Case #7325 (08/05/2024)
**ASO LLC**
***Hydrocolloid Gel Bandages***
***Challenger**:* *Johnson & Johnson Consumer Inc.*
***Product Type**:* *Drugs / Health / Health Aids*
***Issues**:* *Comparative Performance Claims; Express Claims; Health & Safety Claims; Implied Claims / Consumer Perception*
***Disposition**:* *Modified/Discontinued*

**BBB NATIONAL PROGRAMS**

***NATIONAL ADVERTISING DIVISION***

JOHNSON & JOHNSON CONSUMER INC.,
*Challenger*,

ASO LLC,
*Advertiser*.

Case No. 7325
Closed 08/05/2024

## FINAL DECISION

- Claims touting the benefits of health products must be narrowly tailored to conclusions that can legitimately be drawn from reliable scientific research.

## I. Basis of Inquiry

The advertising industry established the National Advertising Division ("NAD") and the National Advertising Review Board ("NARB") in 1971 as an independent system of self-regulation designed to build consumer trust in advertising. NAD reviews national advertising in all media in response to third-party challenges or through inquiries opened on its own initiative. Its decisions set consistent standards for advertising truth and accuracy, delivering meaningful protection to consumers and leveling the playing field for business. Challenger Johnson & Johnson Consumer Inc. ("JJCI" or "Challenger") challenged express and implied claims made by Advertiser ASO LLC ("ASO" or "Advertiser") for its Hydrocolloid Gel Bandages. The following are representative of the claims that served as the basis for this inquiry:

### *A. Express Claims*

- "2x faster healing"

### *B. Implied Claims*

- ASO's hydrocolloid bandages are approved for sale by the FDA as Class III medical devices

## II. Evidence Presented

The Challenger presented the following evidence:

- ASO's trademark registration for "Smart-Heal"
- Examples of ASO product packaging
- Correspondence between JJCI and ASO related to the challenge
- Joel W. Beam, *Management of Superficial to Partial-Thickness Wounds,* J. Atl. Train. 3, 422-424 (2007) ("2007 J. Athletic Training Article")
- Rick Wiechula, *The Use of Moist Wound-Healing Dressings in the Management of Split-Thickness Skin Graft Donor Sites: A Systematic Review,* Int. J. Nursing Pract., 9:S9-S17 (2003) ("2003 Meta-Analsis")
- Henrik Steenfos et al., *Comparison of Sureskin, DuoDERM, and Jelonet Gauze in split skin donor sites - a clinical and histological evaluation,* J. Eur. Acad. Dermatol. & Venereol. 8, 18–22 (1997) ("Steenfos Study")
- Terren J, et al. *A comparative study of three new occlusive dressings for healing of graft donor sites versus conventional therapy,* Eur. J. Plast. Surg. 16, 98–103 (1993) ("Terren Study")
- FDA Warning Letter CMS#281637 to Human Biosciences, Inc. at 1 (May 10, 2012)
- FDA Executive Summary, *Classification of Wound Dressings Combined with Drugs*

The Advertiser presented the following evidence:

- 21 CFR § 878.4020, entitled "Occlusive wound dressing."
- 21 CFR 878.9
- Dictionary Definitions
- Examples of JJCI and other product packaging
- Samples of ASO's advertising
- Memo from Biologics Consulting of August 26, 2016
- 2007 J. Athletic Training Article
- 2003 Meta-Analysis
- Columbia University, Irving Medical Center "How a Scrape Heals" https://www.columbiadoctors.org/health-library/article/how-scrape-heals/ (Last Visited May 1, 2023)
- American Academy of Dermatology Association, "How to Treat Minor Cuts", https://www.aad.org/public/everyday-care/injured-skin/burns/treat-minor-cuts (Last visited May 1, 2023)
- McCain D. Sutherland S. Nursing Essentials: Skin Grafts for Patients with Burns, *Am. J. Nursing* 1998: 98: 34-38
- Joel W. Beam, *Occlusive Dressings and the Healing of Standardized Abrasions,* J. ATL. TRAIN. 2008; 43(6): 600-607 ("Beam Study")
- Wigger-Alberti et. al., Using a Novel Wound Model to Investigate the Healing Properties of Products for Superficial Wounds, *Journal of Wound Care* Vol. 18, No. 3, March 2009 ("Wigger-Alberti Study")

- FDA Warning Letter CMS#281637 to Human Biosciences, Inc. at 1 (May 10, 2012)
- FDA Product Classification for Code FRO
- FDA 510(K) Pre-market classification Number K925545
- Proposed Rule "Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressing Formulated as a Gel, Creams, Ointment; and Liquid Wound Washes". Federal Register 88:229 (Nov. 30, 2023) p. 83776-7

## III. Decision

### *A. Background*

JJCI and ASO are competitors that each manufacture various hydrocolloid bandages. Hydrocolloid bandages are moist wound dressings that contain an ingredient that turns into a gel when it absorbs fluid. ASO's bandages are sold under their own brand names, All-Health and Care Science, as well as its private label customers' brands, such as Rite-Aid and CVS Health. JJCI challenged certain express claims made by ASO that tout its hydrocolloid bandages as promoting (up to) 2x faster healing. JJCI further argued that ASO's advertising implied the unsupported message that ASO's hydrocolloid bandages are approved for sale by the FDA as Class III medical devices.

### *B. Standard of Review*

Advertisers must possess a "reasonable basis" for all messages reasonably conveyed by their advertising, not merely the message it intended to convey.[1] What constitutes a "reasonable basis" depends on several factors, including the type of product, the type of claim, the consumer benefit from a truthful claim, the ease of developing substantiation for the claim, the consequences of a false claim, and the amount of substantiation experts in the field believe is reasonable.[2]

In the absence of consumer perception evidence, NAD relies on its expertise to determine the messages reasonably conveyed by the challenged advertising.[3] In analyzing the express and implied messages conveyed by a particular advertisement, NAD reviews the totality or overall net impression created by an advertisement as a

[1] *Guardian Technologies, LLC (GermGuardian and PureGuardian Air Purifiers and Replacement Filters)*, Report #6319, NAD/CARU Case Reports (November 2019); *Dyper Inc. (Dyper Baby Wipes & Diapers)*, Report #7144, NAD/CARU Case Reports (January 2023).

[2] *Pfizer Inc.*, 81 F.T.C. 23 (1972). *See also* FTC, *Policy Statement Regarding Advertising Substantiation* (Nov. 23, 1984), https://www.ftc.gov/public-statements/1984/11/ftc-policy-statement-regarding-advertising-substantiation.

[3] *Dyper Inc. (Dyper Baby Wipes & Diapers)*, Report #7144, NAD/CARU Case Reports (January 2023).

whole, not merely words or phrases standing alone, taking into consideration both the words and the visual images.[4]

All the Advertiser's claims are health related. It is critical that consumers receive accurate information for the health products they purchase. Health-related claims generally should be supported by competent and reliable scientific evidence, as defined by the Federal Trade Commission ("FTC"), and includes, "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[5]

Independent experts can provide unbiased assessments of the validity of studies, how they fit within the relevant scientific literature, and what conclusions can be legitimately drawn from the results.[6] NAD has found that expert opinions are most reliable when the expert's opinion is coupled with competent and reliable evidence demonstrating scientific consensus on an issue.[7]

### *C. The Advertising*

The challenged "2x faster healing" claims appear in several media, including the hydrocolloid bandage packaging, as well as Amazon and other retailer webpages. The claim most often appears as "promotes up to 2x faster healing" and is adjacent to ASO's "SMART-HEAL® TECHNOLOGY" trademark, such as SMART-HEAL®

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[4] Id.

[5] FTC Health Products Compliance Guidance, page 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf *OrganiCare, LLC (FemiClear Vaginal Yeast Infection Treatment)*, Report #6347, *supra*; *Molekule Inc. (Molekule MH1 Air Purifier)*, Report #6314, *supra*.

[6] FTC Health Products Compliance Guidance, page 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf

[7] Generally, scientific consensus on an issue is more valuable than the opinion of one individual scientist. The FDA, in its guidance to industry on health-related claim substantiation, asserts that "the opinion of a single scientist or small group of scientists is probably not adequate substantiation for [a health-related] claim." U.S. Food & Drug Administration, *FDA Guidance for Industry Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (2009) (example question 3). Thus, expert opinions and reports alone are not a substitute for competent and reliable scientific evidence. This is in accordance with the FTC's decades old standard of review that "where the opinions voiced by experts are not adequately supported we ordinarily give them little weight." *See CEBRIA, LLC (Cebria Supplements)*, Report #6142, NAD/CARU Case Reports (December 2017) (citing *In re Thompson Medical Company, Inc.* 104 FTC 786, 790, and fn 11 (1984); *Thompson Medical Company vs. FTC*, 791 F.2d 189 (1986) (Petition to review FTC order denied by the United States Court of Appeals, District of Columbia Circuit). NAD further noted a similar principle was articulated in *Daubert vs. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 592-595, 597 (1993), where the United States Supreme Court held that expert testimony, to be admissible, must rest on a reliable scientific foundation.

TECHNOLOGY PROMOTES UP TO 2X FASTER HEALING*. Often an asterisked disclosure denotes "*Hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007; 42(3):422-424."

### 1. Product Packaging

On the front panel of the package for ASO's ALL-HEALTH brand ADVANCED FAST-HEALING HYRDOCOLLOID GEL BANDAGES, for example, the text "SMART-HEAL® TECHNOLOGY" appears directly above the text "PROMOTES UP TO 2X FASTER HEALING*." The asterisk is in a much smaller font-size than the main claim text and points to a disclosure on a side panels that reads "Hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters, and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007; 42(3):422-424."[8] The claim also appears on the back of the package with an asterisk that points to the same side panel disclosure. The other side panel also contains the 2X faster healing claim with the text "SMART-HEAL® TECHNOLOGY" above a graphic depicting the mechanism of healing and the text "Moist wound environment facilitates the healing process for up to 2X FASTER HEALING*" where, again, the asterisked disclosure points to the same side panel.

The various other packaging for ASO's hydrocolloid bandages sold under other brand names and private labels are largely the same. On the Rite-Aid brand package, however, the asterisked disclosure has different text than the disclosures on most other packages. The disclosure on the Rite-Aid brand package provides: "The hydrocolloid pad within this product has been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007:42(3):422-424."

### 2. Product Webpages

The challenged claims appear on Amazon and other retail webpages in much the same form as those on the product packaging. Many of the product webpages include images of the product packaging described above, which appear as enlargeable tiles that may be selected and brought into the main view.

For example, on the Amazon webpage for the ALL-HEALTH brand bandages, three selectable tiles (among seven) include images of the package panels: one selectable tile includes an image of the front package panel with the "SMART-HEAL® TECHNOLOGY PROMOTES UP TO 2X FASTER HEALING*" claim. Another selectable tile includes an image of the back package panel with the same claim. A third selectable tile includes the side panel with the conventional asterisked disclosure. A fourth enlargeable tile includes the claim without the "up to" qualifier

[8] Unless otherwise noted, any reference to an asterisked disclosure is a reference to a disclosure with this text.

("2X Faster healing* than traditional bandages") and includes the asterisked disclosure in the same tile beneath the claim in very small text.[9] In addition, in a section of the webpage titled "About this item," the claim appears as "Smart-heal Technology promotes up to 2x faster healing by providing a moist wound environment to facilitate the healing process" and does not include a disclosure.

### *D. Analysis of Messages Conveyed and Their Support*

JJCI argued that ASO's advertising conveys the false and misleading message that ASO's Smart-Heal technology confers the advertised 2x faster healing benefit and the false implied message that ASO's products are FDA approved Class III medical devices. It further argued that neither of these messages, nor the message that hydrocolloids generally confer the advertised 2x healing benefit, are supported by the evidence.

ASO argued that the totality of ASO's advertising, including its disclaimers, associates the faster healing with the moist wound environment created by hydrocolloids and that the average consumer would understand that the faster healing comes from the use of hydrocolloids and not any other aspect of ASO's Smart-Heal Technology or any unique or proprietary aspects of its bandage.

NAD found that, while some consumers looking at ASO's advertising in some contexts may understand ASO's 2x faster healing claim to be limited to a comparison of the benefits of hydrocolloid bandages generally versus traditional or dry bandages, one message also reasonably conveyed by ASO's advertising is that ASO's product, or its Smart-Heal Technology, (as opposed to hydrocolloids generally) promote up to 2x faster healing.

For example, the asterisked disclosure on the Rite-Aid package qualifies the 2x faster healing claim by stating that "The hydrocolloid pad ***within this product*** has been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007:42(3):422-424." (emphasis added). This disclosure specifically conveys the message that ASO's product has been shown to promote up to 2x faster healing compared to dry bandages: In this context, a consumer could reasonably conclude that there is something different about ASO's hydrocolloid pad that provides the up to 2x faster benefit.

In some other versions of the advertising, there is no asterisked disclosure at all. For example, on the Amazon Webpages for the ALL-HEALTH and Care Science brand bandages, the claim appears without an asterisk as "Smart-heal Technology promotes up to 2x faster healing by providing a moist wound environment to facilitate the healing process" and "PROMOTES UP TO 2X FASTER HEALING. Moist wound

[9] The remaining selectable tiles included graphics and images irrelevant to the "2x faster" claims.

environment facilitates the healing process for up to 2X faster healing" respectively. In these contexts, the message conveyed is that the product or its Smart-Heal technology promotes up to 2x faster healing versus an unknown comparator.

NAD found that in some contexts that include the asterisked disclosure indicating that the comparison is between hydrocolloid and dry bandages, the disclosure is not clear and conspicuous. For example, on the front panel of the package for ALL-HEALTH ADVANCED FAST-HEALING HYDROCOLLOID GEL BANDAGES, the claim appears as follows: "SMART-HEAL® TECHNOLOGY PROMOTES UP TO 2X FASTER HEALING*." The asterisk itself is in tiny font and points to a disclosure on the side panel of the package. In reviewing the adequacy of disclosures, NAD has recognized that effective disclosures, regardless of format, must be "clear and conspicuous" such that the disclosure is "displayed in a manner that is readily noticeable, readable, and/or audible, and understandable to the audience to whom it is directed. Disclosures must also be made in close proximity to the triggering claim.

NAD has routinely found disclosures that are on a different panel than the main claim are not clear and conspicuous.[10] NAD determined here that the disclosure is not clear and conspicuous because it appears on the side of the package while the prominent up to 2x faster claim appears on the front of the package with a very small asterisk that is difficult to notice. And without the disclosure, the overall context of the main claim reasonably conveys the message that a proprietary technology marketed as SMART-HEAL gives the ALL-HEALTH ADVANCED FAST HEALING HYDROCOLLOID GEL BANDAGES properties that promote up to 2x faster healing against an unknown comparator (possibly other hydrocolloid bandages that do not have SMART-HEAL Technology or that are not "ADVANCED FAST-HEALING").[11]

Similarly, on the Amazon webpages for the ALL-HEALTH and CARE SCIENCE brand bandages, the up to 2x faster claim appears in various forms on enlargeable tile graphics where the asterisked disclosure appears in separate enlargeable tile graphics. As in previous cases, NAD found disclosures that are on different enlargeable tiles from the main claim are not clear and conspicuous as consumers

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[10] *See, e.g.*, *SlimFast Foods Company (SlimFast Food Products & Weight Loss Plans)*, Report #6952, NAD/CARU Case Reports (August 2021); *The Dannon Company (Light & Fit 0% Plus Yogurt)*, Report #4953, NAD/CARU Case Reports (January 2009); *Campbell Soup Company (Campbell's Select Harvest Soups)*, Report #4981, NAD/CARU Case Reports (March 2009).

[11] Compare *Glad Products Company (Glad ForceFlex MaxStrength Drawstring Bags)*, Report #7309, NAD/CARU Case Reports (March 2024) where one of three panelists found that the claim was not misleading without the disclosure because the comparator in "25% more durable" would be understood to be the advertiser's other products where the name of the product included "Max Strength" and another panelist found that the asterisked disclosure was sufficient because it was on the same panel as the claim.

may never see them.[12] Again, in these contexts, one message conveyed is that the product or its Smart-Heal Technology promotes up to 2x faster healing.

NAD next examined whether the evidence provided reasonable support for the claim that ASO's product, or its Smart-Heal Technology, provides up to 2x faster healing. ASO did not have testing of its own product, but instead argued that testing of hydrocolloids generally substantiated their claims.

NAD, thus, first examined whether ASO's support provided a reasonable basis for qualified claims that hydrocolloids generally promote up to 2x faster healing than dry bandages (i.e., whether it has support for its conventional asterisked disclosure: "Hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007; 42(3):422-424."). The language of the claim that, "Hydrocolloids have been shown," reasonably conveys a message to consumers that, in reliable testing, hydrocolloids have healed a minor wound 2x faster than a simple dry bandage. Further, consumers are likely to interpret "heal … 2x faster" to mean that the wound is completely healed in half the time with a hydrocolloid versus a simple dry bandage. Additionally, while this claim is phrased as "up to" 2X faster, NAD considers a number of factors, including the nature of the product or service at issue and the full distribution of potential results that consumers are likely to attain in reviewing whether the "up to" claim is supported.[13] To support a qualified claim, ASO would need to show that some material number of minor wounds have healed in half the time using a hydrocolloid as compared to a dry bandage.

### 1. ASO's Support for its "up to 2x faster" claims

ASO relied on (1) a 2007 J. Athletic Training Article reporting that wounds treated with moist dressings heal 2-5 days faster than wounds treated with dry ones; (2) a 2003 meta-analysis of moist and non-moist dressing studies summarized by the 2007 J. Athletic Training Article;[14] and (3) a 2016 Biologics Consulting report concluding that the "up 2x faster healing" claim is supported based on the information from the 2007 J. Athletic Training Article. In addition, the Advertiser submitted two additional studies that compared hydrocolloids to other dressings or bandages, and discussed the results of the additional studies submitted by the Challenger comparing hydrocolloids and other dressings.

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[12] *Glad Products Company (Glad ForceFlex MaxStrength Drawstring Bags)*, Report #7309, NAD/CARU Case Reports (March 2024) (appealed on other grounds).

[13] *Dyson, Inc. (Dyson V8 Cordless Vacuums)*, Report #6169, NAD/CARU Case Reports (March 2018).

[14] NAD also reviewed the Steenfos and Terren hydrocolloid studies, provided by the challenger, that are reported on in the 2007 J. Athletic Training Article and 2003 meta-analysis.

*a) The 2007 Journal of Athletic Training Article and 2003 Meta-Analysis*

The J. Athletic Training article is a one-page summary of a 2003 Meta-Analysis that examined the use of moist wound-healing dressings, including hydrocolloids, in the management of split-thickness skin graft donor sites. The FTC specifically cautions against reliance on summaries of studies, because without looking carefully at the specifics of the study design, implementation, and results, there is no way for the advertiser to ascertain whether the research substantiates the product claims.[15] As a result, NAD reviewed the other studies submitted by the parties, some of which were included in the meta-analysis, that compare hydrocolloids to dry dressings to determine whether they provide a reasonable basis for the "up to 2x faster" claims.

*b.) The Steenfos and Terren Studies*

The Steenfos Study referenced in the 2003 Meta Analysis evaluated two brands of hydrocolloid dressings and a gauze dressing control and compared the bandages to each other on 10 split skin donor sites. The authors reported that the two brands of hydrocolloid dressings performed identically to one another (8.5±0.8 days to healing) and significantly better than the gauze control (12±1.6 days to healing). None of the individual data points were provided, but the authors concluded that the two hydrocolloid dressings were equal to each other in healing time and reduce healing time by 33%.[16]

The Terren Study, also referenced in the 2003 Meta Analysis, compared four skin graft donor site dressings: an occlusive hydrocolloid, semiocclusive hydrocolloid, a polyurethane sheet, and a "conventional" dressing. The results showed that the occlusive hydrocolloid dressing significantly decreased the mean time required for complete healing[17] compared with a semiocclusive hydrocolloid,[18] a polyurethane sheet[19] and the conventional dressing.[20] Except for one outlier subject,[21] the individual data points for a given wound in the Terren study are not provided. But it

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[15] FTC Health Products Compliance Guidance, Example 23, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf

[16] Which is about 1.5x faster.

[17] Average of 7.45 days and a range of 6 to 11 days to healing with the occlusive hydrocolloid.

[18] Average of 10.29 days and a range of 8 to 17 days to healing with the semiocclusive hydrocolloid.

[19] Average of 9.4 days and a range of 8 to 15 days to healing with the polyurethane sheet.

[20] Average of 10.04 days and range of 9 to 17 days to healing with the conventional dressing.

[21] The outlier subject (which the authors indicate took the longest to heal with all dressings) took 17 days to heal with the conventional dressing, 15 days to heal with the polyurethane sheet, 17 days to heal with the semiocclusive hydrocolloid dressing, and 11 days to heal with the occlusive dressing; that wound healed approximately 35% or 1.5x faster with the occlusive hydrocolloid dressing compared to the conventional dressing.

is apparent from the data that none of the wounds healed 2x faster with a hydrocolloid than with a conventional dressing.[22]

Neither study compared bandages on wounds that were minor. Neither report any conclusions on healing time in minor wounds, nor do they provide any reason to extrapolate data reported in the studies to more minor injuries on either a percentage basis or absolute basis. Even if one could extrapolate on a percentage basis, none of the data show that any type of wound healed 2x faster using a hydrocolloid dressing. And neither study offer a conclusion (nor data that itself would support the conclusion) that hydrocolloids generally (or ASO's product in particular) have been shown to heal minor wounds up to 2x faster than a simple dry bandage.

*b) The Beam Study*

The 2008 Beam Study[23] examined the effects of occlusive dressings of standardized, partial-thickness abrasions. Sixteen participants were inflicted with four standardized, partial-thickness abrasions. Three of each participants' wounds were treated with three occlusive dressings: (1) film, (2) hydrogel, and (3) hydrocolloid. The other wound had no dressing applied as a control. The author reported that, compared to the control, the occlusive dressings were associated with a faster healing rate of partial-thickness abrasions across time measured by wound contraction, color, and luminance. The author further reported that hydrocolloid dressing were the most effective of the occlusive dressings in the healing of partial-thickness abrasions in the study.

Specifically, the author reported that three hydrocolloid-treated wounds (18% of total) were fully healed by day 7, nine (56%) had fully healed by day 10, and 14 (87%) had fully healed by day 14. The author also reported that one wound (6%) treated with film had fully healed by day 7, seven (43%) had fully healed by day 10, and ten (62%) had healed by day 14. Over the 14-day study period, none of the control wounds without a dressing had healed.

Although more wounds treated with hydrocolloids are reported to have completely healed over the study's observation period than those treated with film, there is no report that any wound completely healed in half the time with a hydrocolloid compared to film and no way to otherwise ascertain from the reported results that any wound completely healed 2x faster with a hydrocolloid than with film. Furthermore, the control in the study did not involve the use of a dressing at all, so

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[22] In the remaining data excluding the outlier, the shortest time to healing of a wound with a hydrocolloid dressing was 6 days and the longest time to healing of a wound with a conventional dressing was 11 days, so even assuming these opposite extremes represent healing times of the same wound, the maximum possible rate of increase in healing time would be approximately 45% or 1.83x faster.

[23] The author of the Beam Study is the same as the author of the 2007 J. Athletic Training Article.

its results would not support claims that compare the healing of hydrocolloid to traditional or dry bandages. Thus, the study does not report any data or conclusions that would support a quantified claim of "up to 2x faster" healing with hydrocolloids compared to traditional or dry bandages.

*c) The Wigger-Alberti Study*

The Wigger-Alberti Study objective was to establish a new wound model that can induce uniform abrasions and use it to assess the healing properties of a range of products commonly applied to those wounds. In the study, ten healthy volunteers each had five standardized, superficial abrasions induced on their forearms by repeatedly scrubbing the skin with a surgical brush. The five wounds were treated with (1) a polyurethane bandage, (2) a hydrocolloid bandage, (3) a hydrogel bandage, (4) a waterproof bandage that served as one control, and (5) a standard air and water-permeable bandage that serves as a second control. On days 2, 5, 8 and 14 ±1, the wounds were evaluated visually and by video microscope to assess the degree of epithelization, with 100% epithelization representing complete healing. After 14 days, seven of the hydrocolloid-treated wounds had completely healed, while only five of the waterproof-bandage-treated wounds and one of the standard-bandage-treated wounds had completely healed. However, there is no report of how many days it ultimately took the rest of the relevant wounds to completely heal.

The authors concluded that, in general, healing rates were better, with an earlier onset of healing, with hydrocolloid bandages than standard bandages. But because the study does not indicate whether or when all of the wounds were completely healed, the study cannot support a quantified claim of "up to 2x faster" healing, as that cannot be ascertained from the reported results. In addition, it is unclear whether the abrasions studied qualify as "minor." Although deemed superficial by the authors, the wounds took much longer to heal with standard treatment than the 3-to-7 day healing period used by ASO's consultant, discussed more fully below.

*d) The Biologics Consulting Memo*

ASO provided a one-page memo that it received in 2016 that stated ASO's claims are supported. The memo was authored by a consultant with 20 years of experience in the Office of Device Evaluation at the Food & Drug Administration ("FDA"), including 11 years at FDA as Chief of the Plastic and Reconstructive Surgery Devices, the branch responsible for regulating most wound care devices. The consultant concluded that ASO's claims that its bandages "promote[] up to 2X faster healing" and that "hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters and scalds up to 2.5 faster than a simple bandage" are supported relying on the 2007 J. Athletic Training Article. The consultant reasoned that because (1) the 2007 J. Athletic Training Article purportedly reported that wounds treated with hydrocolloid bandages healed 2-5 days faster than wounds with dry dressings and (2) minor cuts, scrapes or abrasions in healthy individuals usually heal within 3

to 7 days,[24] the claim that hydrocolloid bandages have been shown to heal minor cuts, scrapes, abrasions, lacerations, blister and scalds 2-2.5 times faster than dry bandages is supported. The consultant did no testing of their own.

*e) Analysis*

NAD found that the research provided by the Advertiser did not support ASO's "2x faster claims." Although the cited articles and studies suggest hydrocolloids may speed the wound healing process, none provided reliable support that hydrocolloids heal minor wounds up to 2x faster than a conventional or dry bandage or any other dressing.

While the Biologics Consulting Memo offers the conclusion that ASO's claims are supported, the consultant's conclusion is not coupled with competent and reliable evidence that supports those conclusions.[25] The 2007 J. Athletic Training Article used to support his conclusions is a summary of a meta-analysis, both of which, as described above, the FTC specifically cautions against using as support. And the specific data from the 2007 J. Athletic Training Article used by the consultant concerned a compilation of various moist bandages and not hydrocolloids specifically.[26]

The underlying hydrocolloid studies show a range of reduction in the time to complete healing that do not support the 2-5 day reduction in healing time the consultant relied on for the conclusion that hydrocolloid bandages heal wounds "up to 2x faster." Rather, the studies show improved healing times, but not a 2-5 day reduction.[27] Furthermore, the wounds involved in all of the provided hydrocolloid studies, with the possible exception of the Wigger-Alberti Study, were more severe than minor wounds.

Additionally, in all studies, the wounds treated with standard dressings took longer to heal than the 3 to 7 days the Biologics Consulting Memo concludes is the healing time for minor cuts, scrapes or abrasions in healthy individuals. Yet, the memo

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[24] The consultant did not provide support for the statement that minor cuts, scrapes, or abrasions in healthy individuals usually heal within 3 to 7 days and did not indicate whether that time is with a dry bandage or no bandage at all. ASO pointed to webpages from Columbia University Medical Center ("minor scrapes may be uncomfortable, but they usually heal within 3 to 7 days") and the American Academy of Dermatology Association ("Most minor cuts heal in one week or less") as further support for that time frame for healing, but again the websites do not indicate whether that is with no bandage or a dry bandage.

[25] See footnote 7.

[26] *Focus Consumer Healthcare (Pamprin Botanicals)*, Report #7247, NAD/CARU Case Reports (January 2024) ("[W]hen advertisers rely on studies to support health-related claims, they must ensure that the study is not only competent and reliable but also that the study results relate to the specific benefits being claimed.").

[27] Even the 2007 J. Athletic Training Article itself reports that the studies of hydrocolloids showed a reduction in time to healing ranging of only 1.5 to 2.89 days.

applies a 2-5 day shortened healing period (from studies on injuries requiring more than the 3 to 7 days to heal) as the improved healing time for less severe wounds. Nothing in the studies or in the Biologics Consulting Memo explains why the reduction in healing days for severe wounds would be the same for minor cuts and scrapes. As a result, NAD determined that the conclusions in the 2016 Biologics Consulting Memo were inconsistent with the evidence in the record.[28]

Accordingly, NAD found that the evidence did not reasonably support qualified claims that hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters, and scalds up to 2x faster than a simple dry bandage. As a result, and because ASO provided no evidence of its own bandages' relative healing times,[29] the evidence also does not support claims that ASO's product or its Smart-Heal Technology promote up to 2x faster healing. Therefore, NAD recommended that ASO discontinue its "2x faster healing" claims.

### 2. The Implied Class III Medical Device Claim

JJCI argued that ASO's "up to 2x faster" claims falsely imply that ASO's hydrocolloid bandages have premarket approval from the FDA as Class III medical devices. It reasoned that because the FDA deems wound dressings intended to accelerate the normal rate of healing to be classified as Class III medical devices and that the FDA has warned that Class I medical devices may not be labeled as having any accelerating effect of wound healing, by making its "up to 2x faster" healing claim, ASO implies its bandages are FDA-approved Class III medical devices.

NAD did not find that any of the challenged advertising or claims reasonably conveyed the message that ASO's hydrocolloid bandages are approved for sale by the FDA as Class III medical devices. The FDA's rules on accelerated healing claims for medical devices are not likely to be known by consumers. And consumers are unlikely to make the logical leap JJCI suggests: that bandages that can be bought off-the-shelf or online without a prescription for treating minor wounds are a Class III medical device.[30]

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[28] *See CEBRIA, LLC (Cebria Supplements)*, Report #6142, NAD/CARU Case Reports (December 2017) (citing *In re Thompson Medical Company, Inc.* 104 FTC 786, 790, and fn 11 (1984) ("Expert opinions alone are not a substitute for competent and reliable evidence.")

[29] *MacuHealth, LP (MacuHealth, MacuHealth Plus+, Vitreous Health, Vision Edge Pro, TG Omega-3)*, Report #7202, NAD/CARU Case Reports (September 2023) ("[H]ealth-related product performance claims generally should be supported by competent and reliable scientific evidence on the actual product itself as marketed to consumers.")

[30] This case is distinguishable from one cited by JJCI in which NAD found that a table comparing the efficacy of a wound healing device marketed for diabetic foot ulcers to other devices that had class III medical device FDA approval implied that the device itself had FDA approval. There NAD noted that the more serious the medical condition, the more likely it may be that consumers and physicians will take away a message that the product is subject to

## IV. Conclusion

NAD found that one message reasonably conveyed by ASO's advertising is that ASO's product, or its Smart-Heal Technology, (as opposed to hydrocolloids generally) provides up to 2x faster healing. NAD determined that the evidence did not provide support for such claims.

NAD found that the evidence did not reasonably support qualified claims that hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters, and scalds up to 2x faster than a simple dry bandage.

As a result, NAD recommended that ASO discontinue its "2x faster healing" claims.

NAD did not find that any of the challenged advertising or claims reasonably conveyed the message that ASO's hydrocolloid bandages are approved for sale by the FDA as Class III medical devices.

## V. Advertiser's Statement

As described herein, ASO LLC agrees to comply with NAD's recommendation. ASO is pleased that the NAD found that the challenged advertising does not convey the message that ASO's hydrocolloid bandages are approved by the FDA as Class III medical devices. NAD's decision also acknowledges studies showing that hydrocolloid bandages offer improved healing times. At the same time, NAD determined that those same studies do not support the claim of "up to 2x" faster healing (hereinafter "the challenged claim"). ASO strongly disagrees with this aspect of the NAD's decision and believes the challenged claim to be fully supported by the referenced studies. Nonetheless, ASO respects the self-regulatory process and will cease use of the challenged claim on its own products upon depletion of current inventories. With respect to third party brands, ASO will recommend that the challenged claim be eliminated upon the next art update or change. **(#7325 SRM, closed 08/05/2024)**

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FDA approval and that the comparison at issue reasonably suggested that the products are comparable, belong in the same classification, and are subject to the same regulatory standards of proof. See *Wright Medical Technology, Inc. (GraftJacket® Ulcer Repair Matrix and GraftJacket® Xpress Scaffold)*, Report #4512, NAD/CARU Case Reports (June 2006). Here, the product treated by the medical condition is minor and can be bought over-the-counter, whereas there, the product was a cadaveric skin graft for a serious, chronic issue that would be treated by a doctor. Furthermore, the comparison of efficacy at issue here is with respect to other class I medical devices.