

IN THE CIRCUIT COURT FOR THE CITY OF RICHMOND

COMMONWEALTH OF VIRGINIA,
EX REL. MARK R. HERRING,
ATTORNEY GENERAL
Plaintiff,
v.
JOHNSON & JOHNSON CONSUMER INC.
and JOHNSON & JOHNSON,
Defendants.

Case No. CL17-2537-4

FINAL CONSENT JUDGMENT

AND NOW, comes the Plaintiff, Commonwealth of Virginia, *ex rel.* Mark R. Herring, Attorney General, having filed an action pursuant to the Virginia Consumer Protection Act, Virginia Code §§ 59.1-196 through 59.1-207, and the parties having consented to entry of this Final Consent Judgment (“Judgment”) without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind.

I. Parties

- A. The Commonwealth, by and through its Attorney General, Mark R. Herring (the “Commonwealth”), is the Plaintiff in this case. The Attorney General is charged with, among other things, the responsibility of enforcing the Virginia Consumer Protection Act (“VCPA”).
- B. Johnson & Johnson Consumer Inc. operates a division known as McNeil Consumer Healthcare Division (“McNeil”). McNeil’s executive offices are located at 7050 Camp Hill Road, Fort Washington, PA 19034. Johnson & Johnson Consumer Inc. is a subsidiary of Johnson & Johnson. Johnson &

Johnson's executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. McNeil engages in trade affecting consumers, within the meaning of the VCPA in the Commonwealth of Virginia, including, but not limited to the city of Richmond. Johnson & Johnson consents to the jurisdiction of the Court solely for the purposes of this Judgment.

II. Preamble

- A. The Attorneys General of the Multistate Working Group (defined below and collectively referred to hereinafter as the "State Attorneys General"), conducted a multistate investigation into certain McNeil acts and practices.
- B. The State Attorneys General have individually and collectively determined to resolve the investigation by entering into similar settlement agreements between defendants and each Signatory Attorney General.
- C. By entering into this Judgment, the Parties have agreed to resolve claims related to certain McNeil business practices under each state's Consumer Protection Laws.
- D. This Judgment does not constitute an admission by McNeil for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute evidence or admission of any liability, fault or wrongdoing, all of which McNeil denies. McNeil does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by Plaintiff before the date of this Judgment.
- E. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. It is the intent of the Parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited

to, any investigation or litigation, 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.

F. McNeil is entering into this Judgment solely for the purpose of settlement of the instant action. This Judgment does not create a waiver of or limit McNeil's legal rights, remedies, or defenses in any other action by the Signatory Attorney General, and does not waive or limit McNeil's right to defend itself from, or make argument in, any other matter, claim, or suit, including, but not limited to, any investigation or litigation relating to the subject matter or terms of this Judgment. Nothing in this Judgment shall waive, release, or otherwise affect any claims, defenses, or positions McNeil may have in connection with any investigations, claims, or other matters the State is not releasing hereunder. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

G. Nothing in this Judgment shall require McNeil to:

1. Take any action that is prohibited by the Federal Food, Drug and Cosmetic Act ("FDCA") or any regulation promulgated thereunder, or by the U.S. Food and Drug Administration ("FDA"); or
2. Fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA.

H. This Judgment (or any portion thereof) shall in no way prohibit, limit, or restrict McNeil from making representations with respect to its products that are permitted or authorized under Federal law, the FDCA, or the FDA or FDA

Guidance for Industry, so long as those representations, taken in their entirety, are not false, misleading, or deceptive. Further, the Judgment shall in no way prohibit, limit, or restrict McNeil from making representations with respect to its products that are required or authorized by, or consistent with, the FDA-approved labeling requirements for McNeil products, so long as the representation, taken in its entirety, is not false, misleading, or deceptive.

I. The acceptance of this Judgment by the Commonwealth shall not be deemed approval by the Commonwealth of any of McNeil's advertising or business practices. Further, neither McNeil, nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the Commonwealth or any other governmental unit of the Commonwealth has approved, sanctioned or authorized any practice, act, advertisement or conduct of McNeil.

J. Any failure by any party to this Judgment to insist upon the strict performance by another party of any provision of this Judgment shall not be deemed a waiver of any such provision. Notwithstanding such failure, the party shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment, the payment of attorney's fees, the imposition of any applicable penalties, and any other applicable remedies, including but not limited to, contempt and civil penalties as set forth in the VCPA and/or other applicable state law.

III. Definitions

A. "Consumer Protection Laws" shall mean the laws of the Commonwealth as cited

among those listed in footnote 1.¹

- B. “Covered Conduct” shall mean McNeil’s business practices relating to the Covered Products that were the subject of recalls or retrievals during the calendar years 2009 through 2011, meaning (1) alleged representations prior to the Effective Date of this Judgment regarding the quality or safety of Covered Products during the above-referenced time period; or (2) the introduction into the stream of commerce of Virginia during the same time period of Covered Products

¹ ALASKA -Alaska’s Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 – 561; ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 et seq.; ARKANSAS - *Ark. Code Ann.* § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a et seq.; DELAWARE –*Delaware Consumer Fraud Act and Uniform Trade Practices Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2536; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 et seq.; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 et. seq.; HAWAII –Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Chpt. 480; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 et seq.; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/1 et seq. and *Uniform Deceptive Trade Practices Act*, 815 ILCS 510/1 et seq.; INDIANA - *Deceptive Consumer Sales Act*, I.C. § 24-5-0.5 et seq.; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq.; KENTUCKY - KRS 367.110 et seq.; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, et seq.; MAINE – *Unfair Trade Practices Act*, 5 M.R.S. §§ 205-A through 214; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law § 13-101 et seq.; MASSACHUSETTS – *Mass. Gen. Laws* c. 93A, §§ 2 and 4; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 et seq.; MINNESOTA - *Minnesota Deceptive Trade Practices Act*, Minn. Stat. §§ 325D.43-48; *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-70; *Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – *Merchandising Practices Act*, Chapter 407, RSMo. MONTANA - *Mont. Code Ann.* § 30-14-101 et. seq.; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 et seq.; NEVADA – *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE – *New Hampshire Consumer Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 et seq.; NEW MEXICO - *New Mexico Unfair Practices Act* NMSA 1978, S 57-12-1 et seq. (1967); NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*, N.C.G.S. §§ 75-1.1, et seq.; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 et seq.; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, et seq.; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 et seq.; RHODE ISLAND - *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-1, et seq.; SOUTH CAROLINA - *South Carolina Unfair Trade Practices Act*, S.C. Code §§ 39-5-10 et seq.; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. § 47-18-101 et seq.; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection Act*, Tex. Bus. And Com. Code 17.41, et seq.; VERMONT – *Consumer Protection Act*, 9 V.S.A. §§ 2451 et seq.; VIRGINIA - *Virginia Consumer Protection Act*, Va. Code Ann. §§ 59.1-196 through 59.1-207; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 et seq.; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W.Va. §46A-1-101 et seq.; WISCONSIN – Wis. Stat. § 100.182 (Fraudulent drug advertising).

that Virginia alleges or could have alleged were not manufactured in accordance with current Good Manufacturing Practices.

- C. “Covered Products” shall mean the products listed in Exhibit A.
- D. “current Good Manufacturing Practices” or “cGMP” shall mean those practices that comply with the current Good Manufacturing Practice regulations promulgated by the FDA at 21 C.F.R. parts 210-211, together with any subsequent amendments or additions.
- E. “Effective Date” shall mean the date on which a copy of this Judgment, duly executed by McNeil and by the Signatory Attorney General, is approved by and becomes a judgment of the Court.
- F. “McNeil” shall mean (i) McNeil Consumer Healthcare, a division of Johnson & Johnson Consumer Inc.; (ii) the legal entity responsible for manufacturing, selling, offering for sale, promoting, or distributing the Covered Products to the extent that such entity manufactures, sells, offers for sale, promotes, or distributes the Covered Products; and (iii) all successors to these entities to the extent that such successor manufactures, sells, offers for sale, promotes, or distributes the Covered Products.
- G. “Multistate Executive Committee” shall mean the Attorneys General and their staffs representing Arizona, Delaware, District of Columbia, Florida, Kentucky, Maryland, Massachusetts, Montana, New Jersey, Ohio, Pennsylvania, and Texas.
- H. “Multistate Working Group” shall mean the Attorneys General and their staffs representing Alaska, Arizona, Arkansas, California, Colorado, Connecticut,

Delaware, District of Columbia, Florida, Hawaii², Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

- I. "OTC Drug Product," for the purposes of this Judgment, shall mean an OTC drug whose product brand name is included on Exhibit A.
- J. "Parties" shall mean McNeil and the Signatory Attorney General.
- K. "Recall" shall mean Recall as defined by 21 C.F.R. §§ 7.3(g), provided that the recall is assigned the classification "Class I" by the FDA as defined in 21 C.F.R. §7.3(m)(1) or assigned the classification "Class II" by the FDA as defined in 21 C.F.R. § 7.3(m)(2).
- L. "Signatory Attorney General" shall mean the Attorney General of Virginia or his or her authorized designee, who has agreed to this Judgment.

IV. Injunctive Terms

IT IS ORDERED THAT McNeil shall not:

- A. Represent on www.mcneil-consumer.com or any other McNeil-operated website that McNeil's OTC Drug Product manufacturing facilities meet current Good Manufacturing Practices (cGMP) outlined by the FDA if McNeil has had a Class I

² Hawaii is being represented in this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

or Class II Recall of OTC Drug products within the prior twelve (12) months caused by cGMP noncompliance at its Fort Washington, Pennsylvania or Las Piedras, Puerto Rico manufacturing facilities.

- B. For a period of five (5) years from the Effective Date, fail to follow its operative internal standard operating policies regarding whether to open a Corrective Action/Preventive Action (CAPA) during the manufacture of OTC Drug Products.
- C. For a period of five (5) years from the Effective Date, fail to provide within sixty (60) days of a written request from the Signatory Attorney General, who shall distribute to any other requesting State Attorneys General, information concerning the identity of wholesalers or warehouses to which any OTC Drug Product that is subject to a Recall was distributed in its State, to the extent that any such requested information is in McNeil's possession. McNeil may enter into agreements with the Signatory Attorney General to ensure the confidentiality of any records or information produced under this provision, and reserves the right to invoke any available protection or privilege for trade secrets or other legally protected information under state or federal law. Nothing in this section shall be interpreted to limit the Commonwealth's CID or investigative subpoena authority.

V. Payment

- A. No later than thirty (30) days after the Effective Date of this Judgment, McNeil shall pay \$33,000,000 to be divided and paid by McNeil directly to the State Attorneys General of the Multistate Working Group in amounts to be designated by and in the sole discretion of the Multistate Executive Committee.

Said payments to the State Attorneys General shall be used by each State Attorney General for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education or litigation or local consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each State Attorney General. The parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

VI. Release

- A. Upon full and complete performance of the monetary provisions set forth in paragraph V, the Commonwealth of Virginia releases McNeil, and its parent, subsidiaries, affiliates, predecessors, and successors, (the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, attorney's fees, and penalties that the Virginia Attorney General has asserted or could have asserted against the Released Parties under the Consumer Protection Laws (as identified in footnote 1) or under common law concerning unfair, deceptive, or fraudulent trade practices, other than those reserved or excluded under Section VI.B below resulting from the Covered Conduct up to and including the Effective Date of this Judgment (collectively, the "Released Claims").
- B. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person or entity, including Released Parties, has or may have to the Commonwealth of Virginia;
2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the Commonwealth of Virginia, under any statute, regulation, or rule not expressly covered by the release in Section VI.A including, but not limited to, any and all of the following claims:
 - a. State or federal antitrust and tax violations;
 - b. Medicaid violations including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to the State's Medicaid program;
 - c. Claims involving "best price," "average wholesale price," or "wholesale acquisition cost"; and
 - d. State false claims violations;
3. Claims to enforce the terms and conditions of this Judgment;
4. Actions of state program payors of the Commonwealth of Virginia arising from the Covered Conduct, except for the release of civil penalties under the relevant State Consumer Protection Laws; and
5. Any claims individual consumers have or may have against any person or entity, including Released Parties.

VII. Dispute Resolution

- A. For purposes of resolving any disputes with respect to compliance with this Judgment, should the Signatory Attorney General believe that McNeil has violated a provision of this Judgment subsequent to the Effective Date, the

Signatory Attorney General shall notify McNeil in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice allegedly violates, and give McNeil thirty (30) business days to respond to the notification.

- B. Upon receipt of written notice from the Signatory Attorney General, McNeil shall provide a good-faith written response to the Signatory Attorney General notification, containing either a statement explaining why McNeil believes it is in compliance with the Judgment or a detailed explanation of how the alleged violation occurred and statement explaining how and when McNeil intends to remedy the alleged violation.
- C. Except as set forth in Section VII, Paragraph D or E below, the Signatory Attorney General may not take any action during the 30-day response period. Nothing shall prevent the Signatory Attorney General from agreeing in writing to provide McNeil with additional time to respond to the notice.
- D. Nothing in this Dispute Resolution Section shall be interpreted to limit the Commonwealth's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and McNeil reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.
- E. The Signatory Attorney General may assert any claim that McNeil 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 McNeil an opportunity to respond to the notification as described above and to remedy the

alleged violation within the 30-day response period as described above, or within any other period as agreed to by McNeil and the Signatory Attorney General; provided, however, that the Signatory Attorney General may take any action if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

VIII. General Provisions

- A. McNeil shall not cause third parties acting on its behalf to engage in practices from which McNeil is prohibited by this Judgment.
- B. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, neither prior versions of this Judgment, nor prior versions of any of its terms that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever. The Parties acknowledge that no other promises, representations, or agreements of any nature have been made or entered into by the Parties. The Parties further acknowledge that this Judgment constitutes a single and entire agreement that is not severable or divisible, except that if any provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect.
- C. This Court retains jurisdiction over 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.
- D. 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.

E. All notices under this Judgment shall be provided to:

For McNeil:



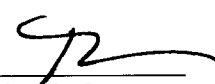
Ethan M. Posner, Esq.
COVINGTON & BURLING LLP
850 Tenth Street NW
Washington, DC 20001
(202) 662-5317
eposner@cov.com

For Attorney General:

Joelle Gotwals
Assistant Attorney General
Office of the Attorney General
202 North 9th St.
Richmond, VA 23219
(804) 786-8789
jgotwals@oag.state.va.us

IT IS SO ORDERED, ADJUDGED AND DECREED.

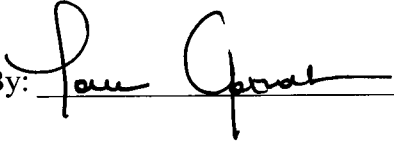
This the 26th day of May, 2017.

Judge, Richmond City Circuit Court

APPROVED:

PLAINTIFF, COMMONWEALTH OF VIRGINIA,
EX REL. MARK R. HERRING,
ATTORNEY GENERAL

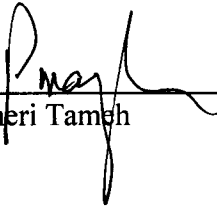
By:  _____

Date: 5/23/17

Joelle E. Gotwals (VSB #76779)
Assistant Attorney General
Consumer Protection Section
202 North 9th Street
Richmond, Virginia 23219
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Defendants Johnson & Johnson Consumer Inc. and Johnson & Johnson

Johnson & Johnson Consumer Inc.

By:  _____
Parisa Mazaheri Tameh
Secretary

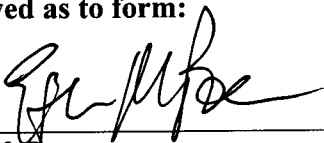
Date: 05/18/2017

Johnson & Johnson

By:  _____
Lacey P. Elberg
Assistant Secretary

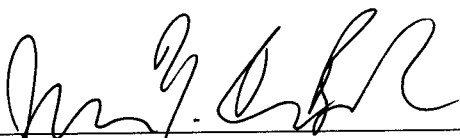
Date: 5/18/17

Approved as to form:

By:  _____

Ethan M. Posner
Stephen P. Anthony
Christopher M. Denig
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001
Counsel for Defendants

Date: 5/17/17

By:  _____

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Date: 5/18/2017