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“HALO-EFFECT” ANALYSIS ON ADVERSE EVENT REPORTING OF WCD PRODUCTS

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1. INTRODUCTION

Cardno ChemRisk was asked by WEN By Chaz Dean (“WCD”) to conduct a comprehensive risk and safety assessment of the cosmetic product commonly known as WEN[®] by Chaz Dean Cleansing Conditioner (the “WEN Products”), and, specifically, whether the product causes hair loss and/or any other adverse dermal event. This risk and safety assessment was triggered by complaints and allegations of hair loss by a small percentage of consumers who attributed their alleged hair loss to use of the WEN Products based on anecdotal evidence. As part of the evaluation, Cardno Chemrisk analyzed the temporal trends the complaints alleging hair loss submitted by consumers to WCD and the Food and Drug Administration (FDA) when compared to certain events relating to the WEN Products, including, among other things, before and after initiation of litigation in March 2014 and large media events, including, among other things, appearances by plaintiffs’ counsel on the widely watched and followed news show Good Morning America in December 2015 and the FDA’s public announcement that it is investigating the WEN Products, and the widely reported New York Times article about the lawsuits over the WEN Products in August 2016.

2. INTRODUCTION

A. FDA Adverse Event Reporting System

The FDA maintains the Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS), which includes product complaint reports submitted to the FDA for foods, dietary supplements, and cosmetics. This database was developed to support the FDA’s post-marketing safety surveillance program. Recently, information from this data source was made publicly available (2004-2018), including adverse event reports for the WEN Products, such as complaints relating to dermal irritation, hair breakage, and hair loss.

B. The Halo Effect on Products

Previous research has demonstratively established that negative news media can alter judgments about a product even when there is minimal scientific support, resulting in a phenomenon known as the halo effect. Specifically, the halo effect is a cognitive bias where an observer’s impression of a company influences the observer’s feelings toward the company’s character or property. An analysis of pharmaceuticals and medical devices demonstrated that public risk percepts are driven by anxiety despite positive clinical outcomes, and that feelings can be sustained regardless of scientific findings in relation to safety (Kerger et al. 2016). Due to negative reporting in the press, a specific product or product line may be viewed negatively across various contexts, and may result in increased fears and a heightened awareness of subjective symptoms due to society shifting their perception to viewing the product line as risky (Nelkin 1989). It has been argued that this response to real or perceived risk may result in lost opportunities for public health gains (Collins et al. 2013). In other words, negative news stories or comments about a product circulated in the press or on social media result in an increase in

complaints about that product despite no identifiable connection between the complaints and the products.

C. The Role of Social Media, News Reporting, and Litigation on Self-Determination of Disease

Mass psychogenic illness, alternatively referred to as “mass hysteria”, describes the outbreaks of illness and symptoms in otherwise healthy people attributable to a toxic agent for which no evidence of existence can be found (Page et al., 2010; Tarafder et al., 2016; Broderick et al., 2011). Incidences of mass hysteria are commonly perpetuated among individuals belonging to a group or having a pre-existing social connection (Page et al., 2010). Social media, news reporting, and litigation are routes by which threatening misinformation can travel rapidly between people (Tarafder et al., 2016; Broderick et al., 2011). Studies have shown that emergency responders and initial media reports of unexplained illnesses or incidences can exacerbate the phenomenon by spreading information on symptoms and leading more people to come forward with similar afflictions (Tarafder et al., 2016). Furthermore, it has been shown that media plays a large role in mass hysteria (Sahu et al. 2015).

D. Important Events In Connection With The WEN Products.

The following dates were major events in relation to the WEN Products:

- March 2014: The first class action lawsuit was filed alleging that the WEN Products caused hair loss. Plaintiffs are posting on social media about the class action lawsuit.
- December 2015: A plaintiff’s counsel and a plaintiff made an appearance on the ABC news show, *Good Morning America*, describing the allegations of hair loss caused by the WEN Products. Notably, *Good Morning America* is a major news show on a major broadcast network that is often viewed in clips on social media.
- July 2016: The FDA announces that it is investigating reports of hair loss, hair breakage, balding, itching, and rash associated with the use of the WEN Products. This announcement is spread throughout social media by the press and others.
- August 2016: The New York Times publishes an article about the allegations of hair loss against the WEN Products, which is repeated throughout the internet and on social media.

3. METHODOLOGY

Publicly available data was extracted from the FDA Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) from 2004 to 2018. Data was restricted to WCD specified products, and were further limited to the cleansing conditioner products, including cleansing hair treatment, styling cream shampoo, cleansing rinse, and treatment/replenishing mist. The following products were not included in the analysis: anti-frizz, floss, moisture spray, body moisturizer, mousse, oil treatment, hair mask, volume spray, smoothing gloss, sculpting foam, hair gel, humidity spray, re-moist, frizz control, paste, and

lotion. Complaints involving unspecified WCD products that may be products other than the WEN Products were included in the analysis.

Daily adverse event start data were counted to include frequency data by month. If no date of event was reported, the date of submission was used. Daily data were grouped into year-specific month categories (with zero data included for months with no daily-specific adverse events reported). Similarly, year-specific month totals for all adverse events in the CAERS database was created (not including the WCD products in this analysis). This was used to account for the general trend in increased awareness and adverse event reporting over time.

Based on the available company sales records, a subset of adverse event data (2005 to 2018) was analyzed using negative binomial regression. For sales data, monthly totals were available from 2016 to 2018. However, only yearly totals were available for 2005 to 2016. Therefore, the monthly distribution of sales from 2016 to 2018 was applied to the 2005 to 2016 data to estimate monthly totals during this time period.

4. RESULTS AND DISCUSSION

A total of 1,997 adverse events were reported among the products that fit the study inclusion criteria. The most prevalent reported adverse events were alopecia, pruritus, trichorrhexis, and rashes. Out of the total number of WCD-specific reported adverse events, 86.1% were reported to occur in or after March 2014 and 60.1% were reported to occur in or after December 2015.

The rate of adverse event reporting specific to WCD cleansing conditioners after March 2014 and December 2015 were statistically significantly higher in comparison to the adverse event reporting before these dates, adjusting for the number of hair cleansing conditioners sold per year and the number of reported non-WCD-specific adverse events.

There was no statistically significant difference in the mean number of the WEN Products sold before and after December 2015, but there was a statistically significant difference in the mean number of WEN adverse events per number of WEN units sold (higher ratio after December 2015 when compared to before December 2015). Specifically, the adjusted incidence rate ratios (IRR; per 10,000 WEN units sold) of adverse event reporting after December 2015 was 16.7 (95% CI: 7.89-35.4). When further stratified by litigation and news dates, March 2014 to December 2015 (IRR: 3.29), December 2015 to January 2016 (IRR 65.0), and January 2016 to December 2018 (IRR 5.67) all had statistically significantly elevated incidence rates (per 10,000 units sold) in comparison to January 2005 to March 2014.

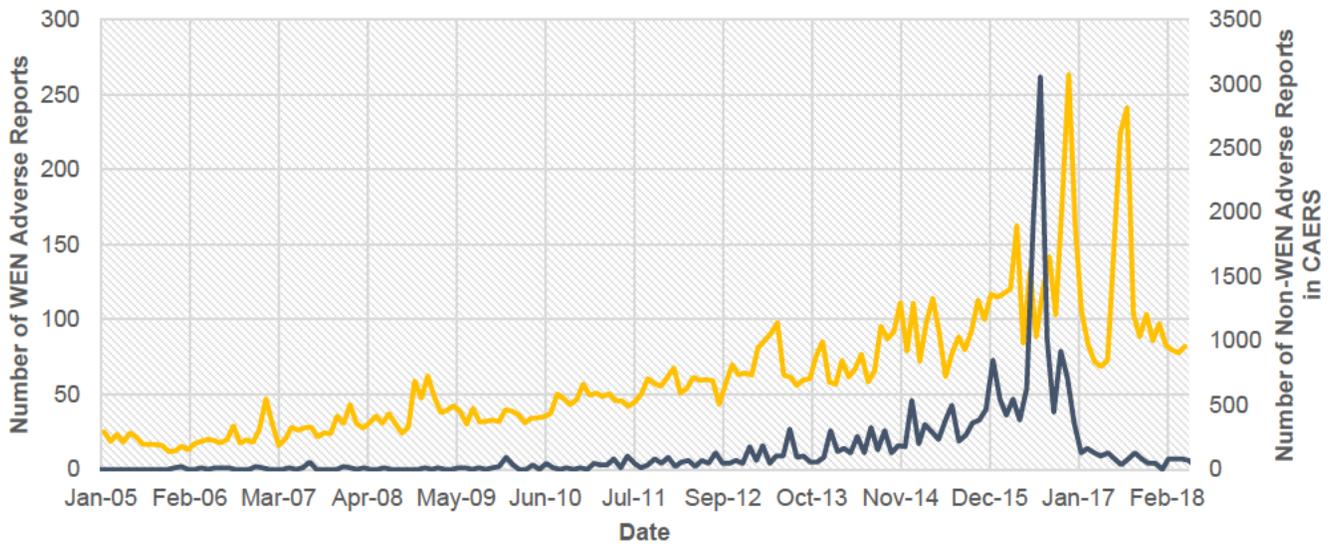


Figure 1. Number of reported WCD-specific events (blue) and number of non-WCD specific events (yellow) in CAERS database (2005-2018)

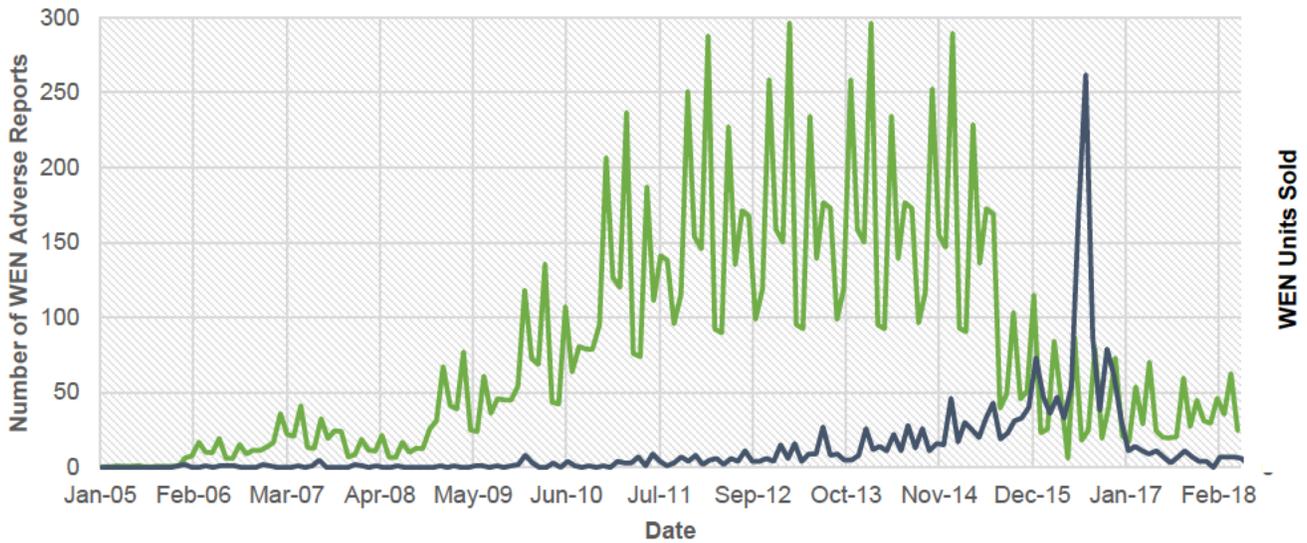


Figure 2. Number of WEN-specific adverse events (blue) and number of WEN units sold (green) from 2005 to 2018

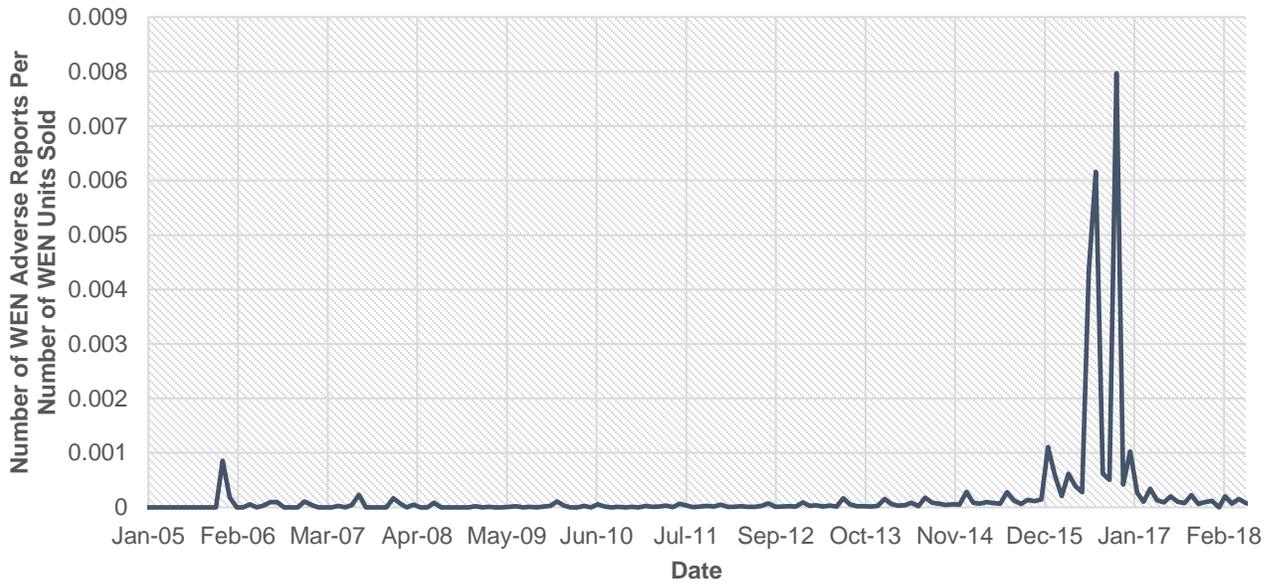
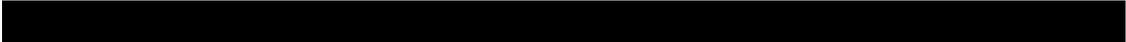


Figure 3. Number of WEN-specific adverse events per 10,000 units of WEN sold, from 2005 to 2018.



5. CONCLUSIONS

As can be seen by above findings, a direct link exists between the number of complaints and the specific news events related to the WEN Products (the 2014 filing of the first lawsuit, the December 2015 Good Morning America appearance, the July 2016 FDA announcement of its investigation; and the August 2016 New York Times articles). A clear spike in complaints occurred at each of these events. Indeed, the initial spike at the time of the WEN Product-related events is extremely dramatic and is followed by a dramatic drop in complaints after the time of the WEN Product-related events. If the WEN Products did cause some sort of adverse event, these spikes should not be as dramatic and there to be a steady rate of complaints. The temporal trends of the complaints fall within the classic halo effect and thus demonstrates that the complaints are unrelated to the WEN Products itself and linked to the WEN Product-related events.