve a move that AM2PAT intended to do one week later.

49. On May 8 and 9, 2007, three B. Braun purchasing and marketing employees visited both AM2PAT's existing Raleigh facility and its new Angier facility. During their visit, they saw that the new Angier facility was empty.

50. On May 8, 2007, AM2PAT notified B. Braun of its intent to change the gamma sterilization company it would use for the SFR syringes. AM2PAT claimed that the new gamma sterilization company used the same equipment and its dose range was the same as the first gamma sterilization company. B. Braun reviewed the rationale for the move, a dose map, dose map data, and sample

certifications. B. Braun did not ask to see test data showing how the new gamma sterilization company's radiation sterilizing process affected the B. Braun syringes made by AM2PAT.

51. On May 15, 2007, Dushyant Patel reported to a B. Braun purchasing employee that AM2PAT had moved its operations to its new facility from May 11 through May 13, 2007, and was back to full production.

52. On or about June 11, 2007, B. Braun began selling B. Braun SFR saline syringes made by AM2PAT even though B. Braun had not seen or audited AM2PAT's new manufacturing plant in Angier, North Carolina, tested the new gamma sterilizer's sterilization process on B. Braun syringes, or even approved either change as required by B. Braun's quality agreement with AM2PAT.

53. On June 26, 2007, B. Braun received a customer complaint indicating that a B. Braun SFR syringe was a "slightly tainted brownish color" and that it looked like it contained water from the "Hudson River."

54. In response to customer inquiries about discoloration of B. Braun syringes, a B. Braun marketing employee suggested responding to the customer that the "discoloration" was merely an expected result of the gamma sterilization process, even though AM2PAT had previously represented to B. Braun in its validation report that the SFR syringes remained bluish-silver

after gamma sterilization with no yellowing or inelegant coloring.

55. Following B. Braun's explanation regarding the brown and yellow "discolored" SFR syringes , some B. Braun customers decided not to file an official Product Incident Report.

B. Braun's quality department relies on Product Incident Reports to trend customer complaints for potential corrective action.

56. On June 26, 2007, Dushyant Patel told a B. Braun purchasing employee that he intended to lower the maximum gamma radiation dose to avoid "overcooking" the B. Braun SFR syringes. The B. Braun purchasing employee expressed concern that B. Braun was "at risk" because it had allowed shipments of syringes that had a different radiation dose than what B. Braun had approved. B. Braun failed to investigate AM2PAT's modifications of the gamma sterilization doses and whether the reported "overcooking" was causing harm to the B. Braun SFR syringes.

57. Despite having already received complaints about discoloration of SFR syringes, and despite having evidence of AM2PAT's modification of the gamma sterilization process, on July 5, 2007, B. Braun approved AM2PAT's change to the new gamma sterilization company by reviewing the rationale for the change, a dose map, dose map data, and sample certifications. B. Braun did not test the new process on the B. Braun syringes.

58. On July 5, 2007, B. Braun also approved AM2PAT's move to the new plant in Angier, North Carolina. B. Braun did not see AM2PAT's manufacturing operations at the new plant and did not confirm AM2PAT's representations that it had properly validated its equipment and clean room prior to re-starting the manufacture of B. Braun saline syringes.

#### The First Recall of B. Braun's Saline Syringes

59. The new radiation process that AM2PAT used to sterilize B. Braun's SFR saline syringes caused white particles to develop in the saline inside the syringes. The particles could be seen floating in the syringes. These particles were dangerous to patients when the syringes were used with a patient.

60. On July 13, 2007, Dushyant Patel told a B. Braun marketing employee in an email that the white particles in the SFR saline syringes were cross-linked silicone that dissolved back into solution when the syringe was shaken. At the time of this email, the marketing employee continued to tell customers and other B. Braun employees who spoke to customers that the B. Braun SFR syringes were safe to use, even when one customer complained of an SFR syringe containing "disappearing flakes."

61. On July 18, 2007, B. Braun informed Dushyant Patel that it was conducting its own testing on the syringes in

response to the customer complaints regarding particulate matter, and that until the testing was complete, all lots in inventory or transit with the SFR suffix numbers would be placed on hold.

62. Following these reports, Dushyant Patel admitted to B. Braun that the new sterilization company's gamma radiation cycle was not identical to the originally-validated procedure at the original gamma sterilization company that B. Braun had approved in April 2007, in that the cycle time at the new sterilization company was longer.

63. On July 18, 2007, B. Braun placed a hold on all SFR lots.

64. On July 19, 2007, a B. Braun quality manager asked AM2PAT to provide complete information about the gamma radiation cycles for both the original gamma sterilizer and the new gamma sterilizer, so B. Braun could assess the differences between the two. AM2PAT never provided this information, and B. Braun never followed up on its request.

65. On July 27, 2007, B. Braun decided to pursue returning to aseptically filled syringes without gamma sterilization.

66. B. Braun continued to receive complaints about particulate matter in the B. Braun SFR syringes. Some of the complaints also referred to particulate matter that was brown, black, and orange. B. Braun never determined whether the brown,

black, and orange particles were the same as the white particles.

67. On July 26, 2007, B. Braun received a draft Health Hazard Report from a medical consultant that concluded that "when adequate therapeutic alternatives exist," B. Braun's SFR syringes "pose[d] an unacceptable risk to human health."

68. On July 30, 2007, less than two months after B. Braun started selling the B. Braun SFR saline syringes made by AM2PAT, B. Braun voluntarily recalled all of these syringes. Because of this recall, B. Braun did not have any B. Braun saline syringes in stock that could be used to fill the orders of its customers.

B. Braun Approved AM2PAT Again To Make B. Braun Saline Syringes

69. After B. Braun's first recall of its saline syringes made by AM2PAT, B. Braun's Director of Quality Assurance wrote a memo stating that B. Braun should audit AM2PAT's manufacturing operations at its new plant in Angier, North Carolina, before allowing AM2PAT to make any more B. Braun saline syringes.

70. On August 3, 2007, AM2PAT faxed B. Braun a list of its recent manufacturing changes. One of these changes showed that AM2PAT moved its syringe filling machine from AM2PAT's old plant in Raleigh to its new plant in Angier without validating that the machine worked as expected following the move.

71. On or about August 29, 2007, B. Braun approved AM2PAT to again manufacture non-gamma sterilized B. Braun saline syringes without auditing AM2PAT's manufacturing operations at its new plant in Angier, North Carolina, but did receive notice from AM2PAT that an FDA inspector had visited this new facility on August 2, 2007, to investigate whether AM2PAT was properly handling a complaint that one of its syringes contained rust. AM2PAT reported to B. Braun that the FDA inspector was satisfied with what she saw.

72. On September 7, 2007, B. Braun notified AM2PAT that it had failed to provide responses to B. Braun concerning a number of customer complaints, including several from 2006. B. Braun took no further action in response to AM2PAT's failure to make a timely assessment of customer complaints related to B. Braun saline syringes made by AM2PAT.

73. On November 27, 2007, in response to a request to share B. Braun's audit report of AM2PAT with B. Braun's parent company in Germany for purposes of potentially selling AM2PAT syringes in Europe, a B. Braun senior quality executive told a B. Braun purchasing executive and a B. Braun marketing director that he was "no where close to being as confident about AM2PAT as you folks are."

## The Second Recall of B. Braun's Saline Syringes

74. Approximately two months after B. Braun's recall of its SFR saline syringes, and two months before a B. Braun senior quality executive indicated his lack of confidence in AM2PAT, AM2PAT manufactured the B. Braun saline syringes in the lot numbered 070917A.

75. On January 17, 2008, AM2PAT initiated a recall of all syringes it had manufactured, including B. Braun saline syringes, and that same day B. Braun notified its customers of the recall. B. Braun cooperated fully and appropriately during the recall of the syringes.

76. Public health officials eventually determined that B. Braun saline syringes from lot number 070917A infected patients with *S. marcescens* bacteria in California, Texas, New York and Nebraska.

## FDA's Inspection of AM2PAT in December 2007 and January 2008

77. From December 18, 2007, to January 16, 2008, FDA inspected AM2PAT's manufacturing plant in Angier, North Carolina. During this inspection, FDA discovered serious problems in how AM2PAT trained its employees and manufactured syringes, including multiple violations of the Quality System Regulations. These violations included manufacturing processes that were not validated and/or were inadequately validated,



laboratory operations that were not adequately validated, production processes that were inadequately controlled and monitored, inadequate finished device testing, non-conforming results that were not documented or investigated, and complaint handling procedures that were not implemented.

78. The FDA also determined that the LAL Testing Log and device history records (DHR) for seven lots, including lot number 070917A, may have been backdated by AM2PAT in violation of the Quality System Regulations. AM2PAT released and shipped all seven of the Lots before AM2PAT tested them, in violation of the Quality System Regulations. Lot number 070917A was manufactured by AM2PAT at the Angier plant in or around September 2007.

79. As a result of its inspection, FDA concluded that these problems could cause the syringes manufactured at AM2PAT to be contaminated. At the end of FDA's inspection, AM2PAT's president and CEO, Dushyant Patel, told FDA that AM2PAT would fire all of its employees and shut down. It did so.

#### B. Braun's Accountability

80. B. Braun, through its employees, distributed B. Braun-labeled syringes from lot number 070917A in interstate commerce when the syringes were adulterated within the meaning of FDCA, 21 U.S.C. § 351(h). B. Braun acknowledges that the acts taken

by its employees as described above were within the scope of their employment, and B. Braun is liable for those acts.

## Attachment B

# Enhanced Compliance Measures & Certifications

## ATTACHMENT B

### ENHANCED COMPLIANCE MEASURES & CERTIFICATIONS

B. Braun agrees to the provisions set forth in this Attachment to the Agreement.

#### I. Quality Compliance Program

B. Braun has in place and/or will implement within sixty (60) days of the Effective Date of this Agreement, and will maintain a Quality Compliance Program that governs B. Braun's United States business operations relating to finished products designed and manufactured by third parties unrelated to B. Braun without further processing and which bear the B. Braun name on the label or logo ("Type II PFGs"). The purpose of the Quality Compliance Program is to (a) prevent, detect, and correct potential violations of law and potential violations of B. Braun's quality policies and procedures; (b) assure the establishment of quality compliance-related policies and procedures for business and quality operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) implement a mechanism for deterring and detecting non-compliance issues; and (e) assure appropriate corrective action is taken to prevent recurrence of quality compliance issues.

The Quality Compliance Program has and will continue to maintain policies and procedures designed to prevent violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") regarding the distribution of Type II PFGs, including quality policies and procedures on the following subjects.

#### A. Supplier Qualification

B. Braun will maintain a dedicated business unit with sufficient resources, including Quality Assurance resources, to manage the qualification of Type II PFG suppliers. This qualification will include an on-site audit of a potential new supplier of Type II PFGs and, if that audit reveals conditions or practices that could adversely affect the safety of the supplier's Type II PFGs or that indicate that the supplier's Type II PFGs are being prepared, packed, or held under conditions whereby the Type II PFGs may have been rendered

injurious to health, B. Braun will conduct an additional on-site audit to verify that the supplier has implemented appropriate corrective actions. B. Braun will complete any such on-site audits before B. Braun first offers for sale any Type II PFG from that supplier and before B. Braun first receives any Type II PFG from that supplier for purposes of sale to B. Braun customers. This qualification further will include sterility, identity and purity testing of Type II PFGs that are (a) within the same market clearance or approval, and (b) manufactured using the same procedures and the same equipment at the same facility, before B. Braun first offers that Type II PFG for sale to B. Braun customers, to corroborate any sterility, identity or purity test results reported to B. Braun by the Type II PFG supplier by means of a Certificate of Analysis or similar representation.

For Type II PFG suppliers B. Braun has already qualified, B. Braun will conduct the on-site audit(s) described in the previous paragraph before offering for sale to B. Braun customers a Type II PFG that: (1) as of the Effective Date of this Agreement, B. Braun does not already purchase from that PFG supplier, and (2) is either (a) not within the same market clearance or approval of a Type II PFG that, as of the Effective Date of this Agreement, B. Braun already purchases from that PFG supplier, or (b) not manufactured using the same procedures and the same equipment at the same facility as a Type II PFG that, as of the Effective Date of this Agreement, B. Braun already purchases from that PFG supplier ("new Type II PFG"), unless B. Braun conducted a successful on-site audit of that supplier within the previous twelve (12) months. For all new Type II PFGs, B. Braun will perform the sterility, identity and purity testing described in the previous paragraph before offering that new Type II PFG for sale to B. Braun customers.

For Type II PFGs for which the Type II PFG supplier holds the market authorization, B. Braun will ensure that the manufacturer is identified on the Type II PFG product's label before B. Braun first receives the Type II PFG to sell to B. Braun customers. For current Type II PFGs distributed by B. Braun, B. Braun will use reasonable best efforts to ensure that the Type II PFG supplier will implement a labeling change on such Type II PFG product labels to identify the name of the manufacturer.

Before approving and finalizing its Quality Agreement with a Type II PFG supplier, B. Braun will perform a final compliance status confirmation of that supplier using publicly available

information. In addition, B. Braun will require the Type II PFG supplier to confirm that, during the negotiation of the Quality Agreement, the Type II PFG supplier had not conducted any product recalls, had not received an increase in the frequency or scope of customer complaints, or had communications with the Food and Drug Administration ("FDA") in any manner concerning the supplier's compliance with the FDCA of which the supplier had not previously made B. Braun aware. B. Braun Quality Assurance will address any identified discrepancies with the Type II PFG supplier before fully executing the Quality Agreement.

#### B. Supplier Monitoring

B. Braun will maintain a procedure for supplier monitoring and metrics to measure and report a Type II PFG supplier's ongoing performance. This procedure will include, at a minimum, an assessment of: (1) the Type II PFG supplier's quality performance as measured through B. Braun product quality rejections, customer inquiries alleging deficiencies related to the quality of Type II PFGs reported to B. Braun under Section I.C below, and supplier quality issues reported to B. Braun under Section I.D below; (2) the Type II PFG supplier's responsiveness to B. Braun regarding such customer inquiries or quality issues; (3) the timeliness of the Type II PFG supplier's communication to B. Braun of interactions with the FDA and changes to the Type II PFG supplier's business and products; and (4) the Type II PFG supplier's efforts to focus on continuous improvement.

Supplier monitoring also will include sterility, identity and purity testing on an annual basis of a Type II PFG supplier's Type II PFGs that are (a) within the same market clearance or approval, and (b) manufactured using the same procedures and the same equipment at the same facility to corroborate any sterility, identity or purity test results reported to B. Braun by or on behalf of the Type II PFG supplier by means of a Certificate of Analysis or similar representation. B. Braun further will conduct such testing any time a Type II PFG supplier communicates (1) a facility move or the commissioning of a new facility; (2) a change to its existing manufacturing facility used to make the Type II PFG where the change could adversely affect safety of the Type II PFG; or (3) a change in the manufacturing equipment, processes, or specifications used to make the Type II PFG where the change could adversely affect safety of the Type II PFG.

B. Braun will conduct an on-site audit of a Type II PFG supplier any time that a supplier communicates (1) a facility move or the commissioning of a new facility; (2) a change to its existing manufacturing facility used to make the Type II PFG where the change could adversely affect safety of the Type II PFG; or (3) a change in the manufacturing equipment, processes, or specifications used to make the Type II PFG where the change could adversely affect safety of the Type II PFG. B. Braun will not sell to its customers a Type II PFG made in such facilities or made with such changes until B. Braun has completed the on-site audit and, if the audit reveals conditions or practices that could adversely affect the safety of the supplier's Type II PFGs or that indicate that the supplier's Type II PFGs are being prepared, packed, or held under conditions whereby the Type II PFGs may have been rendered injurious to health, an additional on-site audit to verify that the Type II PFG supplier has implemented appropriate corrective actions.

B. Braun also will conduct an on-site audit of a Type II PFG supplier in response to any product recall of a Type II PFG distributed by B. Braun or of a Type II PFG in the same product family distributed by the Type II PFG supplier, regardless of whether the recall is a correction, removal, or significant quality or compliance issue associated with that supplier's Type II PFG. B. Braun will conduct this audit as soon as reasonably possible after it learns of the recall.

B. Braun will maintain policies requiring its employees to report to B. Braun Quality Assurance any information an employee may have regarding changes or potential changes to a Type II supplier's manufacturing facility, equipment, processes, or specifications relating to a Type II PFG distributed by B. Braun.

C. Customer Inquiry Reporting and Trending

B. Braun will maintain existing policies, and implement policies and procedures to the extent they do not yet exist, that are designed to ensure that B. Braun Quality Assurance is aware of all customer inquiries alleging deficiencies related to the quality of Type II PFGs to B. Braun, including those made to B. Braun employees off-site, regarding the quality of Type II PFGs, irrespective of whether the customer chooses to file a Product Incident Report. B. Braun Quality Assurance will track and trend all such inquiries to identify issues that may require corrective actions. To the greatest extent possible, the reports to Quality Assurance will include the names and titles

of all B. Braun employees involved in communications with the customer concerning such Type II PFG quality inquiry, including employees who assisted in determining, or otherwise directed, the substance of such communications.

D. Supplier Quality Issue Reporting

B. Braun will implement policies and procedures that are designed to ensure that B. Braun Quality Assurance is aware of issues that become known to B. Braun relating to the quality of B. Braun's Type II PFG suppliers, regardless of the source of the information. These procedures will require that B. Braun employees report all information that alleges deficiencies related to the quality of Type II PFGs or that may adversely impact the quality of a Type II PFG supplier, no matter how identified, to B. Braun Quality Assurance, which in turn will investigate and determine whether corrective actions relating to the Type II PFG distributed by B. Braun are required.

E. Employee Training

B. Braun will maintain programs designed to ensure that the individuals who conduct on-site audits on behalf of B. Braun have the appropriate training and experience to effectively assess a Type II PFG supplier's compliance with the applicable provisions of the FDCA relating to the scope of the audit.

B. Braun will maintain programs designed to ensure that the individuals who perform incoming inspection of Type II PFGs have the appropriate training and experience to determine whether a Type II PFG meets B. Braun's inspection requirements for that Type II PFG. B. Braun will establish policies and procedures that require employees to document any atypical condition, including those unrelated to an inspection requirement, identified during the incoming inspection of a Type II PFG.

B. Braun will maintain programs designed to ensure that the individuals who perform Quality Assurance reviews regarding Type II PFG suppliers and Type II PFGs, whether before, during, or after the qualification stage, have the appropriate training and experience to determine whether B. Braun and its Type II PFG suppliers are in compliance with the applicable provisions of the FDCA relating to the scope of the review.

II. Independent Compliance Auditor

Promptly after the selection process pursuant to this section, B. Braun will retain, at its own expense, an



independent compliance auditor (the "Auditor") mutually acceptable to B. Braun and the Government for the Term of this Agreement. The Auditor's duties and authority, and the obligations of B. Braun with respect to the Auditor and the Government, are set forth in Attachment C, which is incorporated by reference into this Agreement.

Within thirty (30) calendar days after the Effective Date of this Agreement, B. Braun will propose to the Government its preferred candidate, from a pool of at least three qualified Auditor candidates selected by B. Braun, to serve as the Auditor. If the Government determines, in its sole discretion, that B. Braun's proposed candidate is not, in fact, qualified to serve as the Auditor, or if the Government, in its sole discretion, is not satisfied with the proposed candidate, the Government reserves the right to seek an additional nomination from B. Braun out of the original pool of auditors or otherwise. The Auditor candidate will have, at a minimum, the following qualifications:

- (1) demonstrated expertise with respect to Current Good Manufacturing Practices as they relate to the manufacture of drugs and medical devices;
- (2) experience designing and/or reviewing quality compliance policies, procedures, and internal controls;
- (3) the ability to access and deploy resources as necessary to discharge the Auditor's duties as described in the Agreement; and
- (4) sufficient independence from B. Braun to ensure effective and impartial performance of the Auditor's duties as described in this Agreement.

In the event the Government rejects B. Braun's proposed Auditor candidate, B. Braun will propose an additional preferred candidate within ten (10) calendar days after receiving notice of the rejection. This process will continue until an Auditor acceptable to both parties is chosen. The Government and B. Braun will use their best efforts to complete the selection process within sixty (60) calendar days after the Effective Date of this Agreement. If the Auditor resigns or is otherwise unable to fulfill his or her obligations as set out herein and in Attachment C, B. Braun will within thirty (30) calendar days recommend a new preferred candidate from a pool of three qualified Auditor candidates, and the Government will consider the preferred candidate as described above.

B. Braun agrees that it will not employ or be affiliated with the Auditor for a period of not less than one (1) year from the date on which the Term of this Agreement expires. Nor will B. Braun discuss with the Auditor the possibility of further employment or affiliation during the Term of this Agreement.

### III. Notice to Customers

Within forty-five (45) days after the Effective Date of the Agreement, B. Braun will send, by first class mail, postage prepaid, a notice containing the language set forth below to all customers who purchase or purchased from B. Braun pre-filled flush syringes bearing the B. Braun name on the label or logo, including direct sale and distributor customers. This notice will be dated and will be signed by B. Braun's Chief Executive Officer. The body of the notice will state the following:

As you may be aware, B. Braun Medical Inc. ("B. Braun") agreed to enter into a Non-Prosecution Agreement with the Government in connection with the sale and distribution of B. Braun-branded pre-filled flush saline syringes manufactured by AM2PAT in 2007. This letter provides you with additional information about the settlement, explains our commitments going forward, and provides you with access to information about those commitments.

In general terms, in 2007, B. Braun introduced and caused the introduction into interstate commerce of adulterated and misbranded pre-filled flush saline syringes that were manufactured by AM2PAT with whom B. Braun had contracted. To resolve this matter, B. Braun has entered into a Non-Prosecution Agreement with the U.S. Department of Justice and the U.S. Attorney's Office for the Eastern District of North Carolina in which the Government agreed to discontinue criminal prosecution of B. Braun for violating the Federal Food, Drug, and Cosmetic Act ("FDCA"), subject to certain specific conditions, including B. Braun's payment of a monetary penalty of \$1 million, forfeiture of \$3.8 million, and restitution to victims injured by pre-filled flush syringes bearing B. Braun's name on the label or logo that were manufactured by AM2PAT. More information about this settlement may be found at the following:  
[insert links provided by the Government after the Effective Date of the Agreement].

As part of the Non-Prosecution Agreement, which is available at the above websites, B. Braun committed to maintain and enhance our Quality Compliance Program relating to products distributed by B. Braun bearing the B. Braun name on the label or logo, and which are designed and manufactured by unrelated third parties, to undertake certain actions designed to promote compliance with the FDCA, to submit to regular third-party audits of its Quality Compliance Program relating to such products, and to make periodic certifications to the Government. We also agreed to notify our customers who purchased pre-filled flush syringes bearing B. Braun's name on the label or logo about the settlement and remind them that they are encouraged to report any complaints or concerns about the quality of B. Braun's products to B. Braun or the FDA.

B. Braun's Vice-President of Quality (or a designee) will maintain a log of all calls and messages received in response to the above notice. The log will include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

#### IV. Certification and Board Resolution

B. Braun will provide the Log required in Section III above and the following Certification and Board resolution to the Government on an annual basis for the term of the Agreement. Each one-year period, beginning with the one-year period following the Effective Date of the Agreement, will be referred to as a "Review Period." B. Braun will provide the Log, Certification, and Board Resolution to the Government within ninety (90) calendar days following the end of each Review Period.

##### A. Annual B. Braun Chief Executive Officer Certification

On an annual basis, the Chief Executive Officer of B. Braun (the "CEO") will conduct a review of the implementation and maintenance of B. Braun's Type II PFG Quality Compliance Program and independent audits as described in Sections I and II above and Attachment C during the preceding Review Period. Based on his or her review, the CEO will submit to the Government a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) the Quality Compliance Program continued to include the policies and procedures set forth in Section I; (2) the necessary independent

audits took place as set forth in Attachment C; (3) the aforementioned measures were fully implemented; and (4) at the time of his or her certification, the CEO is unaware of any quality problems related to B. Braun's Type II PFGs. The certification by the CEO will summarize the review described above that he or she conducted to provide the required certification. If the CEO is unable to provide any part of this certification, he or she will provide a detailed explanation for why he or she is unable to provide such certification. The certification and detailed explanation will be sworn to under the pains and penalties of perjury and will set forth that its representations may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

B. Annual Board of Directors Resolution

On an annual basis, the Board of Directors of B. Braun, or a designated Committee thereof (the "Board"), will conduct a review of the implementation and maintenance of B. Braun's Type II PFG Quality Compliance Program and independent audits as described in Sections I and II above and Attachment C during the preceding Review Period. This review will include updates and reports by the Corporate Vice-President of Quality and other company personnel about the adoption and implementation of policies, procedures, and practices designed to satisfy the compliance measures set forth in Section I above and about B. Braun's cooperation with the Auditor as set forth in Attachment C. The Board review will not require the retention of third-party experts. Based on its review, the Board will submit to the Government a resolution (the "Board Resolution") that summarizes its review and oversight as set forth above and include the following language:

The Board of Directors of B. Braun Medical Inc. has made a reasonable inquiry as described in Section IV.B of Attachment B to the Non-Prosecution Agreement with B. Braun into the operations of the Type II PFG Quality Compliance Program and independent audits for the applicable time period [insert time period], including the performance of the Corporate Vice-President of Quality and other personnel employed by B. Braun whose scope of responsibilities include the sourcing and distribution of Type II PFG Products. The Board has concluded that, to the best of its knowledge, B. Braun has implemented and maintained the Quality Compliance Program as set forth in Attachment B to

the Non-Prosecution Agreement and has cooperated with the independent auditor as set forth in Attachments B and C to the Non-Prosecution Agreement. Further, at the time of this Board Resolution, to the best of its knowledge, the Board is unaware of any quality problems related to B. Braun's Type II PFGs.

If the Board is unable to provide any part of this statement, it will include a thorough explanation of the reasons why it is unable to provide such a statement.

# Attachment C

## Independent Compliance Auditor

## ATTACHMENT C

### INDEPENDENT COMPLIANCE AUDITOR

The duties and authority of the Independent Compliance Auditor (the "Auditor") and the obligations of B. Braun, with respect to the Auditor and the Government, are as described below:

#### A. Auditor's Mandate

The Auditor's responsibility is to audit and assess B. Braun's compliance with the commitments to implement and maintain the policies and procedures set forth in Section I of Attachment B of the Agreement ("Type II PFG Quality Compliance Program"). During the Term of the Agreement, the Auditor will evaluate, in the manner set forth below, the effectiveness of B. Braun's internal controls, record-keeping, and policies and procedures as they relate to B. Braun's Type II PFG Quality Compliance Program, and take such reasonable steps as, in his or her view, may be necessary to fulfill the foregoing mandate (the "Mandate").

#### B. Company's Obligations

B. Braun will cooperate fully with the Auditor, and the Auditor will have the authority to take such reasonable steps as, in his or her view, may be necessary to be fully informed about B. Braun's Type II PFG Quality Compliance Program in accordance with the principles set forth herein and applicable law. To that end, B. Braun will facilitate the Auditor's access to B. Braun's facilities, documents, and personnel and not limit such access, except as provided in Section C. B. Braun will provide the Auditor with access to all facilities, documents, and personnel, as reasonably requested by the Auditor, that fall within the scope of the Mandate of the Auditor under the Agreement. B. Braun will use its best efforts to provide the Auditor with access to B. Braun's third-party vendors, agents, and consultants.

#### C. Withholding Access

The parties agree that no attorney-client relationship will be formed between B. Braun and the Auditor. In the event that B. Braun seeks to withhold from the Auditor access to

information, documents, records, facilities, or employees of B. Braun that may be subject to a claim of attorney-client privilege or to the attorney work-product doctrine, or where B. Braun reasonably believes production would otherwise be inconsistent with applicable law, B. Braun will work cooperatively with the Auditor to resolve the matter to the satisfaction of the Auditor.

If the matter cannot be resolved, at the request of the Auditor, B. Braun promptly will provide written notice to the Auditor and the Government. Such notice will include a general description of the nature of the information, documents, records, facilities, or employees that are being withheld, as well as the legal basis for withholding access. The Government may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

#### D. Audit Methodology

The Auditor will perform an on-site audit of B. Braun no later than sixty (60) calendar days from the date of the engagement of the Auditor (unless otherwise agreed by the Government), and then every eleven months after that for the duration of this Agreement. In carrying out the Mandate, the Auditor will formulate conclusions based on, among other things: (1) inspection of relevant documents; (2) on-site observation of selected systems and procedures of B. Braun, including internal controls, record-keeping, and quality procedures; and (3) meetings with, and interviews of, relevant employees and other persons at mutually convenient times and places.

#### E. Audit Reports

At the conclusion of each of the audit inspections described in Section D above, the Auditor will prepare a written audit report setting forth the Auditor's assessment of B. Braun's Type II PFG Quality Compliance Program and, if applicable, identifying any deficiencies and making recommendations reasonably designed to remedy the deficiencies. Beginning with the second audit report, the Auditor also will assess the adequacy of all actions taken by B. Braun to correct all previous audit report deficiencies, and include this information in the audit report. The Auditor will deliver audit reports simultaneously to B. Braun and to the Government at the addresses described in Paragraphs 36 and 37 of the Agreement no later than thirty (30) days after the date each audit is completed.



Within thirty (30) calendar days after receiving the audit report, B. Braun will correct any deficiencies the Auditor identified, unless the Auditor notifies B. Braun that a shorter time period is necessary. If, after receiving the audit report, B. Braun believes that correction of the deficiencies will take longer than thirty (30) days, B. Braun will, within ten (10) business days after receipt of the audit report, propose to the Auditor a schedule for completing corrections. The Auditor, at his or her sole discretion, will approve or disapprove the proposed schedule in writing.

As to any deficiency with which B. Braun and the Auditor do not agree, such parties will attempt in good faith to reach an agreement. In the event B. Braun and the Auditor are unable to agree, the Auditor promptly will notify the Government. The Government may consider the Auditor's findings and B. Braun's reasons for contesting the findings in determining whether B. Braun has fully complied with its obligations under the Agreement.

F. Auditor's Discovery of Misconduct

Should the Auditor, during the course of his or her engagement, discover misconduct that poses in his or her opinion a credible risk to public health or safety, the Auditor will promptly report such improper activities to B. Braun's General Counsel and Corporate Vice President of Quality for further action. The Auditor also will report such improper activities to the Government. The Auditor should disclose such improper activities in his or her discretion directly to the Government, and not to B. Braun, only if the Auditor believes that disclosure to B. Braun would be inappropriate under the circumstances, and in such case should disclose the improper activities to B. Braun's General Counsel and Corporate Vice President of Quality as promptly and completely as the Auditor deems appropriate under the circumstances. Further, in the event that B. Braun, or any entity or person working directly or indirectly for or on behalf of B. Braun, withholds information necessary for the performance of the Auditor's responsibilities, if the Auditor believes that such withholding is without just cause, the Auditor will disclose that fact to the Government. B. Braun will not take any action to retaliate against the Auditor for any such disclosures or for any other reason. The Auditor may report any criminal or regulatory violations by B. Braun or any other entity discovered in the course of

performing his or her duties in the same manner as described above.

G. Contemplated Confidentiality of Auditor's Reports

The audit reports likely will include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation, or impede pending or potential government investigations and thus undermine the objectives of the auditorship. For these reasons, among others, the reports and the contents thereof are intended to remain and will remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the Government determines in its sole discretion that disclosure is required by law.