**ANALYSIS OF COMPLAINANTS' SUBMISSIONS IN MASS ACTIONS ALLEGING HAIR LOSS AS A RESULT OF USE OF THE WEN CLEANSING CONDITIONER PRODUCTS**

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## 1. INTRODUCTION

Cardno ChemRisk was requested by WEN® by Chaz Dean, Inc. (WCD) to perform a comprehensive risk and safety assessment to evaluate the potential for adverse dermal health effects, including the potential for hair loss or any other adverse dermal event, associated with the topical use of WCD Cleansing Conditioner hair care products (the "WEN Products"), which evaluation was triggered by complaints and allegations that the Products caused hair loss in a very small percentage of consumers. As part of that comprehensive risk and safety assessment, we analyzed cohort demographics, which is an important step when evaluating the causal association between exposure to a product or chemical and alleged health outcomes. This type of evaluation provides insight into potential commonalities and drivers of alleged health outcomes from which we can discern trends in the injuries, which may help identify a root cause of the alleged injury.

## 2. METHODS

Cardno ChemRisk was provided access to the LMI Sight Medical Information Management System portal (the "Portal") into which 512 plaintiffs from several mass actions from around the United States uploaded completed questionnaires, available medical records, and pictures to support their allegations that the WEN Products caused them to suffer hair loss. We downloaded and reviewed all available the information in the Portal  For each respondent, the following data was abstracted from the questionnaires: name, date of birth, calculated age, occupation, family member history of hair loss, pregnancy status during use of WEN, date of first purchase, WEN product(s) purchased, how soon hair loss symptoms began after purchase or use, description of hair loss, percent of hair loss, discontinued or continued use of WEN, improvement of hair loss, medical professional diagnosis, medical history, scalp symptoms after use of WEN, hair symptoms after use of WEN, and beauty product history. Thereafter, stratified analyses were performed to better understand the distribution of responses among users of the WEN Products whom are alleging hair loss.

## 3. RESULTS

When stratified by age, the age groups with the highest reported prevalence of hair loss were 50-59 years (30%), 40-49 years (23%), and 60-69 years (21%) (Table 1). The median age was 53 years, with a range of 2 to 89 years. This data is similar to adverse event data from the FDA, where the respondents had a median age of 49 years, with a range of 8 to 89 years.

**Table 1: Age**

| Age Group | Number | Percent |
|-----------|--------|---------|
| 0-18 | 7 | 3% |
| 18-29 | 9 | 4% |
| 30-39 | 26 | 13% |
| 40-49 | 48 | 23% |
| 50-59 | 63 | 30% |

| | | |
|---|---|---|
| 60-69 | 44 | 21% |
| 70-79 | 9 | 4% |
| 80-89 | 2 | 1% |
| | 208 | 100% |

There was a general trend of increased purchases of WEN Products through time, with the highest frequency of reported years being 2013 to 2015 (Table 2).  Specifically, the years with the highest prevalence of responses were 2015 (21%), 2014 (21%), and 2013 (18%), while the years with the lowest prevalence of responses were 2016 (1%), 2006 (1%), and 2007 (2%).  This trend suggests that the number of users of the WEN Products increased through the years.

**Table 2: Date of First Purchase**

| Date of First Purchase | Number | Percent |
|---|---|---|
| 2006 | 1 | 1% |
| 2007 | 3 | 2% |
| 2008 | 7 | 4% |
| 2009 | 11 | 6% |
| 2010 | 8 | 4% |
| 2011 | 21 | 11% |
| 2012 | 24 | 12% |
| 2013 | 35 | 18% |
| 2014 | 41 | 21% |
| 2015 | 40 | 21% |
| 2016 | 2 | 1% |
| | 193 | 100% |

The most commonly purchased version of the WEN Products was Sweet Almond Mint (75.9% of consumers), followed by Pomegranate (44.9%), Lavender (40.7%), and Fig (38.9%) (Table 3). These distributions were slightly different from respondents to the FDA adverse event reporting system, with the top 3 reported fragrances being Sweet Almond Mint (51%), Lavender (17%), and 613 (10%).

**Table 3: Fragrances**

| Fragrance | Number | Percent |
|---|---|---|
| Sweet Almond Mint | 164 | 75.9% |
| Pomegranate | 97 | 44.9% |
| Lavender | 88 | 40.7% |
| Fig | 84 | 38.9% |
| Tea tree | 59 | 27.3% |
| Cucumber Aloe | 46 | 21.3% |
| 613 | 22 | 10.2% |

| | | |
|---|---|---|
| Coconut Mango | 20 | 9.3% |
| Cranberry | 20 | 9.3% |
| Summer Honey Peach | 13 | 6.0% |
| Winter Vanilla Mint | 12 | 5.6% |
| Fall Ginger Pumpkin | 11 | 5.1% |
| Spring Orange Blossom | 7 | 3.2% |
| Tuscan Pear | 7 | 3.2% |
| Bamboo Green Tea | 6 | 2.8% |
| Lemon Rosemary Vanilla Bean | 5 | 2.3% |
| Spring Honey Lilac | 5 | 2.3% |
| Spring Gardenia | 5 | 2.3% |
| Children's Watermelon | 4 | 1.9% |
| Summer Mango | 3 | 1.4% |
| Mandarin Italian Fig | 3 | 1.4% |
| White Citrus | 3 | 1.4% |
| Fall Apple | 2 | 0.9% |
| Treat and Style 4 Piece Fig | 1 | 0.5% |
| Summer Coconut Lime Verbena | 1 | 0.5% |
| Wen Men | 1 | 0.5% |
| Kids Apple | 1 | 0.5% |
| Orange Fig Hair Oil | 1 | 0.5% |
| Fig Hair Oil | 1 | 0.5% |

There was no consistent trend in the time to adverse event analysis. Claimants reported a varied time period for symptoms to appear following use of WEN Products (Table 4). The highest prevalence of reported events happened between 2 and 6 months (42%), followed by less than or equal to one month (29%). Some individuals reported that symptoms occurred immediately after first use, while other individuals reported that symptoms occurred five years after first use. If a product is suspected to cause a specific health outcome, it would be expected for the onset of symptoms to cluster around the same time period.

**Table 4. Time to hair loss event beginning after use**

| Time Period | Number | Percent |
|---|---|---|
| ≤1 month | 61 | 29% |
| 2 to 6 months | 86 | 42% |
| 7 to 11 months | 17 | 8% |
| 1 to <2 year | 24 | 12% |
| >2 years | 19 | 9% |

|  | 207 | 100% |
|---|---|---|

The most common scalp symptoms following use of WEN Products were itching (65%), tenderness (43%), and flakiness (37%), while the least common scalp symptoms were swelling (9%) and acne (7%) (Table 5). The most common hair symptoms following use of WEN Products were breakage (87%) and brittleness (80%), while the least common hair symptoms were oiliness (15%) and frizziness (44%) (Table 6). Upon stopping use of WEN Products, 64% of claimants reported that their symptoms improved. Additionally, 48% of respondents stated that they saw a medical professional.

**Table 5: Scalp Symptoms**

| Scalp Symptoms Experienced | Number | Percent |
|---|---|---|
| Itching | 140 | 65% |
| Tenderness | 92 | 43% |
| Flakiness | 79 | 37% |
| Burning | 69 | 32% |
| Bumps | 61 | 28% |
| Swelling | 19 | 9% |
| Acne | 16 | 7% |

**Table 6: Hair Symptoms**

| Hair Symptoms Experienced | Number | Percent |
|---|---|---|
| Breakage | 187 | 87% |
| Brittleness | 172 | 80% |
| Dryness | 126 | 58% |
| Frizziness | 94 | 44% |
| Oiliness | 33 | 15% |

Individuals reported a wide array of percent hair loss, ranging from 1% to 100%. The mean percent hair loss was 38%, while the median percent hair loss was 35%. The highest prevalence (51%) was reported among the 26-50% hair loss group, while the lowest prevalence (5%) was reported among the 76-100% hair loss group (Table 7). There did not appear to be a trend between increasing percent hair loss and date of first purchase; however, the two highest percent hair loss reports were from individuals that first purchased WEN in 2014 and 2013.

**Table 7. Percent Hair Loss**

| Percent Hair Loss | Number | Percent |
|---|---|---|
| 0-25% | 71 | 33% |
| 26-50% | 111 | 51% |
| 51-75% | 24 | 11% |
| 76-100% | 10 | 5% |

216     100%

Claimants also reported underlying medical conditions, with the most prevalent being endocrine system disorders or impairments (14%), dermatological diseases or conditions (10%), and hormonal imbalance (8%). These pre-existing conditions include risk factors for hair loss, independent of WEN use. Other medical history conditions included types of hair loss, including alopecia areata (7%), telogen effluvium (3%), scarring alopecia (1%), and frontal fibrosing alopecia (1%). Only one individual reported traction alopecia.

| Medical History | Number | Percent |
|---|---|---|
| Hormonal Imbalance | 18 | 8% |
| Alopecia Areata | 15 | 7% |
| Scarring Alopecia | 3 | 1% |
| Frontal Fibrosing Alopecia | 3 | 1% |
| Telogen Effluvium | 7 | 3% |
| Traction Alopecia | 1 | 0% |
| Endocrine System Disorders or Impairments | 31 | 14% |
| Dermatological Diseases or Conditions | 21 | 10% |

## 4. SUMMARY AND CONCLUSIONS

Overall, this analysis provides unique insight into the patterns of use, medical history, symptom onset, timeline, and product choice of users of WEN Products that are alleging the WEN Products caused them to suffer hair loss. This survey shows that hair loss tends to be reported among an older population (majority of claimants are >50 years old). Notably, some of these complainants also reported medical conditions and alopecia histories that are associated with hair loss independent of use of the WEN Products. Additionally, there is a lack of consistency in the time to event among claimants, with certain users reporting hair loss after one use, while other users report hair loss after multiple years of use. The lack of trends among these claimants suggest that factors other than WEN may be drivers of hair loss.