JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street – 5th Floor
P.O. Box 45029
Newark, New Jersey 07101
Attorney for Plaintiffs

By: Patricia Schiripo
Deputy Attorney General / Assistant Section Chief
(973) 648-7819

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION,
MERCER COUNTY
Docket No.: C-42-12

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|---|---|
| JEFFREY S. CHIESA, Attorney General of the State of New Jersey, and ERIC T. KANEFSKY, Acting Director of the New Jersey Division of Consumer Affairs,<br><br>Plaintiffs,<br><br>v.<br><br>ABBOTT LABORATORIES,<br><br>Defendant. | Civil Action<br><br>**FINAL CONSENT JUDGMENT** |

## 1. PREAMBLE

1.1 The Attorneys General of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North

Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin (collectively, the "Attorneys General," or "AGs"), conducted an investigation under the State Consumer Protection Laws[1] regarding certain Abbott Laboratories ("Abbott") Promotional practices related to Depakote; and

1.2 Abbott (as defined in the Definitions Section) is willing to enter into a Final Consent Judgment ("Judgment") regarding its Promotional practices and dissemination of information to Health Care Professionals regarding Depakote in the United States ("Covered Conduct") in order to resolve the AGs' investigation under the State Consumer Protection Laws and arrive at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Judgment and thereby avoid unnecessary expense, inconvenience, and uncertainty; and

1.3 The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Judgment. Abbott is entering into this Judgment solely for the purpose of settlement and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Abbott and Pharmaceutical Company (as defined below) expressly deny. Abbott and Pharmaceutical Company do not admit any violation of the State Consumer Protection Laws, and do not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. Except in an

[1] This Final Consent Judgment, filed in the State of New Jersey, is governed by the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

action brought by an Attorney General to enforce this Judgment, this Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Abbott and/or Pharmaceutical Company, including, but not limited, to Abbott's and Pharmaceutical Company's right to defend themselves from, or make any arguments in, any other matter, including, but not limited to, any investigation or litigation relating to the existence, subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of the Parties that this Judgment shall not be admissible in any other matter, including, but not limited to, any investigation or litigation, or bind Abbott or Pharmaceutical Company in any respect other than in connection with the enforcement of this Judgment. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment. All obligations undertaken by Abbott and Pharmaceutical Company in this Judgment shall apply prospectively; and nothing contained herein prevents or prohibits the use of this Judgment for purposes of enforcement of this Judgment by the AGs; and

1.4 The AGs have reviewed the terms of the Judgment and find that such terms serve the public interest; and

1.5 This Judgment (or any portion thereof) shall in no way be construed to prohibit Abbott or Pharmaceutical Company from making representations with respect to Depakote that are permitted under Federal law or in Labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under any Investigational New Drug Application, New Drug

Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or deceptive; and

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:**

## 2. FINDINGS

2.1 This Court has jurisdiction over the subject matter of this lawsuit and over all Parties. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

2.2 The terms of this Judgment shall be governed by the laws of the State of New Jersey.

2.3 Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

## 3. DEFINITIONS

Abbott has publicly announced 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). For the purpose of this Judgment and the provisions herein, the term "Responsible Entity" shall mean the corporate entity that bears the obligations of this Judgment. Abbott shall be the Responsible Entity prior to the Effective Time and Pharmaceutical Company shall be the Responsible Entity after the Effective Time. Abbott also has represented to the States that at the Effective Time of the Transaction, the assets of Abbott's research-based human pharmaceutical products business will be transferred, conveyed, and/or assigned by Abbott to the Pharmaceutical Company and that the Diversified Company shall no longer be involved in the marketing or promotion of research-based human pharmaceutical products in the United States. After the Effective Time, Pharmaceutical Company will be deemed to be the successor in interest, for purposes of this Judgment, and all of Abbott's obligations herein will become the obligations of Pharmaceutical Company. Neither Abbott nor Diversified Company shall have any further obligations under this Judgment after the Effective Time.

The following definitions shall be used in construing this Judgment:

3.1 "Abbott" shall mean Abbott Laboratories, including all of its past and present subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors, successors and assigns, and each and all of its current and former officers, directors, shareholders, employees, agents and contractors.

3.2 "Covered Conduct" shall mean Responsible Entity's Promotional practices and dissemination of information to Health Care Professionals regarding Depakote in the United States.

3.3 "Depakote" shall mean all Responsible Entity Products that are FDA approved drug formulations containing valproate or valproic acid and sold under the trade name Depakote including, but not limited to, Depakote, Depakote ER, Depakote DR, Depakote Sprinkles, Depakene and Depakon, and are approved by the FDA for the treatment of epilepsy, migraine headaches, and acute manic or mixed episodes associated with bipolar disease.

3.4 "Effective Date" shall mean the date on which a copy of this Judgment, duly executed by Abbott and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

3.5 "FDA Guidance for Industry" shall mean final documents issued by the FDA pursuant to 21 *U.S.C.* §371(h) that represent the FDA's latest thinking on the topic.

3.6 "Health Care Professional" or "HCP" shall mean any United States based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products.

3.7 "Labeling" shall mean all FDA-approved labels and other written, printed, or graphic matters: (a) upon any article or any of its containers or wrappers; or (b) accompanying such article.

3.8 "Medical Information Response" shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information from HCPs regarding Depakote.

3.9 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Ohio, Oregon, Illinois, Florida, North Carolina, Pennsylvania, South Carolina, and Texas.

3.10 "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

3.11 "Off-Label" shall mean a use not consistent with the indications section of the Depakote Labeling approved by the FDA at the time information regarding such use was communicated.

3.12 "Parties" shall mean Responsible Entity and the Signatory Attorney General.

3.13 "Promotional," "Promoting," or "Promote" shall mean representations about Depakote and other product-related practices intended to increase sales or that attempt to influence prescribing practices of HCPs.

3.14 "Promotional Materials" shall mean any item that is used to Promote Depakote.

3.15 "Promotional Speaker" shall mean a HCP speaker who is engaged as a non-employee of Responsible Entity to Promote Depakote.

3.16 "Reprints Containing Off-Label Information" shall mean articles or reprints from a scientific or medical journal, as defined in 21 *C.F.R.* 99.3(j), or reference publication, as defined in 21 *C.F.R.* 99.3(i), describing an Off-Label use for Depakote.

3.17 "Responsible Entity Marketing" shall mean Responsible Entity personnel with responsibilities for marketing Depakote in the United States.

3.18 "Responsible Entity Medical" shall mean Responsible Entity personnel in the Global Pharmaceutical Research & Development organization who are assigned to the United States and who have responsibilities related to Depakote.

3.19 "Responsible Entity Sales" shall mean the Responsible Entity sales force responsible for United States Depakote sales.

3.20 "Scientifically Trained Personnel" shall mean Responsible Entity personnel experts with specialized training, scientific and medical knowledge whose roles involve the provision of specialized medical or scientific information, including Medical Affairs and Clinical Science Managers, but excluding anyone performing sales, marketing or other commercial roles.

3.21 "Signatory Attorney General" shall mean the Attorney General of New Jersey, or his/her authorized designee, who has agreed to this Judgment.

3.22 "State Consumer Protection Laws" shall mean the consumer protection laws cited in Footnote 1 under which the Attorneys General have conducted the investigation.

3.23 "Unsolicited Request" shall mean a request for Off-Label information regarding Depakote from a HCP communicated to an employee or contract sales agent of Responsible Entity that has not been prompted by Responsible Entity.

## 4. COMPLIANCE PROVISIONS

**Promotional Activities**

4.1 Responsible Entity shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding Depakote.

4.2 Responsible Entity shall not Promote Depakote for Off-Label uses.

4.3 Responsible Entity shall require that the compensation (including through salaries, bonuses, and contests) of its United States sales representatives be designed to ensure that financial incentives do not motivate such individuals to engage in Off-Label Promotion of Depakote.

4.4 For five years from the Effective Date of this Judgment, Responsible Entity shall inform Responsible Entity Sales and Responsible Entity Marketing personnel of the results of any company-sponsored clinical trial relating to Depakote completed after the Effective Date.

**Dissemination and Exchange of Medical Information**

4.5 The content of Responsible Entity's communications concerning Off-Label uses of Depakote shall not be false, misleading or deceptive.

**Medical Information Responses**

The following subsections shall be effective for five years from the Effective Date of this Judgment.

4.6 Responsible Entity Medical shall have ultimate responsibility for developing and approving the medical content for all Medical Information Responses regarding Depakote, including any that may describe Off-Label information. Responsible Entity shall not distribute any such materials unless:

A. Clinically Relevant Information is included in these materials to provide scientific balance;

B. Data in these materials are presented in an unbiased, non-Promotional manner; and

C. These materials are clearly distinguishable from sales aids and other Promotional Materials.

4.7 Responsible Entity Sales and Responsible Entity Marketing personnel shall not develop the medical content of Medical Information Responses regarding Depakote. This provision does not prohibit Responsible Entity Sales or Responsible Entity Marketing personnel from suggesting topics for Medical Information Responses.

4.8 Responsible Entity Sales and Responsible Entity Marketing personnel shall not distribute Medical Information Responses regarding Depakote.

4.9 Responsible Entity shall not knowingly disseminate any Medical Information Response that makes any false or misleading representation regarding Depakote or any false or misleading statement concerning a competing product.

**Responses to Unsolicited Requests for Off-Label Information**

The following subsections shall be effective for five years from the Effective Date of this Judgment.

4.10 In responding to an Unsolicited Request for Off-Label information regarding Depakote, including any request for a specific article related to Off-Label uses, Responsible Entity shall advise the requestor that the request concerns an Off-Label use, and inform the requestor of the drug's FDA-approved indication(s) and/or dosage and other relevant Labeling information.

4.11 If Responsible Entity elects to respond to an Unsolicited Request for Off-Label information from a HCP regarding Depakote, Responsible Entity Medical shall be required to provide accurate, objective, and scientifically balanced responses. Any such response shall not Promote Depakote for any Off-Label use(s).

4.12 Any written response to an Unsolicited Request for Off-Label information regarding Depakote shall include:

A. Medical Information Response or other document prepared in response to the request in accordance with Paragraphs 4.6, 4.7, 4.8, 4.9, 4.10 and 4.11; or

B. A report containing the results of a reasonable literature search using terms from the request.

4.13 Responsible Entity Sales and Responsible Entity Marketing may respond in writing to an Unsolicited Request for Off-Label information regarding Depakote from a HCP only by informing the HCP of the presence or absence of published studies concerning the Off-Label topic or by acknowledging whether the topic is an area of research, and by offering to request on behalf of the HCP that a Medical Information Response or other information be sent to the HCP in follow up, provided it complies with Paragraph 4.12 set forth above. Responsible Entity Sales and Responsible Entity Marketing shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information.

4.14 Responsible Entity Sales and Responsible Entity Marketing may respond orally to an Unsolicited Request for Off-Label information regarding Depakote from a HCP only by informing the HCP of the presence or absence of published studies concerning the Off-Label topic or by acknowledging whether the topic is an area of research, and by offering to request on behalf of the HCP that a Medical Information Response or other information be sent to the HCP in follow up. Responsible Entity Sales and Responsible Entity Marketing shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information.

**Reprints Containing Off-Label Information**

The following subsections shall be effective for five years from the Effective Date of this Judgment.

4.15 Responsible Entity Medical and/or Responsible Entity's regulatory function shall be responsible for the identification, selection and approval of Reprints Containing Off-Label Information regarding Depakote.

4.16 Reprints Containing Off-Label Information regarding Depakote shall:

A. Be accompanied by the full prescribing information for the product, or a clearly and conspicuously described hyperlink that will provide the reader with such information, and contain a disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

B. Not be referred to or used in a Promotional manner.

4.17 Reprints Containing Off-Label Information regarding Depakote may be disseminated only by Responsible Entity Scientifically Trained Personnel to HCPs. Responsible Entity non-Scientifically Trained Personnel shall not disseminate these materials to HCPs.

**Continuing Medical Education (CME) and Grants**

The following subsections shall be effective for five years from the Effective Date of this Judgment.

4.18 Responsible Entity shall disclose, at least annually, on its company website Depakote-related CME grants in amounts of more than $200. The information posted on the company website shall include: (1) definitions for the types of grants and donations posted; (2) list of recipients in alphabetical order; and (3) payment amount and purpose. Currently Abbott

discloses this information at http://www.abbott.com/citizenship/disclosures/financial-support.htm.

A. Responsible Entity shall maintain this information on its website once posted for at least two years and shall maintain the information in a readily accessible format for review by the States upon written request for a period of three years.

4.19 Responsible Entity's grant-making function shall manage all requests for funding related to CME regarding Depakote. Such approval decisions shall be made by financial and/or other organizations separate from the Responsible Entity Sales and Responsible Entity Marketing organizations.

4.20 Responsible Entity shall not use CME grants to Promote Depakote. This provision includes, but is not limited to, the following prohibitions:

A. Responsible Entity Sales and Responsible Entity Marketing shall not initiate, coordinate or implement grant applications on behalf of any customer or HCP regarding Depakote;

B. Responsible Entity Sales and Responsible Entity Marketing shall not be involved in selecting grantees or CME-funded speakers regarding Depakote; and

C. Responsible Entity Sales and Responsible Entity Marketing shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating HCPs' subsequent prescribing habits, practices or patterns regarding Depakote.

4.21 Responsible Entity shall not condition funding of a CME program grant request regarding Depakote upon the requestor's selection or rejection of particular speakers.

4.22 Responsible Entity shall not control, or attempt to influence selection of the specific topic, title, content, speakers or audience for CMEs regarding Depakote, consistent with ACCME guidelines.

4.23 Responsible Entity Sales and Responsible Entity Marketing shall not approve CME grant requests regarding Depakote, nor attempt to influence the Responsible Entity's grant-making function to reward any customers or HCPs with grants for their prescribing habits, practices or patterns regarding Depakote.

4.24 Responsible Entity shall contractually require providers of Depakote-related CME programs to disclose to CME program attendees Responsible Entity's financial support of the CME program and any significant financial or other relationship with faculty and speakers at such CME.

4.25 After the initial delivery of a CME program, Responsible Entity shall not distribute, arrange, or provide HCPs access to any accredited presentations containing Off-Label Information regarding Depakote. If Responsible Entity's grant-making function or Responsible Entity Medical learns that a CME's program's content has more than an incidental reference to Off-Label Information regarding Depakote, it will not fund the CME program in the future.

**Clinical Research**

The following subsections shall be effective for five years from the Effective Date of this Judgment.

4.26 Responsible Entity shall report research regarding Depakote in an accurate, objective and balanced manner as follows and as required by applicable law:

A. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law No. 110-85), Responsible Entity shall register clinical trials and submit clinical trial results to the registry and results data bank regarding Depakote as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act. With respect to Depakote, Abbott registers on a publicly accessible NIH website (www.clinicaltrials.gov) the initiation of all applicable Abbott-sponsored clinical trials involving individuals beginning after the Effective Date and posts a summary of the results of all applicable Abbott-sponsored clinical trials in patients or volunteers that were completed after the Effective Date.

4.27 When presenting information about a clinical study regarding Depakote in any Promotional Materials, Responsible Entity shall not do any of the following:

A. Present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

B. Use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results;

C. Use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations;

D. Present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

E. Use statistics on numbers of patients or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

4.28 When submitting information about a clinical study regarding Depakote for publication, Responsible Entity shall:

A. Require 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, unless otherwise required by a journal or congress, in which case the journal or congress criteria for authorship will be followed; and

B. Acknowledge Responsible Entity's role as the funding source of all Responsible Entity-initiated research and clinical trials in all related scientific publications.

## 5. TERMS RELATING TO PAYMENT

5.1 No later than 30 days after the Effective Date of this Judgment, Abbott shall pay a total amount of $100 million to be divided and paid by Abbott directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or be placed in, or applied to, a consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, or used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at conditions for which Depakote is used to treat including but not limited to, education and outreach or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.

## 6. RELEASE

6.1 By its execution of this Judgment, the State of New Jersey releases and forever discharges, to the fullest extent permitted by law, Abbott and all of its past and present subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors, successors and assigns, including Pharmaceutical Company and Diversified Company, and each and all of their current and former officers, directors, shareholders, employees, agents and contractors, (collectively, "Released Parties") from the following: all civil claims, causes of

action, damages, restitution, fines, costs, attorneys' fees, and penalties that the New Jersey Attorney General could have asserted against the Released Parties under the above-cited consumer protection statutes, successor statutes, or common law claims concerning unfair, deceptive or fraudulent trade practices impacting consumers or state statutes equivalent to the federal Food, Drug and Cosmetic Act that the Office of the Attorney General has the authority to release resulting from the Covered Conduct up to and including the Effective Date that is the subject of this Judgment.

6.2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the Release in Paragraph 6.1 as to any entity or person, including Released Parties, are any and all of the following:

A. Any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of New Jersey.

B. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of New Jersey not expressly covered by the release in Paragraph 6.1 above including, but not limited to, any and all of the following claims:

i) State or federal antitrust violations;

ii) Reporting practices, including "best price," "average wholesale price" or "wholesale acquisition cost;"

iii) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

iv) State false claims violations;

v) Any liability under the State of New Jersey's above-cited consumer protection laws which any person and/or entity, including Released Parties, has or may have to individual consumers of said State; and

vi) Any liability under the State of New Jersey's above-cited consumer protection laws or other actions of state program payors, which any person and/or entity, including Released Parties, has or may have to State program payors of said State.

## 7. DISPUTE RESOLUTION

7.1 For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Responsible Entity has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Responsible Entity in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Responsible Entity thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a

threat to the health or safety of the public requires immediate action. Upon receipt of written notice, Responsible Entity shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Responsible Entity believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Responsible Entity intends to remedy the alleged breach. Nothing in this paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and Responsible Entity reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.

7.2 Upon giving Responsible Entity thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody or control of Responsible Entity that relate to Responsible Entity's compliance with each provision of this Judgment as to which cause that is legally sufficient in the State has been shown.

7.3 The State may assert any claim that Responsible Entity has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing Responsible Entity an opportunity to respond to the notification described in Paragraph 7.2 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

## 8. GENERAL PROVISIONS

8.1 This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment, and no prior versions of any of its terms that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

8.2 This Judgment may be executed in counterparts, and a facsimile or PDF signature shall be deemed to be, and shall have the same force and effect as, an original signature.

8.3 All Notices under this Judgment shall be provided to the following via Overnight Mail:

General Counsel
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500

And

Patricia Schiripo, Deputy Attorney General/Assistant Section Chief
Department of Law and Public Safety
Division of Law
124 Halsey Street, 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

8.4 To the extent that any provision of this Judgment obligates Responsible Entity to change any policy(ies) or procedure(s) and to the extent not already accomplished, Responsible

Entity shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

**IT IS SO ORDERED, ADJUDGED, AND DECREED**

**This ____ day of ____, 2012**

**PAUL INNES, P.J. Ch.**

JOINTLY APPROVED AND
SUBMITTED FOR ENTRY:

For Plaintiffs:
JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY

By: Patricia Schiripo

Patricia Schiripo
Deputy Attorney General
124 Halsey Street, 5th Floor
P.O. Box 45029
Newark, New Jersey 07101
973-648-7819
patricia.schiripo@dol.lps.state.nj.us

Date: 5/4/2012

For Abbott Laboratories:

By: _____

Karen Hale
Divisional Vice President and Associate General Counsel
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500

Date: May 2, 2012

By: _____

Henry J. DePippo
Kirkland & Ellis, LLP
601 Lexington Ave.
New York, NY 10022

Date: 5/2/2012

Approved as to form:

By: _____

Michael E. Helmer
DLA Piper LLP (US)
300 Campus Dr., Suite 100
Florham Park, NJ 07932-1039
T 973.520.2552
F 973.520.2572
michael.helmer@dlapiper.com
Bar Number: 049651988

Date: 5/3/12

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street - 5th Floor
P.O. Box 45029
Newark, New Jersey 07101
Attorney for Plaintiffs

By: Patricia Schiripo
Deputy Attorney General / Assistant Section Chief
(973) 648-7819

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO.: MER-C- 43-12

JEFFREY S. CHIESA, Attorney General of the State of New Jersey, and ERIC F. KANEFSKY, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

Civil Action

**COMPLAINT**

1. Plaintiffs, Jeffrey S. Chiesa, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Eric T. Kanefsky, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") bring this action against Abbott Laboratories ("Defendant") for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1et seq. ("CFA"), by among other

things, advertising, selling or offering for sale the prescription drug Depakote® ("Depakote") for off-label uses for which there was no substantiated efficacy.

2. This Complaint is being filed concurrently with a Final Consent Judgment.

## JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to the CFA and over Defendant pursuant to the CFA. Venue is proper under R. 4:3-2 because Mercer County is a county in which the Defendant has advertised and conducted business and is a county in which at least one of parties resides.

## THE PARTIES

4. The Attorney General is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and the Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19, against Defendant for engaging in unconscionable commercial practices in connection with the advertising, offer for sale and sale of its prescription drug Depakote.

5. The Defendant is incorporated in Illinois, with its principal place of business at 100 Abbott Park Road, D-322 AP6D, Illinois, 60064. The Defendant has marketed, distributed, offered for sale and sold Depakote to consumers throughout the United States, including New Jersey.

## GENERAL ALLEGATIONS

6. Drug companies are prohibited by the Food Drug and Cosmetic Act of 1938, 21 USCA § 321 et seq. ("FDCA"), from promoting drugs for indications (uses) that are not approved by the United States Food and Drug Administration ("FDA").

7. In order to obtain FDA approval to lawfully market a drug in the United States, a drug company must submit clinical trials that prove by substantial evidence that the drug is safe and effective for its intended use.

8. Abbott obtained FDA approval to market the prescription drug Depakote only for treatment of seizure disorders, mania associated with bipolar disorder, and prophylaxis of migraines.

9. In addition to the indications approved by the FDA, Abbott knew that doctors prescribed Depakote "off-label" to treat a number of other indications, including agitation associated with dementia, and as combination therapy with antipsychotic medications to treat schizophrenia.

10. Although Abbott did not possess substantial evidence to substantiate a claim that Depakote is effective for the treatment of agitation associated with dementia, or as adjunct therapy with antipsychotics to treat schizophrenia, Abbott chose to bypass the regulatory process and to engage in off-label promotion for these indications.

11. The decision to promote Depakote off-label was driven by Abbott's understanding that the studies required by the FDA to demonstrate safety and efficacy for these indications would be expensive and the results of the required studies might not be sufficient to support Abbott's application.

12. Abbott was also concerned that even if the FDA approved the new indications, the patent on Depakote would expire at about the same time as FDA's approval, and Abbott would not be able to take advantage of the approval before cheaper generics captured the market.

13. Abbott instructed its sales representatives to distribute and detail studies that found Depakote to be effective for the off-label uses. However, these studies were not competent and reliable scientific evidence and did not substantiate efficacy.

14. Abbott also promoted Depakote at supposedly independent Continuing Medical Education events. In fact, these events were promotional in nature and an integral part of the Abbott's scheme to promote for the off-label uses.

15. To support its efforts to promote Depakote for schizophrenia in combination with antipsychotic drugs to treat schizophrenia, Abbott conducted a clinical trial relating to this use. However, the result of this study was negative and showed the addition of Depakote to be ineffective. Nonetheless, Abbott continued to promote Depakote as an adjunct with antipsychotic medications to treat schizophrenia and failed to timely publish or publicize the negative study results.

16. Similarly, even after Abbott learned about a well conducted, well designed clinical trial that found Depakote to be ineffective for treatment of agitation associated with dementia, Abbott continued to promote Depakote off-label for this indication.

## COUNT I

## VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES)

17. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 16 as if more fully set forth herein.

18. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or knowing[] concealment, suppression or omission of any material fact with intent that others rely upon such

> concealment, suppression or omission, in connection with the sale or advertisement of any merchandise. . .

19. All of the acts and practices engaged in and employed by Defendant as alleged herein, are unconscionable commercial practices in violation of the CFA, namely that Defendant violated the CFA by advertising, selling or offering for sale the prescription drug Depakote for off-label uses for which there was no substantiated efficacy.

20. Each unconscionable commercial practice by Defendant constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

## PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

(a) Finding that the acts and omissions of Defendant constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;

(b) Permanently enjoining Defendant and its owners, officers, directors, shareholders, members, founders, managers, agents, servants, employees, representatives, corporations, independent contractors, subsidiaries, affiliates, successors, assigns, and all other entities or persons directly under its control, to cease and desist from engaging in, continuing to engage in, or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in the Complaint;

(c) Directing the assessment of restitution amounts against Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any practice alleged herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;

(d) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;

(e) Directing the assessment of costs and fees, including attorneys' fees, against Defendant for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19;

(f) Granting such other relief as the interests of justice may require.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: May 7, 2012
Newark, New Jersey

## RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 et seq., is not the subject of any other action pending in any other court of this State. I further certify that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: May 7, 2012
Newark, New Jersey

## RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(c).

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: May 7, 2012
Newark, New Jersey

## DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Patricia Schiripo is hereby designated as trial counsel on behalf of Plaintiffs in this action.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section