

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

MAY 07 2012

JULIA C. DUDLEY, CLERK
BY: *[Signature]*
DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES :
 :
v. : Criminal No. *1:12CR26*
 :
ABBOTT LABORATORIES :

PLEA AGREEMENT

ABBOTT LABORATORIES (EIN: 36-0698440) ("ABBOTT") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this agreement are as follows:

1. CHARGE TO WHICH ABBOTT IS PLEADING GUILTY AND WAIVER OF RIGHTS

ABBOTT will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), 352(a) and 352(f)(1) by introducing and delivering for introduction into interstate commerce and causing the introduction and delivery for introduction into interstate commerce from Illinois and Puerto Rico to various locations throughout the United States, including the Western District of Virginia, of Depakote, Depakote ER and Depakote Sprinkle that were misbranded.

The parties agree and stipulate that the maximum statutory penalty is a fine of \$800,000,000.00 (twice the gross gain), pursuant to Title 18, United States Code, Section 3571(d), plus a period of probation of up to five years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, ABBOTT's assets may be subject to forfeiture. ABBOTT understands that fees may be imposed to pay for probation and that there will be a \$125 special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). ABBOTT's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before ABBOTT could be found guilty as charged.

ABBOTT acknowledges that ABBOTT has had all of its rights explained to it. ABBOTT expressly recognizes that, as a corporation, ABBOTT may have the following constitutional rights and that by voluntarily pleading guilty ABBOTT knowingly waives and gives up these valuable constitutional rights:

- The right to plead not guilty and persist in that plea.
- The right to a speedy and public jury trial.
- The right to assistance of counsel at that trial and in any subsequent appeal.
- The right to remain silent at trial.
- The right to testify at trial.
- The right to confront and cross-examine witnesses.

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Authorized Corporate Officer's Initials: *[Signature]*

- The right to present evidence and witnesses.
- The right to compulsory process of the court.
- The right to compel the attendance of witnesses at trial.
- The right to be presumed innocent.
- The right to a unanimous guilty verdict.
- The right to appeal a guilty verdict.

ABBOTT is pleading guilty as described above because ABBOTT is in fact guilty and because ABBOTT believes it is in its best interest to do so and not because of any threats or promises, other than the terms of the Plea Agreement, described herein, in exchange for its plea of guilty. ABBOTT agrees that all of the matters set forth in the Information are true and correct.

ABBOTT understands that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

Based upon the evidence currently known to the United States, the parties agree that the 2011 version of the United States Sentencing Commission Guidelines Manual is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree that the fine shall be \$500,000,000.00 (five hundred million dollars).

The parties agree and stipulate that a term of probation for five years will be imposed subject to modification as set forth in the section of this Plea Agreement titled "SUCCESSION ISSUES." ABBOTT understands and agrees that if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum of \$800,000,000.00 (eight hundred million dollars) may be imposed.

The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence, this Plea Agreement will be null and void, and ABBOTT will be free to withdraw this guilty plea. In the event the Court refuses to accept the Plea Agreement with the agreed-upon sentence and ABBOTT withdraws this guilty plea, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to proceed criminally against ABBOTT or any other entity or individual on any charge.

3. FINANCIAL OBLIGATIONS

The parties agree and understand that any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept the Plea Agreement with the agreed-upon sentence and, as a result, ABBOTT withdraws its guilty plea. If the Court rejects the plea agreement, the United States will return all money paid by ABBOTT, without interest, not more than 3 days after ABBOTT withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia, in writing, that it wishes to have the money returned.

a. Criminal Resolution Payments

Not more than 3 days after the entry of ABBOTT's guilty plea, ABBOTT will make the following disbursements:

- (1) \$125.00 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment;
- (2) \$500,000,000.00 (five hundred million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;
- (3) \$1,500,000.00 (one million five hundred thousand dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund; and
- (4) \$198,500,000.00 (one hundred ninety-eight million five hundred thousand dollars), made payable to the United States Department of the Treasury, as directed by the United States Attorney's Office as payment of a forfeiture.

b. Forfeiture

ABBOTT agrees to forfeit \$198,500,000.00 (one hundred ninety-eight million five hundred thousand dollars), and agrees to sign any documentation necessary to accomplish the forfeiture. ABBOTT agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of this sum to the United States. These steps include but are not limited to making the sum available to the United States, as directed by the United States. ABBOTT agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. ABBOTT understands and agrees that forfeiture of this property is proportionate to the degree and nature of the offense. ABBOTT freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. ABBOTT further understands and agrees that this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution should be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, ABBOTT withdraws its plea, ABBOTT agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny that it committed the crimes to which it has pled guilty; (4) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent

with this Plea Agreement; (5) comply with its obligations under the Civil Settlement Agreement (attached as Attachment D); and (6) enter into a Corporate Integrity Agreement (attached as Attachment E).

ABBOTT will not (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts (attached as Attachment B). If ABBOTT makes a public statement that in whole or in part contradicts a statement of fact contained in the Agreed Statement of Facts, ABBOTT may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by ABBOTT's directors, officers, management employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) ABBOTT website. Notwithstanding the above, any ABBOTT entity may avail itself of any legal or factual arguments available to it (1) in defending litigation brought by a party other than the United States or (2) in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, ABBOTT agrees that ABBOTT will not appeal the conviction or sentence imposed. ABBOTT is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). ABBOTT expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. ABBOTT understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, ABBOTT may file a cross-appeal of that same sentence. ABBOTT agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this agreement.

6. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

ABBOTT understands that if: (1) ABBOTT attempts to withdraw its plea (in the absence of the Court refusing to accept the Plea Agreement) or fails to comply with any provision of this Plea Agreement prior to the completion of the term of probation; (2) ABBOTT's conviction is set aside, for any reason; (3) ABBOTT fails to execute all required paperwork prior to the imposition of judgment; and/or (4) ABBOTT fails to comply with its obligations under the Civil Settlement Agreement (attached as Attachment D) the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by



indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, ABBOTT will still be bound by its obligations under this Plea Agreement. ABBOTT hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of the Plea Agreement. ABBOTT hereby waives any statute of limitations argument as to any such charges.

7. INFORMATION ACCESS WAIVER

ABBOTT agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

8. DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT

By signing this Plea Agreement, ABBOTT consents to the destruction of all items obtained by law enforcement agents during the course of the investigation. However, ABBOTT expressly agrees that, within 30 days of being informed by the United States Attorney's Office that records and/or other items obtained from ABBOTT are available for removal, it will remove, at its cost, all such records and/or other items from the premises designated by the United States Attorney's Office.

9. ATTORNEY CLIENT PRIVILEGE

Nothing in this Plea Agreement shall be construed to require ABBOTT to waive any attorney-client privilege or work-product protection.

10. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), so long as ABBOTT complies with all of its obligations under the Plea Agreement, the United States agrees that, other than the charge in the attached Information, it shall not further prosecute ABBOTT or its present or former parents, affiliates, divisions, or subsidiaries or their predecessors, successors, or assigns for: (a) any additional federal criminal charges or forfeiture action with respect to the conduct covered by the Information; or (b) any violations of law that were the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States

Department of Justice Consumer Protection Branch or based on facts currently known to the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Consumer Protection Branch regarding the sale, promotion, or marketing of Depakote, Depakote ER, Depakote Sprinkle, Depacon or Depakene in the United States occurring on or before May 7, 2012.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

The non-prosecution provisions in this Plea Agreement are not binding on the United States with respect to any investigations of ABBOTT, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division of the United States Department of Justice regarding possible violations of the Foreign Corrupt Practices Act and related offenses.

11. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state or local authority.

12. EFFECTIVE REPRESENTATION

ABBOTT has discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, ABBOTT has no dissatisfaction or complaint with its attorneys' representation. ABBOTT agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint ABBOTT may have with its attorneys' representation.

13. SUCCESSION ISSUES

ABBOTT has publicly announced and represents to the Court that it plans to separate into two publicly traded companies, one a diversified medical products company, which may retain the ABBOTT name, ("Diversified Company") and the other a research-based pharmaceutical company ("Pharmaceutical Company") which will not be a subsidiary or corporate affiliate of ABBOTT (this separation is hereinafter referred to as the "Transaction" and the "Effective Time" shall be the date and time that the Transaction becomes effective). The conduct for which ABBOTT was investigated and that led to this Plea Agreement relates solely to ABBOTT's research-based pharmaceutical products business and not to its diversified medical products business. Upon completion of the Transaction, the assets of ABBOTT's research-based pharmaceutical products business will be transferred, conveyed and/or assigned by it to the Pharmaceutical Company and ABBOTT shall no longer be involved in the marketing or promotion of research-based pharmaceutical products in the United States. As part of the Transaction, ABBOTT agrees that it will include the following in a contract or agreement with the Pharmaceutical Company relating to the transfer, conveyance or assignment of the assets of

the research-based pharmaceutical products business to the Pharmaceutical Company: (a) a provision stating that the Pharmaceutical Company agrees that the conditions of probation and all other provisions of this Plea Agreement are fully binding on the Pharmaceutical Company and (b) a provision stating that the Pharmaceutical Company will be deemed to carry a prior conviction for purposes of Title 21, United States Code, Section 333(a)(2), and waives any right it may have to argue that it does not have such prior conviction.

In the event the Transaction takes place and the Pharmaceutical Company agrees to (a) and (b) in the last sentence of the preceding paragraph, the United States Department of Justice and ABBOTT agree to the following:

- A. The Pharmaceutical Company will be deemed the successor in interest, for purposes of this Plea Agreement, and all of ABBOTT's obligations under this Plea Agreement, including any and all conditions of probation, will become obligations of the Pharmaceutical Company as of the Effective Time of the Transaction. The term of probation shall be modified to three years from the Effective Time. As of the Effective Time, neither ABBOTT nor the Diversified Company will have any further obligations under this Plea Agreement. The Pharmaceutical Company will be the only entity that will have any further obligations under this Plea Agreement, including any and all conditions of probation, which will be terminated with respect to ABBOTT. Any violation of this Plea Agreement or any term of probation that occurs after the Effective Time shall not be a basis to impose any sanction on ABBOTT, the Diversified Company, or any of their subsidiaries after the Effective Time. After the Effective Time, all releases that run to the benefit of ABBOTT, including those set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION," will continue to apply fully to ABBOTT, the Diversified Company, the Pharmaceutical Company and their subsidiaries;
- B. ABBOTT will be deemed to no longer carry a conviction by the United States Department of Justice and the United States Department of Justice agrees it will not use the conviction of ABBOTT pursuant to this plea agreement:
 1. In any future calculation of the Criminal History Category under the United States Sentencing Guidelines in any future sentencing of ABBOTT or the Diversified Company; or
 2. As a prior conviction for purposes of 21 U.S.C. §§ 331 and 333(a)(2) in any future criminal case against ABBOTT or the Diversified Company. The United States Department of Justice waives any right it might have to argue that either ABBOTT or the Diversified Company has such a conviction for such purposes.
- C. The Pharmaceutical Company's certification, resolution, and reporting requirements will cover ABBOTT's conduct for any time period for which ABBOTT did not submit a certificate, resolution or report because the Effective Time occurred prior to the due date of the certificate, resolution or report.

For purposes of this Plea Agreement and the conditions of probation, the term "Responsible Entity" refers to the corporate entity that bears the obligations of this Plea Agreement, including the conditions of probation. ABBOTT shall be the Responsible Entity until the Effective Time and Pharmaceutical Company shall be the Responsible Entity after the Effective Time.

14. CONDITIONS OF PROBATION

The parties agree that the following will be included as the only conditions of probation:

- A. *All definitions set forth in the Plea Agreement shall be incorporated by reference and are included in the conditions of probation.*
- B. *The Responsible Entity shall make the following reports to the probation office:*

- 1. *Annual Chief Executive Officer ("CEO") Certification:* *On an annual basis, the Responsible Entity's CEO shall conduct a review of the effectiveness of the Responsible Entity's Compliance Program as it relates to the marketing, promotion, and sale of pharmaceutical products during the preceding twelve-month period. The review shall consist of a review of updates and reports by the Responsible Entity's Chief Compliance Officer and/or a representative from the Responsible Entity's U.S. Pharmaceutical Compliance Committee about the Responsible Entity's Compliance Program and the effectiveness of that program during the preceding twelve-month period. Based on the review described above, the Responsible Entity's CEO shall submit to the probation office a signed certification stating that, to the best of his or her knowledge, during the preceding twelve-month period:*

- a. *The Responsible Entity's Compliance Program continued to include the compliance policies and procedures set forth in the section of this Plea Agreement titled "COMPLIANCE MEASURES," and*

- b. *To the extent that a Reportable Event (as that term is defined below) has been determined to have occurred, the Responsible Entity has fully complied with the Reportable Event reporting requirements of this Plea Agreement.*

The CEO's certification shall summarize the review described above that he or she conducted to provide the required certification.

- 2. *Annual Board of Directors Resolution:* *On an annual basis, the Responsible Entity's Board of Directors ("Board") or a designated Committee of the Board of Directors ("Board Committee") shall conduct a review of the effectiveness of the Responsible Entity's Compliance Program as it relates to the marketing, promotion, and sale of pharmaceutical products. This review shall consist of updates and reports by the Responsible*

Entity's Chief Compliance Officer and/or a representative from the Responsible Entity's U.S. Pharmaceutical Compliance Committee about the Responsible Entity's Compliance Program and the effectiveness of that program during the preceding twelve-month period. Based on the review described above, the Responsible Entity's Board shall submit to the probation office a resolution adopted by the Board stating that, to the best of its knowledge, the Responsible Entity has had in effect policies and procedures designed to prevent the Responsible Entity from violating 21 U.S.C. §§ 331(a) or (k) by directly or indirectly causing the introduction or delivery for introduction into interstate commerce of any pharmaceutical product that was misbranded within the meaning of 21 U.S.C. § 352 or by directly or indirectly causing any pharmaceutical product to be misbranded within the meaning of 21 U.S.C. § 352 while such product was held for sale after shipment of it or any of its components in interstate commerce. The Board's resolution shall summarize the review described above that it, or the Board Committee, conducted to provide the required statement. If the Board is unable to provide this statement, it shall submit a resolution explaining the reasons why it is unable to provide this statement about the effectiveness of the Responsible Entity's Compliance Program.

3. *Reportable Events: Fifteen days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending September 30) and 10 days prior to the termination of probation ("Final Report"), the Responsible Entity shall submit a report to the probation office in writing stating whether any Reportable Events have been determined to have occurred during the preceding calendar quarter (or, in the case of the Final Report, during the period since the calendar quarter last covered by a regular quarterly report) and providing updated information about Reportable Events that occurred during any prior calendar quarters. A Reportable Event is any matter that a reasonable person would consider a probable violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) or (k), related to the misbranding of a pharmaceutical product within the meaning of 21 U.S.C. § 352. A Reportable Event may be the result of an isolated event or a series of occurrences. The reporting of a Reportable Event shall not be considered by the Probation Officer as a per se violation of the terms of probation. Instead, other factors will be taken into account, including, but not limited to, whether the Reportable Event violated policies the company has adopted, whether the company provided training*

addressing the subject matter of the Reportable Event, whether the Reportable Event was an isolated or systemic occurrence, the company's response to the Reportable Event, and any remedial actions taken after the company learned of the Reportable Event. Any Reportable Event determined to have occurred by the Responsible Entity shall be promptly reported to the Responsible Entity's Chief Executive Officer.

4. *The first set of annual certifications and reports shall be submitted not more than 350 days after the Responsible Entity is sentenced and shall cover the period of time commencing one month prior to the date of sentencing to the date of submission of the certification and report. Each subsequent set of annual reports and certifications shall be due one year thereafter and cover the one year period that follows the year covered in the prior annual reports and certifications.*
5. *The probation office may share any information it receives from the Responsible Entity with the United States Attorney's Office.*
6. *For the purpose of this Plea Agreement and the conditions of probation, the following terms shall have the following meaning:*
 - a. *The term "Chief Compliance Officer" refers to the person at the Responsible Entity with ultimate responsibility for developing and implementing policies, procedures, and practices designed to ensure compliance with the FDCA and FDA's regulations and guidance documents relating to the marketing, promotion, and sale of pharmaceutical products. During the term of probation, the Chief Compliance Officer shall be a member of the Responsible Entity's senior management and the Responsible Entity's U.S. Pharmaceutical Compliance Committee. Not more than thirty (30) days from the imposition of sentence in this matter, the Responsible Entity shall notify the probation office in writing of the name of the Responsible Entity's Chief Compliance Officer and provide a written description of that person's responsibilities with respect to complying with the FDCA and FDA's regulations and guidance documents relating to the marketing, promotion, and sale of pharmaceutical products. The Responsible Entity shall, in writing, report to the probation office any changes in the identity of or any material changes in the position and responsibilities of the Chief Compliance Officer. This report shall be provided within fifteen (15) days after such a change.*
 - b. *The term "U.S. Pharmaceutical Compliance Committee" refers to the committee established or to be established by the Responsible Entity to, in conjunction with the Chief*

Compliance Officer, assist in the implementation and enhancement of the Compliance Program's policies and procedures relating to compliance with the FDCA and FDA's regulations and guidance documents concerning the marketing, promotion, and sale of pharmaceutical products. During the term of probation, this committee shall, at a minimum, include the Responsible Entity's Chief Compliance Officer and other members of the Responsible Entity's senior management with responsibilities concerning the marketing, promotion, and sale of the Responsible Entity's pharmaceutical products. Not more than thirty (30) days from the imposition of sentence in this matter, the Responsible Entity shall notify the probation office in writing of the names of the Responsible Entity's senior managers on the U.S. Pharmaceutical Compliance Committee and provide a written description of their responsibilities with respect to complying with the FDCA and FDA's regulations and guidance documents relating to the marketing, promotion, and sale of pharmaceutical products. The Responsible Entity shall, in writing, report to the probation office any changes in the identity of or any material changes in the position and responsibilities of these senior managers. This report shall be provided within fifteen (15) days after such a change.

c. The term "Compliance Program" refers to the policies, procedures, practices, and other measures that the Responsible Entity has established or will establish to address regulatory compliance issues, relating to the marketing, promotion and sale of pharmaceutical products, including the Responsible Entity's compliance with FDCA and FDA regulations and guidance documents.

d. The term "pharmaceutical products" means drugs marketed, promoted, or sold in the United States and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or drugs intended to affect the structure or any function of the body of humans. 21 U.S.C. § 321(g)(1)(B) & (C).

C. The Responsible Entity shall not commit any federal health care fraud offense, any offense under Titles 21 or 42 of the United States Code, or any felony during the term of probation. The commission of an offense shall not be considered by the Probation Officer as a per se violation of the terms of probation. Instead, other factors will be taken into account, including, but not limited to, whether the offense violated policies the company has adopted, whether the company provided training addressing the subject matter of the offense, whether the offense was an isolated or



systemic occurrence, the company's response to the offense, and any remedial actions taken after the company learned of the offense.

- D. *Within 7 days of filing, the Responsible Entity shall submit to the probation office a copy of each Securities and Exchange Commission Form 10-Q.*

15. COMPLIANCE MEASURES

ABBOTT agrees that, prior to entering its plea of guilty, as the Responsible Entity it has instituted a Compliance Program, under which policies, procedures, practices, and other measures are set forth to address, among other matters, regulatory compliance issues with respect to the marketing, promotion and sale of pharmaceutical products in the United States, including compliance with the Food, Drug and Cosmetic Act ("FDCA") and Food and Drug Administration ("FDA") regulations and guidance documents. The Responsible Entity's Compliance Program includes the policies and procedures relating to pharmaceutical products as set forth below:

- A. The Responsible Entity requires that the compensation (including through salaries, bonuses, and contests) of its United States sales representatives be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in off-label marketing, promotion, and sales of the Responsible Entity's pharmaceutical products.
- B. The Responsible Entity requires Continuing Medical Education ("CME") grant-making decisions to be approved by the Responsible Entity's financial or other organizations separate from sales and marketing, and requires financial support to be provided only to programs that foster increased understanding of scientific, clinical or healthcare issues. The Responsible Entity requires a third-party CME provider to maintain full responsibility for, and control over, the selection of content, faculty, educational methods, materials and venue for CME programs.
- C. The Responsible Entity requires medical information letters to be accurate and unbiased. The Responsible Entity's policies and procedures prohibit the prompting of requests for medical information letters; and
- D. The Responsible Entity requires clinical trials funded or controlled by the Responsible Entity to be approved by ABBOTT's medical and/or scientific organizations and that the scientific research and any resulting publications foster increased understanding of scientific, clinical or healthcare issues. The Responsible Entity's policies and procedures require that it will not approve scientific research purely for the purpose of developing an article or reprint for sales representative use. The Responsible Entity requires all investigators to disclose the Responsible Entity's support for their research and financial relationships between the Responsible Entity and investigators (including any interest in any Responsible Entity product). The Responsible Entity has a publication policy designed to ensure that the Responsible Entity develops publications in a consistent and transparent manner, reporting complete



and accurate results, presented objectively and with discussion of the strengths and limitations of the study. The Responsible Entity requires that a person can be considered an "author" only if he or she has made substantial contributions to the conception and design of the study, acquisition or analysis of data and has final approval of the version to be published. The Responsible Entity requires acknowledgement in all related scientific publications of its role as the funding source of all research and clinical trials initiated by the Responsible Entity.

The Responsible Entity agrees to maintain the policies and procedures set forth above through the completion of the term of probation.

16. EFFECT OF ABBOTT'S SIGNATURE

ABBOTT understands that its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. ABBOTT understands that the United States has not accepted ABBOTT's offer until the authorized representative of the United States has signed the Plea Agreement.

17. GENERAL UNDERSTANDINGS

ABBOTT understands that a presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

ABBOTT understands the United States and ABBOTT will be free to allocute or describe the nature of this offense and the evidence in this case.

ABBOTT understands the United States and ABBOTT retain the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court.

ABBOTT willingly stipulates that there is a sufficient factual basis for the Court to accept the plea.

ABBOTT understands that this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

ABBOTT has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. ABBOTT understands that its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. ABBOTT understands that ABBOTT will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing and the Agreed Statement of Facts (attached as Attachment B), Civil Settlement Agreement (attached as Attachment D), Corporate Integrity Agreement (attached as Attachment E), and Agreed Order of Forfeiture (attached as Attachment C) are the complete and only agreements between the United States and ABBOTT concerning resolution of this matter. In addition, ABBOTT has no objection to the filing of the Information (Attachment A) (which

will incorporate the Agreed Statement of Facts). The agreements and documents listed in this paragraph set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and ABBOTT and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and ABBOTT. ABBOTT consents to public disclosure of all of the agreements and other documents referenced in this paragraph.

ABBOTT has consulted with its attorneys and fully understands its rights. ABBOTT has read this Plea Agreement and carefully reviewed every part of it with its attorneys. ABBOTT understands this Plea Agreement and ABBOTT voluntarily agrees to it. Being aware of all of the possible consequences of its plea, ABBOTT has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer below.

The Authorized Corporate Officer, by her signature below, hereby certifies to the following:

- (1) She is fully authorized to enter into this plea agreement on behalf of ABBOTT;
- (2) She has read the entire Plea Agreement and documents referenced herein and discussed them with ABBOTT's Board of Directors;
- (3) ABBOTT understands all the terms of the Plea Agreement and those terms correctly reflect the results of plea negotiations;
- (4) ABBOTT is fully satisfied with ABBOTT's attorneys' representation during all phases of this case;
- (5) ABBOTT is freely and voluntarily pleading guilty in this case;
- (6) ABBOTT is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and
- (7) ABBOTT understands that it is waiving its right to appeal the judgment and conviction in this case.

ABBOTT acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Authorized Corporate Officer. A copy of a certification by ABBOTT's Board of Directors authorizing the Authorized Corporate Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of ABBOTT is attached.

Date: 5/7/12 

Laura J. Schumacher
Executive Vice-President, General Counsel, and Secretary
of Abbott Laboratories
Authorized Corporate Officer
ABBOTT LABORATORIES

Counsel has fully explained to the Board of Directors of ABBOTT the facts and circumstances of the case; all rights with respect to the offense charged in the Information;

possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. We have reviewed the entire Plea Agreement and documents referenced herein with my client, through its Authorized Corporate Officer. In our judgment, ABBOTT understands the terms and conditions of the Plea Agreement, and we believe ABBOTT's decision to enter into the Plea Agreement is knowing and voluntary. ABBOTT's execution of and entry into the Plea Agreement is done with our consent.

Date: 5/7/12

Theodore V. Wells
Theodore V. Wells, Esquire
Paul, Weiss, Rifkind, Wharton & Garrison
Counsel for Abbott Laboratories

Date: 5/7/12

Mark Filip
Mark Filip, Esquire
Kirkland & Ellis LLP
Counsel for Abbott Laboratories

Date: 5/7/12

Timothy J. Heaphy
Timothy J. Heaphy
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Carol Wallack, Trial Attorney, U.S. Dept. Of Justice
Lauren Bell, Trial Attorney, U.S. Dept. Of Justice
Jill Furman, Asst. Director, Consumer Protection Branch

CERTIFICATE

I, John A. Berry, do hereby certify that I am a duly appointed and qualified Assistant Secretary of Abbott Laboratories and acting as such; that Abbott Laboratories is a corporation duly organized and validly existing under the laws of the State of Illinois with its principal office at 100 Abbott Park Road, Abbott Park, Lake County, Illinois; that I am a keeper of its books and records and its corporate seal; that the following resolution is a true, complete and correct copy of the resolution adopted at a regular meeting of its Board of Directors on April 27, 2012; that said meeting was duly called, a quorum was present there at; and that that such resolution is still in effect:

RESOLVED, that the Executive Vice President, General Counsel and Secretary is hereby authorized to enter or cause to be entered on behalf of this Corporation: the Plea Agreement, civil settlement agreements with the federal government and the coordinating states, a Corporate Integrity Agreement with the HHS Office of Inspector General, and all other documents necessary or appropriate to effectuate the settlement of all aspects of the investigation of the Corporation's sales and marketing practices for Depakote from 1998 to 2008 by the United States Department of Justice at any time on or after the date of this meeting.

IN WITNESS WHEREOF, I have affixed my name as Assistant Secretary and have caused the corporate seal of Abbott Laboratories to be hereunto affixed as of this 30th day of April, 2012.



John A. Berry
Assistant Secretary

