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14 CV 4659

JUDGE CARTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.,

Plaintiff,

v.

MCNEIL-PPC, INC.,

Defendant.

Civil Action No.

Hon. _____, U.S.D.J.

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Pfizer Inc. ("Plaintiff" or "Pfizer"), by and through its attorneys, brings this action for declaratory judgment and alleges against Defendant McNeil-PPC, Inc. ("Defendant" or "McNeil-PPC") as follows:

NATURE OF THE ACTION

1. This is a case about Pfizer's competitor, McNeil-PPC, trying to expand impermissibly the scope of a 25-year-old stipulated court order, which was drafted and agreed to by the parties, regarding Pfizer's **adult** Advil medication in an effort to suppress truthful advertising about **pediatric** Advil products that were not even in existence at the time the order was entered.

2. As a consequence, physicians and consumers are being deprived of useful, truthful advertising information that would permit them to make informed decisions about the best fever and pain relief treatment options available for their pediatric patients.

3. Pfizer markets and sells Advil brand ibuprofen products, which include, among other things, (1) Advil products for ages 12 and over ("Adult Advil"); (2) Children's Advil products for ages 2 to 11[1]; and (3) Infants' Advil for ages 6 to 23 months. McNeil-PPC markets and sells Tylenol brand acetaminophen products, including (1) Tylenol products for ages 12 and over ("Adult Tylenol"); (2) Children's Tylenol for ages 2 to 11; and (3) Infants' Tylenol for ages 4 months to 3 years.

4. Advil is one of the best-selling brands of over-the-counter ("OTC") pain relievers/fever reducers in the United States. Advil products have well-established efficacy and safety profiles and are widely considered safe when used as directed. Tylenol is a competitor in the OTC market.

5. In 1985, shortly after the U.S. Food and Drug Administration ("FDA") approved Adult Advil as an OTC product, McNeil-PPC's predecessor, McNeilab, Inc. (collectively with McNeil-PPC "McNeil"), and Pfizer's predecessor, American Home Products Corp. ("AHP"),

[1] Children's Advil products include Children's Advil suspension, Junior Strength Advil chewable tablets, and Junior Strength Advil swallow tablets.

became involved in a series of legal disputes concerning various advertising claims relating to Adult Tylenol and Adult Advil (the "1980s Litigations").

6. The 1980s Litigations proceeded before Judge William C. Conner and resulted in two consent judgment orders that set forth certain limitations on the types of advertising claims that McNeil and AHP could each make about their respective Adult Tylenol and Adult Advil products. The consent judgment order at issue in this lawsuit limited certain claims AHP could make about the comparative gastrointestinal effects of Adult Advil and Adult Tylenol (the "1989 Order").

7. The 1989 Order did not address any advertising claims concerning Children's Advil or Infants' Advil, or advertising for use of ibuprofen in infants and children under age 12. The reason for that is simple. Children's Advil and Infants' Advil were not available—even by prescription—until after the conclusion of the 1980s Litigations. Indeed, those pediatric products were not even approved by the FDA for OTC sale until **several years** later (1996 for Children's Advil and 1998 for Infants' Advil).

8. Moreover, the FDA would not approve ibuprofen for OTC use in pediatric populations unless safety data from clinical trials studying use in children and infants was provided. Thus, the FDA required both Pfizer's predecessor and McNeil to submit evidence that ibuprofen is safe for pediatric use before approving their respective New Drug Applications for Children's Advil and Children's Motrin (another ibuprofen product), respectively.

9. When the parties negotiated the terms of the Consent Final Judgment that became the 1989 Order, they were dealing with the adult products before them and did not intend the 1989 Order to apply to the pediatric products that are currently before the Court.

10. In short, AHP's advertising of Children's Advil or Infants' Advil was not—and could not have been—at issue in the 1980s Litigations. No discovery was done concerning any pediatric ibuprofen products. McNeil therefore was not required to, and did not, prove that any advertising claims for Children's Advil or Infants' Advil were false or misleading.

11. Because the 1989 Order does not cover Children's Advil and Infants' Advil, the 1989 Order does not address Pfizer's advertising of those pediatric products.

12. In the fall of 2013, Pfizer ran a professional medical journal advertisement for its Infants' Advil product that truthfully stated, among other things, that results from a large study of young children found that ibuprofen, the active ingredient in Infants' Advil, has a "comparable incidence of digestive system adverse events overall" to acetaminophen, the active ingredient in Infants' Tylenol.

13. After the ad appeared, McNeil sent Pfizer a cease-and-desist letter demanding that Pfizer discontinue its truthful advertising campaign to medical professionals, arguing that the 1989 Order precluded Pfizer from claiming that Infants' Advil is "like" or "comparable to" Infants' Tylenol.

14. McNeil is improperly attempting to expand the scope of the 1989 Order to block advertising of Infants' Advil or other ibuprofen products for use in pediatric populations, such as Pfizer's 2013 advertisement for Infants' Advil. No court has ever determined that the claims in the Infants' Advil ad are false.

15. In response to McNeil's cease-and-desist letter and litigation threat, Pfizer decided to discontinue the subject advertisement, but disagreed with McNeil's assertion that the 1989 Order applies to advertising for Infants' Advil or Children's Advil. Pfizer has filed this complaint in order to obtain a judicial declaration regarding the limited scope of the 1989 Order

and make it clear that McNeil cannot use that order and the threat of contempt proceedings to prevent Pfizer's truthful advertising about Infants' Advil and Children's Advil. If McNeil believes Pfizer's advertisements are false or misleading, then McNeil has other avenues for challenging those advertisements without inappropriately relying on the 1989 Order. Pfizer has not run new ads with the comparability claim at issue since McNeil objected and is instead proactively seeking the Court's ruling that McNeil's attempt to expand the 1989 Order is improper.

16. Pfizer therefore seeks a declaratory judgment that, contrary to McNeil's assertions, the 1989 Order does not apply to Children's Advil, Infants' Advil, or other ibuprofen products approved for use in people under the age of 12 (referred to collectively herein as "Pediatric Advil").

THE PARTIES

17. Plaintiff Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017, and is qualified to do business and is doing business in the State of New York and in this judicial district. Pfizer is the successor of AHP, the company that first sold Advil.

18. Upon information and belief, Defendant McNeil-PPC, Inc. is a New Jersey corporation, with offices at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034, and is transacting business in the State of New York and in this judicial district. McNeil markets and sells Tylenol products.

JURISDICTION AND VENUE

19. The Court has jurisdiction over this declaratory judgment action pursuant to the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201(a) and 2202, as well as under 28 U.S.C. § 1331.

20. The Court has personal jurisdiction over Defendant because, upon information and belief, Defendant transacts and solicits business in the State of New York within this judicial district.

21. This Court also has jurisdiction over this action and the parties because the 1989 Order expressly provides that this Court retained jurisdiction over the parties for purposes of enforcing the 1989 Order. Docket No. 60, *McNeilab, Inc. v. Am. Home Prods. Corp.*, No. 87 Civ. 3712 (WCC) (S.D.N.Y. Mar. 31, 1989)

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c).

FACTUAL BACKGROUND

I. THE 1980s LITIGATIONS INVOLVING ADULT ADVIL AND ADULT TYLENOL

23. One of Pfizer's best-known products is Adult Advil, the active ingredient in which is ibuprofen. Ibuprofen is also the active ingredient in Pfizer's Children's Advil and Infants' Advil products.

24. Ibuprofen was first approved for prescription use by adults (*i.e.*, people ages 12 and older) in the United States in 1974. In 1984, the FDA approved ibuprofen for non-prescription (*i.e.*, OTC) use by adults. Soon thereafter, Pfizer's predecessor, AHP, introduced Adult Advil to consumers.

25. Before OTC ibuprofen became available to consumers, the two primary OTC pain relievers on the market were aspirin and acetaminophen. Acetaminophen is the active ingredient in McNeil's Adult Tylenol, Children's Tylenol and Infants' Tylenol.

26. Shortly after Adult Advil launched in 1984, McNeil began running an aggressive advertising campaign disparaging the safety profile of Adult Advil as compared to Adult Tylenol. Consequently, in 1985, AHP filed a complaint against McNeil for false advertising of

Adult Tylenol in the United States District Court for the Southern District of New York, Case No. 85 Civ. 4858 (WCC) (the "1985 Litigation"). McNeil, in turn, filed counterclaims against AHP in the 1985 Litigation, alleging that various advertising claims for Adult Advil were false and misleading.

27. All of the advertisements in the 1985 Litigation concerned OTC analgesic products approved only for use in adults. All of the studies and resulting data presented to the Court during the course of the 1985 Litigation related only to the use of Adult Advil and Adult Tylenol.

28. On February 25, 1987, the Court issued its decision in the 1985 Litigation, ruling that both McNeil and AHP could not make certain advertising claims about Adult Advil and Adult Tylenol. 654 F. Supp. 568 (S.D.N.Y. 1987). Among the many findings in its written opinion, the Court concluded that Adult Advil and Adult Tylenol carry similarly low risks of causing "stomach upset" in consumers, which it referred to as "*subjective* gastrointestinal symptoms of physical discomfort, such as dyspepsia, nausea, flatulence, heartburn and diarrhea." *Id.* at 583. The Court also concluded that acetaminophen poses a lower risk of "*objective* gastrointestinal side effects, such as ulceration, hemorrhage and occult bleeding" than ibuprofen. *Id.* at 584.

29. In 1987, following the Court's decision in the 1985 Litigation, AHP began running consumer television advertisements for Adult Advil that included the statement: "Like Tylenol, Advil doesn't upset my stomach." In May 1987, McNeil filed a lawsuit against AHP, alleging that this Adult Advil television advertising campaign was false and misleading under the Lanham Act (the "1987 Litigation"). All of the advertisements at issue in the 1987 Litigation concerned Adult Advil and did not relate to any pediatric products. At that time, McNeil

marketed and sold Children's Tylenol and Infants' Tylenol, but Children's Advil and Infants' Advil did not exist. In fact, it was not until two years later, in September 1989, that ibuprofen was first approved for use in children under the age of 12—and even then only by prescription.

30. McNeil alleged in the 1987 Litigation that, despite the Court's prior finding that Adult Advil and Adult Tylenol carried comparable risks for stomach upset, many consumers viewing the television ads at issue would take away a broader, implied message that Adult Advil was "like" Adult Tylenol in all respects relating to potential effects on the stomach.

31. On December 1, 1987, the Court in the 1987 Litigation determined that McNeil was likely to meet its burden that the overall impression generated by AHP's television advertising campaign for Adult Advil was false and misleading, and therefore granted McNeil's motion for a preliminary injunction. The parties later negotiated, drafted and agreed to two Consent Final Judgments, one for the 1985 Litigation and a second for the 1987 Litigation. The Court entered both Consent Final Judgments on the same day, March 31, 1989. The second Consent Final Judgment related to the 1987 "stomach upset" litigation and is the 1989 Order at issue here. A true and correct copy of the 1989 Order is attached hereto as Exhibit A.

32. The 1989 Order "permanently enjoined [AHP] from stating in words or substance in any advertisement that ADVIL is 'like TYLENOL' in the respect of adverse effects on the stomach, provided, however, that nothing herein shall be construed as preventing AHP from advertising that ADVIL does not cause stomach upset, without a comparison to TYLENOL." *See* Ex. A, ¶ 1.

II. THE 1989 ORDER WAS ISSUED BEFORE PEDIATRIC IBUPROFEN WAS EVEN AVAILABLE AND THUS DOES NOT APPLY TO CHILDREN'S ADVIL OR INFANTS' ADVIL

33. There can be no dispute that in the 1980s Litigations, including the action giving rise to the 1989 Order, the parties did not present, and the Court did not consider, any

information relating to the use of ibuprofen in, or effects of ibuprofen on, infants and children under the age of 12. Pediatric Advil was not available to consumers—even by prescription—until **after** the 1989 Order was issued.

34. The first AHP ibuprofen product labeled for use by children under age 12 was "Children's Advil Suspension." After Pfizer's predecessor submitted a New Drug Application to the FDA, the FDA approved Children's Advil Suspension for prescription use only on September 19, 1989—almost six months **after** the Order was issued.

35. Children's Advil Suspension was approved by the FDA as a prescription-only drug for the treatment of juvenile rheumatoid arthritis and osteoarthritis. Children's Advil Suspension was also indicated for the reduction of fever for children ages twelve months and older.

36. Several years after the FDA approved Children's Advil Suspension for prescription use, Pfizer's predecessor sought the FDA's approval to sell Children's Advil Suspension on an OTC basis.

37. The FDA approved Children's Advil Suspension for OTC use in children ages 2-11 years in June 1996—more than seven years after the 1989 Order was issued.

38. The FDA approved Infants' Advil for OTC use in children ages 2-3 years in January 1998—nearly nine years after the 1989 Order was issued. (This approval was subsequently modified to relate to children ages 6 to 23 months.)

39. None of the advertisements at issue in the 1980s Litigations concerned pediatric products, and none of the evidence considered by the Court concerned pediatric products, because such advertisements and evidence did not exist. All of the advertisements at issue were

for OTC analgesic products approved only for use in adults (*i.e.*, Adult Advil and Adult Tylenol).

40. The parties negotiating the 1989 Order were dealing with the Adult Advil and Adult Tylenol products before them. The parties did not intend for the 1989 Order to apply to Pediatric Advil. Those products did not yet exist and could not even be sold by prescription until the FDA approved New Drug Applications for the products.

41. Both McNeil and Pfizer were required by the FDA to submit pediatric safety data with their New Drug Applications seeking the OTC approval of pediatric ibuprofen products. McNeil, in support of its New Drug Application for Children's Motrin, conducted and submitted the results from the Boston Fever Study, a double-blind acetaminophen-controlled study conducted between September 1990 and March 1994 in which 84,000 children between 6 months and 12 years old received either acetaminophen or ibuprofen. Similarly, Pfizer's predecessor conducted and submitted the results from the Children's Analgesic Medicine Project (the "CAMP Study"), a multi-center, open-label, all-comers, actual-use study conducted between March 1993 and July 1995 that compared the safety of acetaminophen and ibuprofen in children with fever and pain. The CAMP Study ultimately enrolled over 41,000 children, more than 14,000 of whom were infants under the age of two.

III. McNEIL DEMANDS THAT PFIZER CEASE RUNNING ITS TRUTHFUL MEDICAL PROFESSIONAL ADVERTISEMENT FOR INFANTS' ADVIL

42. In November 2013, Pfizer ran a medical professional advertisement for Infants' Advil in medical journals such as *Pediatric News, AAP News, The Clinical Advisor,* and *Consultant for the Clinician* (the "Infants' Advil Ad"). A true and correct copy of the Infants' Advil Ad is attached hereto as Exhibit B.

43. The Infants' Advil Ad stated, among other things, that "Results from a large actual-use trial including infants and toddlers (n=14,281) [showed that] Ibuprofen: The active ingredient in Infants' Advil (n=7381) [has a] COMPARABLE incidence of digestive system adverse events overall [to] Acetaminophen: The active ingredient in Infants' Tylenol (n=6900)." Pfizer cited to the CAMP Study to support its claim.

44. On November 22, 2013, McNeil sent a cease-and-desist letter to Pfizer, demanding that the Infants' Advil Ad "be immediately discontinued" because the 1989 Order bars Pfizer from claiming that Advil is "'like Tylenol' in respect to adverse effects on the stomach." A true and correct copy of McNeil's November 22, 2013 letter is attached hereto as Exhibit C.

45. On December 6, 2013, Pfizer responded to McNeil, strongly disagreeing with McNeil's position. Pfizer set forth that:

- "[T]he 1989 Order was entered based on a dispute over the relative safety profiles of Advil® and Tylenol® in adults, not children."
- "Infants' Advil was not available in 1989."
- "The Court could not have intended for the 1989 Order to apply to the Advertisement because Infants' Advil was not approved by the FDA until 1998, almost a decade after entry of the 1989 Order."
- "[I]buprofen was not even available by prescription for use in children under age 12 prior to 1989."
- "[T]he Court did not and could not have considered evidence of ibuprofen's safety profile in this population."

- "[I]t is not reasonable to conclude that the Court would have intended for the Order to apply to pediatric products."

46. Pfizer nevertheless stated that it would discontinue use of the comparative claim at issue. Pfizer notified McNeil that "[w]e will continue to consider your position on the applicability of the 1989 Order and reserve all our rights with regard to that issue." A true and correct copy of Pfizer's December 6, 2013 letter is attached hereto as Exhibit D.

47. In the face of McNeil's demand, Pfizer has decided that it has no other choice but to bring the current action to confirm the scope of the 1989 Order. In the meantime, Pfizer has not disseminated ads with the comparability claim at issue. However, Pfizer wants to be able to provide truthful information to doctors and consumers and to provide them with accurate scientific information about the efficacy and safety of Pediatric Advil. While McNeil may wish to silence Pfizer about these scientific truths, it cannot misuse the 1989 Order to try to stop informative communications.

48. Pfizer therefore seeks a declaration from this Court that the 1989 Order does not apply to Pediatric Advil.

COUNT I

DECLARATORY JUDGMENT (28 U.S.C. § 2201 *et seq.*)

49. Pfizer repeats and incorporates herein by reference each and every one of the allegations contained in the foregoing paragraphs of this complaint with the same force and effect as if herein again set forth in full.

50. Pfizer seeks a declaration from this Court that Pfizer's Pediatric Advil products (including Children's Advil and Infant's Advil) are not subject to the 1989 Order—namely, the Consent Final Judgment dated March 31, 1989 in Case No. 87 Civ. 3712.

51. Pediatric Advil did not exist at the time of the 1989 Order. Indeed, the 1989 Order was issued on March 31, 1989, nearly six months before the first Pediatric Advil product was approved by the FDA for prescription use by children, and years before the first Pediatric Advil product became available to consumers on an over-the-counter basis for use by children and infants.

52. The 1987 Litigation between AHP and McNeil related to advertising for, and relied upon conclusions based upon clinical data derived from use of, Adult Advil and Adult Tylenol-brand products in adult populations only.

53. There was no information before the Court in the prior litigation about the use of ibuprofen in pediatric populations.

54. For the foregoing reasons, the 1989 Order does not apply to Pediatric Advil, and McNeil should not be permitted to use that order to block truthful advertising about Pediatric Advil.

PRAYER FOR RELIEF

WHEREFORE, Pfizer prays for a declaration as follows:

A. The Consent Final Judgment dated March 31, 1989 in Case No. 87 Civ. 3712 does not apply to Pfizer's Pediatric Advil products (including Children's Advil and Infant's Advil); and

B. Pfizer may have such other and further relief as the Court may deem just and proper.

Dated: New York, New York
June 25, 2014

Respectfully submitted by:

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Attorneys for Plaintiff
PFIZER INC.

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

McNEILAB, INC.,

Plaintiff,

- against -

AMERICAN HOME PRODUCTS CORPORATION,

Defendant.

87 Civ. 3712 (WCC)

CONSENT FINAL JUDGMENT

CONNER, D.J.

IT IS ORDERED, in accordance with this Court's Opinion and Order dated December 1, 1987, and pursuant to the agreement and consent of the parties, that

1. Defendant, its agents, servants, officers and all those in privity with it, are permanently enjoined from stating in words or substance in any advertisement that ADVIL is "like TYLENOL" in the respect of adverse effects on the stomach, provided, however, that nothing herein shall be construed as preventing defendant from advertising that ADVIL does not cause stomach upset, without a comparison to TYLENOL.

2. Except as set forth in this Consent Final Judgment, all claims of violation of the Lanham Act or

of state law are dismissed with prejudice. All claims for damages, attorneys' fees, and costs are likewise dismissed with prejudice.

3. The Court shall retain jurisdiction for purposes of enforcing the injunctions contained in this Consent Final Judgment.

DATED: NEW YORK, NEW YORK
MARCH 31, 1989

William C. Conner
United States District Judge

Dated: New York, New York
March 30, 1989

CONSENTED TO:

ARNOLD & PORTER

By: _____
A Member of the Firm

Attorneys for Plaintiff

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New York, New York
Telephone: (212) 750-5050

PATTERSON, BELKNAP, WEBB & TYLER

By: _____
A Member of the Firm

Attorneys for Defendant

30 Rockefeller Plaza
New York, New York 10112
Telephone: (212) 698-2500

THIS DOCUMENT WAS ENTERED

Exhibit B

It's time to reassess gentle infants' fever relief…

Infants' Advil®

Unsurpassed fever relief that baby can stomach[1,2]

- Nothing works **faster***[1]
- Nothing keeps fever down **longer**†[1]
- **Gentle** on baby's stomach[2]

Results from a large actual-use trial including infants and toddlers (n=14,281)‡[2]

Ibuprofen: The active ingredient in Infants' Advil® (n=7381)

COMPARABLE incidence of digestive system adverse events overall§

Acetaminophen: The active ingredient in Infants' Tylenol® (n=6900)

Learn more at **Advil**Aide.com/CA

Recommend Infants' Advil® first-line starting at 6 months and 12 pounds.

For fever relief that's safe and effective when used as directed.

Use as directed.

Relief you can trust

* Based on reducing fever below 100°F.
† Among leading over-the-counter pain relievers/fever reducers.
‡ Less than 2 years old.
§ No statistically significant difference between ibuprofen and acetaminophen in children under 2 years of age.

References: 1. Kelley MT, Walson PD, Edge JH, Cox S, Mortensen ME. Pharmacokinetics and pharmacodynamics of ibuprofen isomers and acetaminophen in febrile children. *Clin Pharmacol Ther*. 1992;52(2):181-189. **2.** Ashraf E, Ford L, Geetha R, Cooper S. Safety profile of ibuprofen suspension in young children. *Inflammopharmacology*. 1999;7(3):219-225.

Pfizer Consumer Healthcare

Exhibit C

McNeil
Consumer Healthcare

Robert Pineda
Senior Counsel

Tel: 215-273-8145
Fax: 215-273-4293
E-mail: RPineda@its.jnj.com

November 22, 2013

By Email and FedEx

Larry Miller
Chief Counsel
Pfizer Consumer Healthcare
Five Giralda Farms
Madison, New Jersey 07940

Re: Stomach Safety Claims For Infants' Advil®

Dear Mr. Miller:

Per the recent communications you have exchanged with Elizabeth Forminard, I am sending this letter on behalf of the McNeil Consumer Healthcare Division of McNeil-PPC ("McNeil"). As you know, McNeil makes TYLENOL® brand acetaminophen products, including Infants' TYLENOL®.

Pfizer is currently running an ad for Infants' Advil® that claims that (1) ibuprofen is "comparable to" acetaminophen in terms of gastrointestinal (GI) side effects, and (2) ibuprofen is "gentle on the stomach." A copy of the ad, which appears in the October 2013 issues of Pediatric News, AAP News, The Clinical Advisor, and Consultant for the Clinician, is enclosed as Exhibit A. These claims are false, and we request that they be immediately discontinued.

Pfizer's Advertising

The disputed ad asks doctors to recommend Infants' Advil® as their first-line antipyretic for infants. Infants' TYLENOL® is referenced in the ad by name, and the headline states that "it's time" for physicians to "reassess gentle infants' fever relief." Below that headline, the ad lists reasons that supposedly warrant this clinical reassessment. The ad states, among other things, that Infants' Advil® delivers "unsurpassed fever relief that baby can stomach," is "Gentle on baby's stomach," and has "COMPARABLE incidence of digestive system adverse events overall" as compared to Infants' TYLENOL®. Each one of these claims is false.

Comparative GI Safety Claim

Pfizer is under a permanent injunction that bars it from stating in words or substance that Advil® products are "like Tylenol" in respect to adverse effects on the stomach. This injunction has been in place since 1989 when McNeil successfully sued Pfizer's predecessor (American Home Products or "AHP") over ads that falsely claimed that ibuprofen is similar to acetaminophen in terms of GI effects. See American Home Prods. Corp. v. Johnson & Johnson, 654 F. Supp. 568, 576-77 (S.D.N.Y. 1987) ("Advil I"); McNeilab, Inc. v. American Home Prods. Corp., 675 F. Supp. 819, 825-26 (S.D.N.Y. 1987), aff'd, 848 F.2d 34 (2d Cir. 1988) ("Advil II").

The comparative GI safety claim in Pfizer's current ad clearly states, in words and substance, that Advil® is like TYLENOL® in terms of adverse effects on the stomach. Indeed, the ad

includes a literal claim that the overall adverse events on the digestive system caused by Infants' Advil® are "comparable" to Infants' TYLENOL®. Such claims are contrary to the letter and the spirit of the 1989 Consent Final Judgment.

The propensity of ibuprofen to cause adverse stomach effects is well-established and stems from its mechanism of action, which suppresses certain prostaglandins that help to protect the GI tract from damage. Indeed, for precisely this reason, FDA in 2009 mandated stomach-specific warnings on all ibuprofen products. Thus, like other Advil® products, the Infants' Advil® label warns that the product "may cause severe stomach bleeding." Infants' TYLENOL® does not carry this, or any other, stomach warning.

Since Pfizer is legally enjoined from making comparative GI safety claims versus acetaminophen, we need not address the limitations of the scientific study on which Pfizer's current claim is reportedly based. See Ashraf, E., et al., Safety profile of ibuprofen suspension in young children, Inflammopharmacology, Vol. 7, No. 3, pp. 219-225 (1999). Nevertheless, it is noteworthy that the incidence of overall adverse GI events for young children in the study, in fact, was higher among ibuprofen patients versus acetaminophen patients, even if that difference was not statistically significant. Moreover, children taking ibuprofen suffered abdominal pain at a statistically significant higher rate than children taking acetaminophen.

Gentle on the Stomach

McNeil also has serious concerns about Pfizer's "gentle on baby's stomach" claim. As noted above, the Infants' Advil® label expressly warns parents and physicians that the product may cause "severe" stomach bleeding. No product that causes severe stomach bleeding at recommended label doses can fairly or accurately be described as "gentle" on the stomach. Pfizer should not promote its products with claims that contradict or dissuade consumers from heeding mandatory label warnings. Your current ad for Infants' Advil® does just that.

Conclusion

Last year, McNeil protested a similar advertisement by Pfizer directed to doctors. A courtesy copy of that protest letter is enclosed. That advertisement, like the Infants' Advil® ad that Pfizer is currently running, falsely claimed that Advil® products are comparable to acetaminophen in terms of adverse effects on the GI tract. In response to our protest letter, Pfizer represented that "so long as the 1989 Consent Final Judgment remains in place" Pfizer "will not make" unsubstantiated comparative GI safety claims. It is extremely disappointing that Pfizer has already gone back on that promise.

In any event, McNeil requests that Pfizer immediately retract advertisements for Infants' Advil® that claim that ibuprofen is comparable to acetaminophen in terms of adverse GI effects and that Infants' Advil® is gentle on the stomach. I would appreciate if you would advise me or Liz of Pfizer's intentions with respect to this advertising by the close of business on Wednesday, December 4, 2013.

Sincerely

Robert Pineda

cc: Liz Forminard, General Counsel
Consumer Group

Enclosures - Exhibit A

Exhibit A

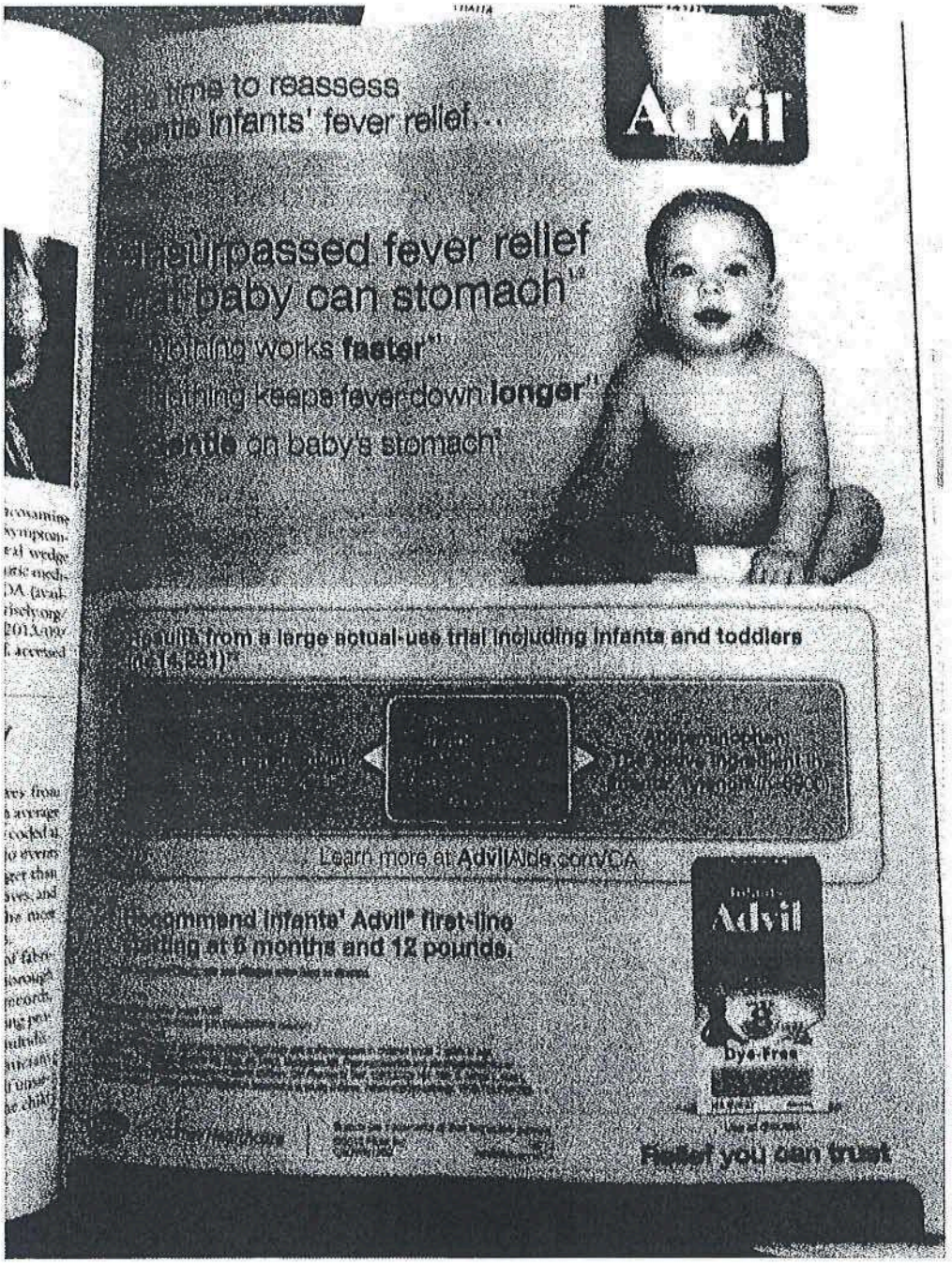
Advil
to reassess
infants' fever relief...
surpassed fever relief
baby can stomach"
works faster"
keeps fever down longer"
on baby's stomach"
results from a large actual-use trial including infants and toddlers
Learn more at AdvilAids.com/CA
recommend Infants' Advil® first-line
at 6 months and 12 pounds.
Advil
Dye-Free
Relief you can trust

Exhibit D

Pfizer Inc
Five Giralda Farms
Madison, New Jersey 07940
Tel: 973-660-6530
Fax: 973-660-8239
david.m.moss@pfizer.com

Legal Division
David M. Moss
Assistant General Counsel
Pfizer Consumer Healthcare

December 6, 2013

VIA E-MAIL AND FEDEX

Robert Pineda, Esq.
McNeil Consumer Healthcare
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Re: Infants' Advil® Medical Professional Advertisement

Dear Robert:

I write on behalf of Pfizer Consumer Healthcare ("PCH") in response to your November 22, 2013 letter (the "Letter"), which objects to certain statements in a recent medical professional advertisement for Infants' Advil (the "Advertisement"). Specifically, the Letter takes issue with two statements in the Advertisement: first, the comparative claim that "a large actual-use trial including infants and toddlers" found a "comparable incidence of digestive system adverse events overall" as between ibuprofen and acetaminophen; and second, the monadic claim that Infants' Advil is "gentle on baby's stomach." While the Letter makes the conclusory statement that these claims are "false," no evidence is submitted in support of this allegation.

The 1989 Court Order Does Not Apply to Infants' Advil

Lacking evidence that the claims in the Advertisement are false, the Letter instead relies almost exclusively on the argument that a 1989 Consent Final Judgment (the "1989 Order") bars PCH from claiming that Infants' Advil is "gentle on baby's stomach" and has a "comparable incidence of digestive system adverse events overall." But the Letter's repeated references to the 1989 Order cannot overcome the fact that the 1989 Order was entered based on a dispute over the relative safety profiles of Advil® and Tylenol® in adults, not children. Indeed, the Letter misstates the clear terms of the 1989 Order by claiming that it bars PCH from claiming "that Advil products are 'like Tylenol'" (emphasis added). That is simply not true. The 1989 Order does not refer to all Advil-brand "products"—nor could it have, given that Infants' Advil was not available in 1989. Instead, the 1989 Order only precludes PCH from stating "that Advil is 'like

Tylenol' in respect of adverse effects on the stomach." McNeil's attempt to expand the 1989 Order is improper.

The Court could not have intended for the 1989 Order to apply to the Advertisement because Infants' Advil was not approved by the FDA until 1998, almost a decade after entry of the 1989 Order. Indeed, ibuprofen was not even available by prescription for use in children under age 12 prior to 1989. Consequently, the Court did not and could not have considered evidence of ibuprofen's safety profile in this population, and it is not reasonable to conclude that the Court would have intended for the Order to apply to pediatric products. As described below, scientific evidence reported after the 1989 Order demonstrates that, in fact, when used in children, ibuprofen and acetaminophen carry comparable risk profiles with respect to the digestive system.

It is also worth noting that, when it comes to the monadic "gentle on baby's stomach" claim in the Advertisement, the Letter does not even allege that it is barred by the 1989 Order. This is understandable given that, even if the 1989 Order did apply to Infants' Advil, the order specifically found that PCH could make a monadic claim that Advil does not cause stomach upset.

The Advertisement is Truthful and Not Misleading

PCH strongly disagrees with the Letter's summary assertion that the statements at issue in the Advertisement are false. To the contrary, all of the claims in the Advertisement are fully substantiated with competent and reliable scientific evidence. The Ashraf study, which is the referenced support for both of the claims at issue, was a national, multi-center, prospective actual-use study designed to compare the safety of acetaminophen and ibuprofen in children with fever and pain. The study ultimately enrolled over 41,000 children, more than 14,000 of whom were children under the age of two. As endpoints to compare the safety profiles of the two drugs, the study looked at the incidence of numerous categories of adverse events, including digestive system adverse events. In children under the age of two, the incidence of any digestive system adverse events for each of the drugs was very low. Moreover, the difference between the drugs was marginal and generated a p-value of 0.495, which was nowhere near the threshold of ≤ 0.05 required to demonstrate statistical significance.

The Ashraf study results on overall digestive system adverse events in children under the age of two are precisely and accurately reflected in the Advertisement. The Advertisement makes clear that the comparison is based on the subset of infants and toddlers under the age of two, and further refers to results as showing "comparable" digestive system adverse events overall (with a footnote underscoring that the difference between the two drugs was not statistically significant). Indeed, the Letter acknowledges the lack of a statistically significant difference on overall digestive system adverse events.

Likewise, the claim "gentle on baby's stomach," a monadic claim appearing separately from the comparative claim regarding the incidence of digestive system adverse events, is well-supported by the Ashraf study. The Ashraf study found a low incidence of digestive system

adverse events in children under the age of two that had taken ibuprofen. The Letter completely mischaracterizes the Advertisement—which is a medical professional advertisement appearing in medical journals—by referring to the stomach bleeding class labeling for NSAIDs. The Advertisement does nothing to contradict class labeling for NSAIDs, and instead provides doctors with information they can use to best treat their patients. Doctors, not consumers, are the audience for the Advertisement, and as well-trained medical professionals, they are entirely capable of understanding the difference between rare instances of stomach bleeding as described on the NSAID class labeling, and the very low incidence of subjective stomach discomfort reflected in the study results on overall digestive system adverse events. The Advertisement offers important scientific information to doctors on the rates of subjective side effects of ibuprofen and acetaminophen in infants—information that is critical for doctors to have when recommending a fever reducer for young children. It is disappointing that McNeil seeks to prevent PCH from making this information available to healthcare professionals.

The Ashraf study findings are consistent with other scientific literature concluding that both acetaminophen and ibuprofen carry a very low risk of any adverse events, and that there is no significant difference between acetaminophen and ibuprofen on the digestive system when used in children. This includes the McNeil-sponsored Boston Fever Study (Lesko, 1995), which found no statistically significant difference between ibuprofen and acetaminophen in the incidence of gastrointestinal adverse effects.

Resolution of the 2012 Advil Advertisement was Limited to the Statement at Issue

Perhaps as an acknowledgement of the weakness of McNeil's position on the merits, the Letter resorts to taking out of context a representation made by PCH to resolve a dispute regarding an Advil advertisement in 2012. That dispute centered on the following single statement in an adult Advil medical journal ad: "In a study by Moore et al, GI tolerability of OTC ibuprofen was at least as favorable as acetaminophen during 7-day therapy." McNeil argued that this statement was contrary to the 1989 Order. In response, while maintaining that the statement did not violate the 1989 Order and was otherwise well-substantiated, in order to resolve the dispute PCH agreed to discontinue that particular claim about Advil. But rather than attaching the correspondence, the Letter describes PCH's commitment as follows: "Pfizer represented that 'so long as the 1989 Consent Final Judgment remains in place' Pfizer 'will not make' unsubstantiated comparative GI safety claims." To the contrary, the letter actually stated: "so long as the 1989 Consent Final Judgment remains in place, [PCH] will not make the challenged statement in future advertisements" (emphasis added). As with the Letter's attempts to re-write the 1989 Order to broaden its scope, the effort to revise PCH's commitment through creative excerpts merely underscores that, in this dispute, McNeil simply has overreached.

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For all of the above reasons, we disagree with McNeil's assertions that the claims at issue in the recent Infants' Advil professional advertisement are false or contrary to the 1989 Order. Despite our disagreement with your position, other than medical professional advertisements in

December that are too late to withdraw, we will discontinue use of the comparative claim. We will continue to consider your position on the applicability of the 1989 Order and reserve all our rights with regard to that issue. As for the claim "gentle on baby's stomach," however, please be advised that PCH will continue to use that claim, which as noted above is both substantiated and undisputedly consistent with the 1989 Order.

Sincerely,

David M. Moss