NARB PANEL #307 – Jan. 30, 2023

Appeal of NAD's Final Decision #7108 Regarding Claims for Genexa Inc., OTC Kids' Pain & Fever Medicine

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REPORT OF NARB PANEL 307

Decision Issued: Jan. 30, 2022

Appeal of NAD's Final Decision #7108 Regarding Claims for Genexa Inc., OTC Kids' Pain & Fever Medicine

Genexa Inc. ("Genexa"), the advertiser, manufactures an acetaminophen-based children's analgesic sold as "Kid's Pain & Fever." The challenger is Johnson & Johnson Consumer, Inc., McNeil Healthcare Division ("McNeil"), the manufacturer of "Children's TYLENOL Pain & Fever Oral Suspension" ("Children's Tylenol").

While the active ingredient in both medications (acetaminophen) is the same, Genexa has disseminated superiority claims for Kids' Pain & Fever compared to competing brands (including Children's Tylenol) based on asserted advantages attributable to its product's **inactive** ingredients. For example, Genexa promotes its product as preferred by pediatricians over Children's Tylenol "for their own children based upon comparing the ingredients."

McNeil challenged at the National Advertising Division ("NAD") nine express and three allegedly implied claims being disseminated for the Genexa product. See NAD Case #7108 (10/27/2022). NAD recommended that all 12 claims be discontinued or modified, and Genexa sought review of NAD's decision and recommendations by a panel of the National Advertising Review Board ("NARB"). There is no cross-appeal.

A. Background

Genexa asserts that it is the first and only OTC medicine company that uses only natural (not artificial) inactive ingredients in its products. Thus, the inactive ingredients in Kid's Pain & Fever are all natural, not artificial. The advertiser argues that this is a point of difference between its children's analgesic product and competitive products that is of interest to many consumers.

Children's Tylenol has been on the market for over 60 years. McNeil argues that certain of the challenged ingredient claims imply that Children's Tylenol contains unhealthy or unwholesome ingredients. These claims are unsupported, McNeil argues, because the challenger's medication "is an established OTC monograph product, including inactive ingredients generally recognized as safe and thus considered lawfully marketed by the FDA." See NAD Decision at 9. The advertiser, however, citing literature references, argues that artificial inactive ingredients do present health risks to some categories of consumers.

In support of its claim that pediatricians prefer Kid's Pain & Fever, the advertiser relies on a survey that sought to determine pediatrician preferences based solely on comparing the ingredients in the

advertiser's product with ingredients in the various flavors of Children's Tylenol. In the survey, a national sample of 301 pediatricians (who indicated that they lived with children ages 2-11) were shown images of the Kid's Pain & Fever and five flavors of Children's Tylenol, as well as a listing of the ingredients from each product taken from website disclosures. The survey participants were then asked to indicate, based solely on their review of the ingredients in each product, which they would "prefer to give to [their] own children ages 2-11 to relieve their pain or reduce their fever." The results in the survey favored the advertiser's product by 68.1% to 26.3%, a statistically significant difference.

McNeil has not challenged the survey design or methodology. Rather, it argued to NAD (and argues on appeal) that the survey results do not support the claim, i.e., were not a "good fit" for the advertiser's pediatricians prefer claim, because the survey did not measure actual practice, i.e., whether the surveyed physicians actually gave Kid's Pain & Fever to their own children and/or recommended the medication to their patients.

B. Challenged Claims/NAD's Conclusions

Set forth below are the twelve challenged claims (see NAD Decision at 1-2), with a brief summary of NAD's analysis and recommendations as to each. (Given the absence of consumer perception evidence, NAD determined the reasonable messages that were conveyed by the challenged claims.)

1. Express Claims:

   i) Pediatrician Claims

   - **"Pediatricians prefer Genexa's Kids' Pain & Fever over Children's TYLENOL Pain + Fever liquid products for their own children based upon comparing the ingredients."**

NAD concluded that the pediatricians prefer claim conveyed the message that doctors recommend Kid's Pain & Fever to their patients and that they give the product to their own children. The advertiser's survey, however, did not measure actual physician conduct, and therefore, according to NAD, did not support the pediatricians prefer claim. NAD recommended that the claim be discontinued, or modified "to make clear that the surveyed pediatricians expressed a preference only as to 'ingredients.'" NAD Decision at 16.

   - **"The doctors have spoken."**

NAD's analysis of "the doctors have spoken" claim was similar to its analysis of the pediatricians prefer claim. NAD concluded that the "doctors have spoken" claim communicated the implied

message that pediatricians recommend the advertiser's product to their patients. NAD recommended that this claim be discontinued, or modified "to make clear that the surveyed pediatricians expressed a preference only as to 'ingredients.'" NAD Decision at 16.

ii) The Ingredient Claims

With respect to the ingredient claims, the advertiser argued to NAD that they were "true" and "meaningful to consumers." See NAD Decision at 9. NAD, however, concluded that the challenged ingredient claims "reasonably imply that other products are unsafe or pose potential risks or dangers." NAD Decision at 11.

- **"When we looked around the medicine aisle, we found something that made us sick."**

The advertiser argued that the "made us sick" claim was puffery because it expressed the opinion of the company's founders and could not be measured or quantified. NAD, however, concluded that in the context of the advertising in which it appeared, the claim "references specific attributes of competing OTC medications and reasonably communicates that Genexa's product is comparatively better in a recognizable or measurable way and that it is reasonable for consumers to take away the message that there is something undesirable about competing medicines like Children's Tylenol." NAD Decision at 15.

NAD recommended that, in the context in which it appeared, the "made us sick" claim be discontinued. NAD concluded that "[t]here is no evidence in the record to support the claim that the ingredients in competitors' products are unsafe, harmful, or dangerous." NAD Decision at 13.

- **"Your kid's pain medicine shouldn't give you a headache."**

The advertiser also argued that the "give you a headache" claim constituted puffery, and that consumers would recognize that the reference to a "headache" should not be taken literally. NAD, however, concluded that, in the context in which it was used, the "headache" claim conveyed a comparative message to the effect that the ingredients in the advertiser's medicine are superior and that competitor's products are dangerous, harmful, or unsafe. NAD recommended that, in the context in which it appeared, this claim be discontinued.

- **Genexa Kids' is "MADE WITH REAL INGREDIENTS" in contrast to competing children's OTC medicines.**

NAD recommended that, in the context of the commercial in which the "real ingredients" claim

appeared,[1] the claim communicated that "competitor's formulations contain ingredients that are dangerous, harmful, or unsafe" and should be discontinued in the context in which it appeared. See NAD Decision at 13. NAD further recommended that the advertiser "avoid conveying the message that competing products with different inactive ingredients are generally unsafe, harmful or dangerous." Id. at 14. Assuming compliance with these standards, NAD concluded that the advertiser was free to highlight in advertising the "real ingredients" in its product. Id.

- **"PARABENS is stuff you'll find in ALL PURPOSE CLEANER. And, for some reason, in kids' fever medicine."**

The advertiser defended its parabens claim by arguing inter alia that it was literally true. NAD concluded that the claim communicated that inactive ingredients in competitive products are dangerous or unsafe, and recommended that the claim be discontinued. See NAD Decision at 11.

- **"Un-Fun Fact: Red dye no. 40 is made from petroleum."**

As with the parabens claim discussed above, NAD concluded that the red dye claim conveyed the message that competitive products used ingredients that are dangerous or unsafe, and recommended discontinuance.

- **Propylene Glycol is "ALSO FOUND IN ANTIFREEZE."**

Applying an analysis similar to the analyses of the claims containing references to parabens and red dye, NAD recommended that the propylene glycol claim be discontinued.

- **"Things that shouldn't exist," accompanied by a list of OTC medicine ingredients, including "all artificial dyes in medicine" and "parabens in medicine," interspersed with phrases like "showers that make you dirty" and "food that makes you hungry."**

Analyzing the "things that shouldn't exist" advertisement, NAD rejected the advertiser's argument that the references to ingredients in competitive products were puffery. Rather, NAD concluded that one reasonable message conveyed by the claim is that the Genexa product is superior to competitive products and further that competitive products are dangerous, harmful, or unsafe. NAD Decision at 16. NAD specifically noted that the challenged language referred to the ingredients in competitors' products as "things that shouldn't exist." NAD recommended that the interspersed ingredient claims be discontinued "in the context in which they appear in the challenged advertisement."

[1] The claim appeared in a commercial that was no longer running. See NAD Decision at 2, n. 1. The withdrawn commercial is described at NAD Decision at 12-13.

2. Implied Claims:

- **Pediatricians recommend Genexa Kids' in their daily practice.**

NAD found that the challenged "pediatricians recommend" implied claim was communicated by the challenged advertising, and further that there was no support for the claim. NAD recommended that "the Advertiser avoid stating or implying, in the absence of supporting evidence, that pediatricians use the Advertiser's product over the Challenger's products in their practices." NAD Decision at 8.

- **Pediatricians use Genexa Kids' to treat their own children's fevers and headaches.**

NAD found that this "pediatricians use" implied claim was communicated by the challenged advertising and recommended that this claim be discontinued "in the absence of supporting evidence." As with the "daily practice" claim discussed above, NAD found that there was no support for this implied claim.

- **Children's TYLENOL and other competing OTC medicines contain inactive ingredients that are harmful for human consumption and for children.**

NAD found that this "harmful ingredient" implied claim was communicated by Genexa's advertising. NAD recommended that the claim be discontinued and that the advertiser "avoid conveying the message that competing products with different inactive ingredients are generally unsafe, harmful, or dangerous." NAD Decision at 17.

C. The Advertiser's Arguments on Appeal

In support of its appeal, Genexa argues that the core value proposition of its brand is that it offers to consumers clean but effective medicine without the artificial inactive ingredients that many consumers seek to avoid. It argues that its ingredient claims are an essential, and a proper, means of communicating to consumers its brand point-of-difference. It also argues that its ingredient claims are literally true, and that this is not disputed.

Genexa maintains that a number of its claims, such as the ones with references to finding something that "made us sick" or gave a consumer "a headache" are puffery, in that they can't be quantified and/or represent expressions of opinion of the founders of the company.

As concerns the claim "Made from Real Ingredients," Genexa argues that it is factually true. It further argues that the claim is "inherently monadic" and therefore NAD should not have

concluded that it communicated a superiority message, even in context. The advertiser also argues that no reasonable consumer would interpret the Made from Real Ingredients claim as communicating that Children's Tylenol is "dangerous, harmful, or unsafe," given the latter product's prominent presence on the market for many decades. Finally, Genexa argues that because the advertisement analyzed by NAD had been withdrawn, NAD should not have evaluated the Made From Real Ingredients claim in that context.

Further defending its ingredient claims, Genexa argues that all comparative advertising conveys a message that competitive products are "undesirable," and that the allegedly implied messages that competitor products are "harmful" or "dangerous" are not defensible interpretations of the challenged ingredient claims. Citing standards applied to consumer perception studies to determine whether a surveyed claim misleads consumers, Genexa contends that NAD misapplied the well-established "reasonable consumer" standard in finding implied health-risk messages directed at competitive products. Alternatively, the advertiser argues that the record includes studies demonstrating that artificial inactive ingredients in competitor products can lead to health issues for certain categories of individuals.

Turning to the pediatricians prefer claim, Genexa principally argues that NAD misinterpreted the claim language in finding that the claim conveys implied messages regarding doctor practices. The advertiser asserts that its survey in fact directly supports the pediatricians prefer claim because the claim is properly qualified with the phrase "based upon comparing the ingredients." Genexa argues that NAD ignored the quoted qualifying phrase notwithstanding the phrase's prominence.

D. The Challenger's Arguments In Support of the NAD Decision

In responding to the advertiser, the challenger makes the following arguments, among others:

- The challenger contends that the ingredient claims cross the line from truthful comparative advertising to denigrating claims that are false and unsubstantiated.

- As concerns Genexa's claim that inactive ingredients in competitive products can elicit adverse reactions in certain individuals, McNeil argues that all of the inactive ingredients in Children's Tylenol (and in other competitive medications as well), given their GRAS (generally recognized as safe) status, have been shown to be safe in the general population, and only may present concerns for individuals with special medical conditions such as lactose intolerance.

- McNeil argues that the advertiser's puffery position in defense of certain of the advertiser's ingredient claims is not credible because the claims are conveying messages denigrating the safety of FDA-approved ingredients in competitive children's

analgesic products.

- In response to the argument by Genexa that reasonable consumers will not interpret its ingredient claims as conveying that Children's Tylenol products are unsafe because McNeil's product has been on the market for years, the challenger contends (among other arguments) that Genexa contradicts itself when it argues in support of the same claims that the safety assessment of inactive ingredients can change over time with new scientific evaluations.

- McNeil argues that the pediatricians prefer claim is not supported by the survey because (i) the survey did not measure actual pediatrician conduct, whereas (ii) NAD has long recognized that physician recommendation or preference claims hold tremendous sway over consumers and should be supported with highly reliable evidence that reflects actual physician experience and daily practice.

- McNeil argues that NAD's analysis of the pediatricians prefer claim was correct in that the claim is not qualified by the ending phrase "based upon comparing the ingredients." Rather, as NAD found, that clause (according to the challenger) simply offers a reason for the alleged preference by pediatricians, and therefore does not limit the claim as asserted by Genexa to an analysis of ingredients only.

E. Discussion

The panel will begin its analysis of the issues with the study published in 2019 entitled "Inactive Ingredients in Oral Medications" (see NAD Decision at 2, n. 3), cited by the advertiser to support any implied claims communicating that there are health risks from the consumption of competitive children's medication products due to their inactive ingredients. The panel concludes that this article does not provide the advertiser with support for any such implied claim. It is not disputed that the inactive ingredients in the competing children's pain and fever medications, in the concentration included in these formulas, have been approved for use by the Food and Drug Administration and found to be generally recognized as safe.

The advertiser also argues that future scientific analyses may determine that there are risks from the use of the inactive ingredients. However, the panel agrees with the challenger's view that this is speculation that does not constitute proper support for an implied claim that such ingredients are unsafe, harmful, or dangerous.

With this preliminary issue addressed, the remainder of the issues concerning Genexa's ingredient claims principally depend on an assessment of the consumer communication, i.e., whether the challenged advertising conveys the message that the inactive ingredients in competitive products

are unsafe, harmful, or dangerous. As recognized by NAD and is well-accepted, the context in which claims are made contribute to the message consumers take away from an ad.

After carefully reviewing the arguments of the parties and the challenged advertising, the panel concludes that NAD's conclusions and recommendations concerning the challenged ingredient claims should be affirmed. Key points in the panel's analysis are set forth below:

With respect to the "made us sick" claim, the advertiser as noted argues that the claim should be considered puffery as the expression of the opinion of the Genexa founders, and therefore cannot be measured or quantified. The panel, however, agrees with NAD that one message communicated by the claim to reasonable consumers is that there are health risks associated with the inactive ingredients in competing medications. The panel finds that "made us sick" is strong and inflammatory language when used in the context of medicines for children, and conveys a message that disparages competitive products and associates them with health risks.

The "give you a headache" claim is not puffery in part because it is not presented as expressing the views of Genexa's founders. The claim, moreover, appears in a commercial (described by NAD in its Decision at 12-13) that includes representing competitor products as "THE OTHER GUYS," referring to a competitive inactive ingredient as "whatever this is," having a Genexa-branded bottle "knocking over" the bottle labelled "THE OTHER GUYS," and a depiction of the inactive ingredients in competitive products in a laboratory setting which includes a smoking beaker. In this context, the "headache" message communicates a concern over safety.

Turning to the "Made with Real Ingredients" claim, the panel notes at the outset that NAD concluded that the claim could be used in a proper context, specifically one not conveying a message that inactive ingredients in competitive children's medicines are unsafe, harmful, or dangerous. The panel agrees with NAD's analysis, and also agrees with NAD that, in the context of the use considered by NAD, the claim conveys an unsafe message.[2]

Next, the panel considered the claims: (i) referring to parabens ("stuff you'll find in ALL PURPOSE CLEANER"); (ii) Red dye No. 40 ("made from petroleum"); and (iii) propylene glycol (ALSO FOUND IN ANTIFREEZE"). The panel agrees with NAD that these three claims, each referring to substances that would be dangerous if consumed, also convey a message that the

[2] That context is described above in the discussion concerning the "give you a headache" claim. The panel notes that, in addition to disputing that the consumer communication conveys an "unsafe" message, Genexa argues that NAD should not have considered the commercial because the video at issue had been permanently withdrawn before the filing of the challenge. NAD apparently concluded that it was informed by Genexa that certain claims in the commercial (not the commercial itself) had been withdrawn. See NAD Decision at 2, n. 1; 12-13. In any event, the argument that the "now discontinued video" (id. at 12) should not have been considered by NAD is a procedural issue not properly raised before this panel. See NARB Policies and Procedures Section 2.1-O, Appeal of Non-Merits Issues.

inactive ingredients referred to are unsafe.

Finally, on the ingredient claims, the panel considers the advertising presentation that identifies "things that shouldn't exist." Among those "things" are "all artificial dyes in medicine" and "parabens in medicine." The panel agrees with NAD that one message communicated to reasonable consumers is that the inactive ingredients referred to present health risks. The panel notes that the advertising does not present the rationale that Genexa represents was the motivation for the founding of the company – to offer consumers OTC drugs with natural, not artificial, inactive ingredients. Without a reference to that rationale, consumers are left to reach their own conclusions as to why artificial inactive ingredients are "things" that should not exist, and health risks to children is a likely "why."

Next, the panel considers the pediatricians prefer claims. The first is the claim set forth that Genexa argues is supported by its survey of pediatricians. The second is "the doctors have spoken."

The panel concludes that the "doctors have spoken" claim communicates to reasonable consumers that pediatricians prefer Genexa's medication to competitive products on the market. That preference includes recommending the Genexa medicine in their practice. Genexa, however, has no support for this communication.

As concerns the "pediatricians prefer" claim, the panel agrees that one message communicated is that pediatricians prefer the Genexa product for use by their own children, a claim for which there is no support. The advertiser argues that the phrase at the end of the claim, "based upon comparing the ingredients," qualifies the claim and limits it to a preference for the ingredients, not the product. While some consumers may interpret the claim that way, another reasonable interpretation is that pediatricians prefer the product, and that an analysis of the ingredients is the reason given for the product preference. The panel notes that it finds support for its conclusion that the survey is not a "good fit" for the claim in Genexa's having left out of the claim the words "**SOLELY**" and "**ONLY**," which were used in the survey instructions to the pediatricians. The advertiser also changed the tense from "would you prefer" (survey questionnaire) to "prefers" (advertising claim).

Finally, the panel considered the three challenged allegedly implied claims. The panel agrees that all three are conveyed, and all three are unsupported.

In conclusion, the panel notes that it has considered the advertiser's argument that the challenged claims support its "core value proposition," which is that consumers may prefer "effective medicine without the artificial inactive ingredients that many seek to avoid." Based on the record evidence, it does appear to the panel that Genexa's medications offer a point of difference that may resonate with consumers. NAD was careful in its recommendations to not proscribe advertising that promotes this difference, without unsupported disparagement of competing children's pain

and fever medications containing FDA-approved inactive ingredients.

Because NAD carefully, and in the panel's view properly, made narrowly-tailored recommendations to discontinue or modify the challenged claims, the panel's recommendations, set forth in the next section of this decision, will closely track NAD's recommendations.

F. Recommendations

The panel recommends that Genexa discontinue the claims "Pediatricians prefer Genexa's Kids' Pain & Fever over Children's Tylenol Pain + Fever liquid products for their own children based upon comparing the ingredients" and "the doctors have spoken," or modify them to make clear that the surveyed pediatricians expressed a preference only as to "ingredients." The panel further recommends that the advertiser avoid stating or implying, in the absence of supporting evidence, that pediatricians prefer or use the advertiser's product over the challenger's products in their practices or for their own children.

The panel also recommends that the advertiser discontinue the claims that "PARABENS is stuff you'll find in ALL PURPOSE CLEANER. And, for some reason, in kids' fever medicine," "Un-Fun Fact: Red dye no. 40 is made from petroleum," and that Propylene Glycol is "ALSO FOUND IN ANTIFREEZE."

The panel recommends that the advertiser discontinue the "MADE WITH REAL INGREDIENTS" claim in the context presented in the now-discontinued challenged video advertisement and avoid conveying the message that competing products with different inactive ingredients are generally unsafe, harmful, or dangerous. Nothing in this decision prevents the advertiser from highlighting the "real ingredients" in its product, provided, that the advertising does not otherwise convey the message that competing products contain inactive ingredients that are generally unsafe, harmful, or dangerous.

The panel also recommends that the advertiser discontinue the claims: (1) "When we looked around the medicine aisle, we found something that made us sick"; (2) "Your kid's pain medicine shouldn't give you a headache"; and (3) "Things that shouldn't exist," with a list of items like "showers that make you dirty," "food that makes you hungry," "all artificial dyes in medicine" and "parabens in medicine," in the context in which they appear in the challenged advertisement.

G. Advertiser's Statement

Genexa is deeply troubled by the implications of NARB's decision on both Genexa and the industry more broadly, but Genexa will comply with NARB's recommendations. Genexa is the first and the only company to provide families with effective over-the-counter medicine that does not contain any artificial fillers. This ingredient profile is the reason for Genexa's existence, and what sets it

apart from the competition. NARB's decision effectively bars Genexa from informing consumers of this critical distinction by prohibiting claims that truthfully describe ingredients that are found in competing medicines. Genexa is also disappointed that NARB failed to recognize that some statements in its advertising are clearly puffery. Genexa appreciates, however, that nothing in NARB's decision prevents Genexa from touting the "real ingredients" in Genexa's medicines, provided that such a claim does not convey the message that competing products are harmful or dangerous. Finally, Genexa appreciates NARB's finding that Genexa can make a "pediatricians prefer" claim as to the products' ingredients. Genexa is a supporter of the self-regulatory process and appreciates NARB's time and attention in this matter.