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ATTORNEY GENERAL

News Release

Office of Attorney General, The Capitol, Tallahassee, Florida 32308-1050

October 16, 1996

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FOR IMMEDIATE RELEASE

DRUG FIRM, ARTHRITIS FOUNDATION SETTLE ALLEGATIONS

TALLAHASSEE -- Nearly \$2 million in payments and a consumer refund offer are part of an agreement to settle allegations that a major drug manufacturer and a prominent volunteer health organization deceptively marketed pain relievers, Attorney General Bob Butterworth announced today.

Entering the agreement with Florida and 18 other states were McNeil Consumer Products Company of Fort Washington, Pennsylvania, and The Arthritis Foundation of Atlanta, Georgia.

McNeil and the Foundation were accused of deception in the marketing of Arthritis Foundation brand pain relievers, a group of four over-the-counter drugs manufactured by McNeil under a financial arrangement with the health organization.

Among the alleged deceptions were claims that the oral pain relievers were specially formulated with help from the Foundation and were therefore more effective than comparable drugs, and that some proceeds of each purchase would benefit the Foundation's efforts to cure arthritis. The claims were made in multi-media advertising and in-store promotional materials beginning in 1994.

"These drugs contain analgesics common to other pain relief products and were developed with no assistance from The Arthritis Foundation," Butterworth said. "The Foundation was paid \$1 million a year for use of its name regardless of sales, which never reached a level necessary to earn the group royalties on individual purchases."

Under the settlement agreement, McNeil will pay \$250,000 to

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the National Institute of Arthritis and Musculoskeletal and Skin Diseases, an agency of the National Institutes of Health, to fund research. In addition, the company will pay \$90,000 to each of the 19 states to cover costs of their investigation.

Both McNeil and the Foundation are offering to refund the price of Arthritis Foundation brand pain relievers bought prior to implementation of terms of the settlement agreement. Refund requests should include either a product receipt or a signed statement reflecting the product purchased and the price paid. Refund requests should be sent to either of the following addresses:

McNeil Consumer Products Company
Camp Hill Road
Fort Washington, PA 19034

The Arthritis Foundation
1330 West Peachtree Street, N.W.
Atlanta, GA 30309.

While in settlement negotiations with the states, McNeil announced late last month that it was discontinuing the Arthritis Foundation line of drugs but would contribute \$1.3 million a year to the organization over the next three years.

In addition to Florida, the agreement was entered into by Arizona, California, Connecticut, Illinois, Kentucky, Maryland, Massachusetts, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Pennsylvania, Tennessee, Texas, Vermont and Wisconsin.

The agreement was handled for Florida by Chief of Special Prosecutions Jack Norris and Assistant Attorney General Todd Stone.

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In the Matter of
McNeil-PPC, Inc.,
McNeil Consumer Products Company,
and the Arthritis Foundation

**ASSURANCE OF DISCONTINUANCE/
ASSURANCE OF VOLUNTARY COMPLIANCE**

This Assurance of Discontinuance/Assurance of Voluntary Compliance ("Assurance") is entered into by the States of Arizona, California, Connecticut, Florida, Illinois, Kentucky, Maryland, Massachusetts, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Pennsylvania, Tennessee, Texas, Vermont and Wisconsin ("States"), by their respective Attorneys General, and McNeil-PPC, Inc., McNeil Consumer Products Company and The Arthritis Foundation. This Assurance follows an investigation by the States into the advertising and marketing of Arthritis Foundation pain relief products, which is alleged by the States to be in violation of their respective consumer protection statutes.¹

STATES' POSITION

Based upon their investigation the States contend that:

1. McNeil-PPC, Inc., is a Pennsylvania corporation engaged in the manufacture and sale of over-the-counter ("OTC") drugs. McNeil-PPC, Inc., operates by and through its division, McNeil Consumer Products Company. McNeil-PPC, Inc. and McNeil Consumer Products Company are located at Camp Hill Road, Ft. Washington, Pennsylvania 19034.

1. Ariz. Rev. Stat. Ann. §§ 44-1521 *et seq.*; California Business & Professions Code § 17500 *et seq.* and 17200 *et seq.*; Conn. Gen. Stat. § 42-110a *et seq.*; Chapter 501, Part II, Florida Statutes; 815 ILCS 505/1 *et seq.*; Ky. Rev. Stat. 367.110 *et seq.*; Maryland Consumer Protection Act, Md. Com. Law Code Ann. § 13-301 *et seq.*; Mass. Gen. L. ch. 93A, §§ 1, *et seq.* (1993); Minn. Stat §§ 325D.44, 325F.67, and 325F.69 (1994); Missouri Merchandising Practices Act, Section 407 RSMo. (1994); N.J.S.A. 56.8-1 *et seq.*; Section 57-12-1 and 57-12-9, NMSA 1978 (1995 Repl.); New York Executive Law § 63(12) and General Business Law §§ 349 and 350; N.C. Gen. Stat. § 75-1.1; Pa. Stat. Ann., tit. 73, §§ 201-1-201-9.2; Tenn. Code Ann. § 47-18-101, *et seq.*; Tex. Bus. & Comm. Code Ann. §§ 17.41 *et seq.*; 9 V.S.A. § 2451 *et seq.*; sec. 100.18(1) Wisconsin Statutes.

McNeil-PPC, Inc. and McNeil Consumer Products Company are subsequently referred to in this Assurance as "McNeil."

2. The Arthritis Foundation, Inc., is a Georgia non-profit corporation with a principal place of business at 1330 West Peachtree Street, N.W., Atlanta, Georgia 30309. The Arthritis Foundation is a national volunteer health agency having 150 chapter and branch offices, more than 400,000 members and an annual budget exceeding \$82 million. The mission of the Arthritis Foundation is to support research to find the cure for and prevention of arthritis and to improve the quality of life for those affected by arthritis. The Arthritis Foundation is recognized as a source of expertise and services for people with arthritis, as well as for funding arthritis research. Millions of Americans with arthritis recognize the Arthritis Foundation as experts on arthritis.

3. In June 1994, the Arthritis Foundation and McNeil entered into an agreement under which the Arthritis Foundation licensed its name and logo to McNeil for use in marketing certain over-the-counter (OTC) analgesic products manufactured by McNeil. In return, McNeil agreed to pay the Arthritis Foundation royalties of a certain percentage of net sales of the products, with a minimum guaranteed annual payment of \$1 million to be paid regardless of whether total sales reach certain specified levels.

4. Beginning in approximately October, 1994, McNeil and the Arthritis Foundation launched a nationwide advertising campaign for four oral analgesic products manufactured by McNeil and sold under the Arthritis Foundation name. These four products are: Arthritis Foundation Pain Reliever, Aspirin Free (the active ingredient of which is acetaminophen); Arthritis Foundation Pain Reliever, Safety Coated Aspirin (the active ingredient of which is aspirin); Arthritis Foundation Pain Reliever/Fever Reducer, Ibuprofen (the active ingredient of which is ibuprofen); and Arthritis Foundation Pain Reliever/Sleep Aid (the active ingredients of which are acetaminophen with diphenhydramine). These products are subsequently referred to in this Assurance as "Arthritis Foundation Pain Relievers."

5. McNeil manufactures or causes to be manufactured each of the above OTC oral analgesic products. As allowed by the 1994 licensing agreement, the advertising and packaging of each of these products prominently features the Arthritis Foundation name and logo.

6. Arthritis Foundation Pain Relievers contain active ingredients that are chemically identical to the active ingredients found in other OTC oral analgesic products.

7. Arthritis Foundation Pain Relievers provide no greater efficacy than other OTC oral analgesics containing the same active ingredients.

8. Since 1994 McNeil periodically has advertised and promoted the Arthritis Foundation Pain Relievers through a nationwide advertising campaign consisting of television, radio, print, in-store promotional materials, coupons, product samples, and direct mailings to consumers. Such advertising and promotion has not been continuous. Attached as Exhibit 1 is a copy of the text of an illustrative television advertisement for Arthritis Foundation Pain Relievers, which was broadcast nationally and extensively, from November 12, 1994 through January 16, 1995, with substantially similar television advertisements having been broadcast from January through May 1995.

9. The Arthritis Foundation actively reviewed and approved all advertising, packaging and other promotional materials used in the marketing of Arthritis Foundation Pain Relievers.

10. McNeil and the Arthritis Foundation targeted the advertising campaign for Arthritis Foundation Pain Relievers primarily to consumers over 50 years of age, especially women.

11. Television advertisements for Arthritis Foundation pain relievers have reached millions of American consumers.

12. The States believe that, for reasons that include the following, advertising for Arthritis Foundation Pain Relievers has had the capacity and tendency to mislead, deceive and confuse consumers:

a. Advertisements for Arthritis Foundation Pain Relievers through approximately June 1, 1995, represented, directly and by implication, that the products themselves, rather than the brand, were "new," and the products' packaging and inserts through approximately July 1995 represented that the products were "new." In fact, the active ingredients of all four the Arthritis Foundation Pain Relievers are and have been available for some period of time to consumers in various other OTC oral analgesic products.

b. Advertisements for Arthritis Foundation Pain Relievers have represented that the Arthritis Foundation "helped to create" the products when, in fact, all four products were manufactured by or for McNeil. The Arthritis Foundation did not contribute any funds nor provide any assistance for creation or development of any of the products. Additionally, McNeil did not "create" Arthritis Foundation Pain Relievers, because the active ingredients do not represent any new analgesic formulations not already available on the OTC market and approved by the United States Food and Drug Administration.

c. Advertisements for Arthritis Foundation Pain Relievers have represented, directly and by implication, that Arthritis Foundation Pain Relievers are effective because they have been created by, produced by or are endorsed by the Arthritis Foundation. In fact, Arthritis Foundation Pain Relievers are no more effective than other OTC oral analgesics containing the same active ingredients.

d. Advertisements for Arthritis Foundation Pain Relievers have represented, directly or by implication, that with each purchase of the products, consumers will be supporting the Arthritis Foundation or contributing to finding a cure for arthritis. In fact, under the trademark licensing agreement between McNeil and the Arthritis Foundation, the Arthritis Foundation receives a guaranteed minimum \$1 million payment annually from McNeil. To date, sales of Arthritis Foundation Pain Relievers have not

reached sufficient levels to trigger any additional royalties from McNeil to the Arthritis Foundation above the guaranteed minimum.

e. Advertisements for Arthritis Foundation Pain Relievers have represented that a portion of each product purchase will go to research to help find a cure for arthritis but have failed to disclose that: (i) McNeil will pay \$1,000,000 annually to the Arthritis Foundation regardless of whether consumers purchase the products; and (ii) until product sales reach a certain level, the consumer's purchase of the product will not affect the annual amount paid by McNeil to the Arthritis Foundation for arthritis research.

f. Advertisements for Arthritis Foundation Pain Relievers have not disclosed clearly and conspicuously the source or manufacturer of the products (McNeil) and the affiliation, connection or relationship between Arthritis Foundation and McNeil.

g. Advertisements for Arthritis Foundation Pain Relievers when representing that such products were "doctor recommended" failed to clearly and conspicuously disclose that such representations were for the specific ingredients of the Arthritis Foundation Pain Relievers and not for the Arthritis Foundation Pain Reliever products themselves.

h. Advertisements for Arthritis Foundation Pain Relievers have represented, directly or by implication, that such products contain "four different . . . formulas" and are "especially formulated" when, in fact, none of the products' ingredients or formulas are special or different from other OTC analgesics containing the same active ingredients, although the aspirin formulation is safety coated.

MCNEIL'S AND THE ARTHRITIS FOUNDATION'S POSITION

13. McNeil and the Arthritis Foundation contend that Arthritis Foundation Pain Relievers are a complete line of medicines that include all of the major OTC internal analgesic medicines commonly utilized by physicians in treatment programs for the most common forms

of arthritis, combined with public education and informational messages and offerings that the Arthritis Foundation felt were important to get out to persons with arthritis.

14. McNeil and the Arthritis Foundation contend that the advertising, packaging or labeling for Arthritis Foundation Pain Relievers products is in all respects true and not false, misleading or deceptive, and further contend that:

a. Use of the term "new" in product advertising, through approximately June 1, 1995, and on product packaging and inserts through approximately July, 1995, was truthful and nondeceptive, because: (i) "new" referred to the Arthritis Foundation brand of pain relievers and not to their active ingredients; and (ii) the products have unique attributes in addition to the pain relief products themselves, including an offer of a free full one year membership in the Arthritis Foundation, an 800 telephone number for consumers to call for more information and the fact that a portion of sales proceeds is devoted to arthritis research;

b. The Arthritis Foundation "helped to create" this new brand of pain reliever products by licensing use of the Arthritis Foundation name and logo in the advertising and sale of the products and participating in brand offerings and marketing strategy. The Arthritis Foundation also "helped to create" Arthritis Foundation Pain Relievers by developing the free membership offering, the 800 telephone number arthritis information line, and other aspects of the total product offered under the Arthritis Foundation Pain Relievers brand;

c. Each Arthritis Foundation Pain Reliever is an effective analgesic product, based on many years of research and expertise with respect to the use of acetaminophen, ibuprofen and aspirin. Therefore, any efficacy claims arising from advertisements for Arthritis Foundation Pain Relievers are true;

d. The claim that "part of your purchase price goes to research to help find a cure for arthritis" is true and not misleading and does not have the tendency and capacity to mislead consumers about the nature of their purchasing decision or the amount of

proceeds from the sales of the products that will be contributed to the Arthritis Foundation:

e. Advertisements for Arthritis Foundation Pain Relievers need not identify the product manufacturer or describe McNeil's relationship with Arthritis Foundation and the failure to do so is not deceptive or misleading. McNeil and the Arthritis Foundation further contend that in the case of Arthritis Foundation Pain Relievers, the packaging for the products clearly states, "Distributed by McNeil-PPC, Inc., a Johnson & Johnson Company, Fort Washington, PA 19034 U.S.A."

f. Advertisements for Arthritis Foundation Pain Relievers that contain "doctor recommended" claims are true, nondeceptive and substantiated. Such claims refer to doctors recommending the products' active ingredients.

g. Advertisements for Arthritis Foundation Pain Relievers that make the claims "four different . . . formulas" or "especially formulated" are nondeceptive in that Arthritis Foundation Pain Relievers include different types of pain relievers with different active ingredients, each of which is designed for temporary relief of certain types of arthritis pain and the pain of inflammation. One is formulated to minimize stomach irritation that might otherwise occur with use of the active ingredient.

GENERAL PROVISIONS

15. This Assurance does not constitute any admission by McNeil or the Arthritis Foundation for any purpose, or of any violation of any state or federal law or regulation. McNeil and the Arthritis Foundation state that they are entering into this Assurance solely to avoid the significant expense of defending against the States' allegations in nineteen states, and do so without admitting any wrongdoing and for settlement purposes only.

16. This Assurance shall be governed by the laws of the above named States.

17. This Assurance does not constitute an approval by the States of any of McNeil's or the Arthritis Foundation's advertising, programs or practices and neither McNeil nor the Arthritis Foundation shall make any representation to the contrary.

18. This Assurance may be executed in counterparts.

19. The signatory States shall not institute any civil proceeding or take any civil action against McNeil or the Arthritis Foundation under the States' above cited consumer protection statutes for any advertisement for any Arthritis Foundation Pain Reliever product published prior to the execution date of this Assurance.

DEFINITIONS

20. As used in this Assurance, the following terms shall have the following meanings:

a. "Advertisement" means any oral, written, graphic or pictorial statement or representation directed to consumers in the course of business, regardless of the medium of communication employed, and includes product packages, labels or product inserts.

b. "Clear and conspicuous" or "clearly and conspicuously" means that the statement, representation or term being disclosed is of such size, color, contrast and audibility and is so presented as to be readily noticed and understood by the person to whom it is being disclosed.

c. "Competent and reliable scientific evidence" means such tests, analyses, research, studies, or other scientific evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate, reliable and reproducible results.

d. "Covered product" includes the four Arthritis Foundation Pain Relievers identified in paragraph 4, and any internal analgesic products, whether prescription or non-prescription, which may be developed or marketed pursuant to the 1994 license agreement entered into between the Arthritis Foundation and McNeil.

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21. This Assurance applies to McNeil-PPC, Inc., McNeil Consumer Products Company, and the Arthritis Foundation, together with their subsidiaries, employees, agents, successors and assigns.

22. In any future advertisement for any of the Arthritis Foundation pain reliever products described in paragraph 4, neither McNeil nor the Arthritis Foundation shall:

a. Represent, directly or by implication, that the product is "new."

b. Represent, directly or by implication, that the Arthritis Foundation has "helped to create" the product, or represent that the product is manufactured by or comes from the Arthritis Foundation.

c. Represent, directly or by implication, that the product is recommended by doctors unless: (i) the advertisement clearly and conspicuously discloses that such representation applies to the specific ingredient(s) of the product and not to the product itself, if that is the case; and (ii) McNeil and the Arthritis Foundation possess, at the time any such claim is made, competent and reliable scientific evidence to substantiate the claim.

d. Represent, directly or by implication, that a portion of the proceeds of each purchase will go to the Arthritis Foundation or to fund research to find a cure for arthritis, unless the advertisement: (i) accurately represents the financial terms of the licensing agreement between the Arthritis Foundation and McNeil; or (ii) clearly and conspicuously discloses that McNeil pays the Arthritis Foundation a guaranteed \$1 million each year plus 4% or 5% of net product sales, if sales reach agreed minimum levels. Nothing in this Assurance shall be construed to prevent McNeil or the Arthritis Foundation from truthfully representing in advertisements for Arthritis Foundation Pain Reliever products that the Arthritis Foundation uses the proceeds it receives from McNeil to fund research to find a cure for arthritis, if that is the case.

e. Represent, directly or by implication, that the product is "especially formulated" or contains a different formula than other OTC oral analgesic products, if the product's active ingredients are the same as those found in other OTC analgesic products already cleared for OTC marketing by the United States Food and Drug Administration; provided, however, nothing herein prevents the representation that the

Arthritis Foundation Pain Relievers contain formulas that differ one from another or from advertising that the aspirin is safety coated to reduce stomach irritation.

23. With respect to any advertising for a covered product, McNeil and the Arthritis Foundation shall clearly and conspicuously disclose or cause to be disclosed:

a. That McNeil is the manufacturer or, as applicable, distributor of the product;

b. The active ingredient of the product.

24. In the event that any consumer requests in writing from McNeil or the Arthritis Foundation a refund of the price paid for an Arthritis Foundation Pain Reliever purchased prior to the execution of this Assurance or prior to compliance by McNeil and the Arthritis Foundation with this Assurance, whichever entity received the request shall promptly refund to the consumer the full purchase price of the Arthritis Foundation Pain Reliever. McNeil and/or the Arthritis Foundation may require, as a condition of entitlement to such a refund, that the consumer furnish proof of purchase, which, at the consumer's option, may include either a receipt for the purchase of the product or a writing, signed by the consumer, which states the name of the specific product purchased, the date and place of purchase and the amount paid for the product. If there is a dispute about the amount paid for the product, McNeil or the Arthritis Foundation may refund an amount equal to the product's prevailing retail price in the retail outlet or geographic area in question, as reasonably determined by McNeil or the Arthritis Foundation.

25. McNeil and the Arthritis Foundation shall provide a copy of this Assurance to all officers and employees who have responsibility for developing, placing, or authorizing marketing programs, advertisements, or promotional materials for any covered product.

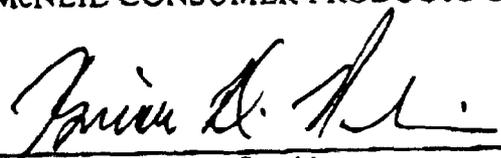
26. No later than 90 days following the execution of this Assurance, McNeil and the Arthritis Foundation shall provide to each of the States a report setting forth in detail the steps McNeil and the Arthritis Foundation have taken to comply with the terms of this Assurance.

27. McNeil agrees to pay directly to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMSD), an agency of the National Institutes of Health (NIH), within ten (10) business days after the execution date of this Assurance, the sum of \$250,000, for the express and sole purpose of conducting or supporting scientific research relating to the detection, diagnosis, treatment and/or prevention of arthritis; provided that such payment shall be restricted so as to preclude its use for payment of administrative expenses of NIAMSD or NIH or for allocating arthritis research grants from such payment by NIAMSD or NIH to either the Arthritis Foundation or McNeil.

28. McNeil agrees to pay to the States, within ten (10) business days after the execution date of this Assurance, the sum of \$90,000 to each of the participating States. Such sum is to be used by the individual States for attorney fees or costs of investigation, or it shall be placed in or applied to the consumer education, litigation, local consumer aid, or revolving account or fund of any of the States or used for consumer protection or education purposes, at the discretion of the Attorneys General as permitted under their respective state laws.

Dated: _____, 1996

McNEIL-PPC, INC. and
McNEIL CONSUMER PRODUCTS COMPANY



Brian D. Perkins, President,
its duly authorized agent

Kathryn A. Meisel 10/1/96
Kathryn A. Meisel, Esquire
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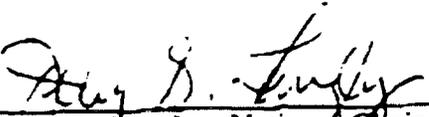
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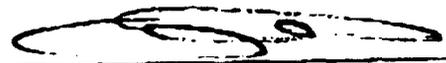
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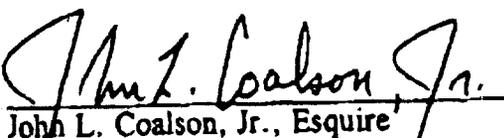
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[States' counterpart signature pages to follow

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