RESEARCH LETTER

Adverse Events Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products

The US Food and Drug Administration (FDA) defines cosmetics as articles for beautification, cleansing, or altering physical appearance. There have been multiple public health controversies surrounding cosmetics involving lip balms, lipsticks, and eyelash makeups adulterated with prostaglandins. In 2014, the FDA began investigating WEN by Chaz Dean Cleansing Conditioners after directly receiving 127 consumer reports. The FDA later learned the manufacturer had already received 21,000 complaints of alopecia and scalp irritation. The product remains on the market with the FDA currently soliciting additional consumer reports. To encourage greater transparency and more reporting, the FDA’s Center for Food Safety and Applied Nutrition’s Adverse Event Reporting System (CFSAN), a repository of adverse events related to foods, dietary supplements, and cosmetics, was made publicly available in 2016. Our objective was to examine adverse events in CFSAN to inform future policymaking.

Methods | We extracted the entire CFSAN data file (2004-2016), including all voluntary submissions by consumers and health care professionals. We categorized all cosmetic-related adverse events by FDA-designated product class. For 5% of entries, no product class was identifiable. We collected self-reported adverse health outcomes (nonserious injury, serious injury, disability, congenital defects, or death) for each event. We used a logit transform to estimate 95% CIs for proportions, and a logistic regression model to compare the proportion of serious adverse health outcomes (serious injury, disability, congenital defect, or death) reported for each product class compared with the global average. Because this study used only publicly available data, it was exempt from Northwestern University institutional review board approval.

Results | From 2004 to 2016, a total of 5144 events were submitted (an average of 396 events per year). From 2015 (n = 706) to 2016 (n = 1591), there was an increase in adverse events, with 78% in 2015 and a 300% increase in 2016 compared with the mean across the entire time period (2004-2016). This increase was largely driven by the hair care products class, specifically the WEN product line by Chaz Dean.

Figure 1. Adverse Event Reports for Cosmetics and Personal Care Products From 2004 to 2016

The US Food and Drug Administration (FDA) provides definitions for all product classes. Briefly, skin care products constitute a broad range of items, including cleansing lotions and creams, deodorants, sprays, moisturizers, and anti-wrinkle products. Personal cleanliness products included bath soaps, deodorants, and douches. Baby products included shampoos, lotions, oils, creams, and powders marketed toward newborns and infants. Hair care products, which include shampoos (noncoloring), rinses (noncoloring), hair spray, and hair straighteners, constituted 35% (n = 1805) of all adverse health reports. Skin care products were the next most common source of complaints at 22% (n = 1148). Five percent of products (n = 257) were not classifiable based on the available data. The data label for each year indicates the total number of adverse events reported. On average, 396 cosmetic-related adverse events were sent to the FDA every year. There was a 78% increase in 2015 and a 300% increase in 2016 for adverse event reports compared with the mean across the entire time period (2004-2016).
There are several limitations to this analysis. Although the FDA removes duplicate reports, there is no causality determination and health outcomes are all self-reported. Demographic information is also limited to sex and age. Additional data on medical comorbidities or concomitant product use would be relevant. Finally, we cannot distinguish reports from consumers vs those from health care professionals.

In 2014, the FDA expressed “profound disappointment” with the industry’s draft legislation to modernize cosmetics regulation and refused to invest additional taxpayer dollars for further negotiations. Since then, California’s Senator Diane Feinstein has introduced the Personal Care Products Safety Act (PCPSA) with a coalition of supporters. The bill’s key components include granting the FDA authority to recall unsafe cosmetics, mandatory manufacturer reporting of adverse events, and a yearly safety review of 5 ingredients. However, the law does not provide more investment to the National Toxicology Program for more rigorous scientific testing. For products blurring the line between drug and cosmetic (cosmeceuticals), a form of premarket approval should be considered. Ultimately, PCPSA is a first step in the right direction to protect consumers.

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Less is More
Persistent Gaps in Use of Advance Directives Among Nursing Home Residents Receiving Maintenance Dialysis

Patients with end-stage renal disease receiving dialysis have a symptom burden and prognosis comparable to patients with incurable cancer. They frequently and increasingly receive intensive procedures near the end of life. Because the benefits of these interventions remain controversial, a key question is whether increasing intensity of end-of-life care reflects changes in the extent to which patient preferences are elicited and documented with advance directives. Nursing homes offer an important setting to evaluate advance directive use because they accept full responsibility for care during patient stay.

To shed light on a potentially remediable care gap, we sought to determine whether changes in the use of advance directives between 2000 and 2010 are related to changing patterns of end-of-life care among nursing home residents receiving dialysis.

Methods | We used data from a national registry of patients receiving dialysis linked to Medicare claims and the Minimum Data Set to identify 153,285 nursing home residents who died in 2000 or 2010 with continuous Medicare coverage in the last 6 months of life and a nursing home record between 31 and 365 days before death. The institutional review board at Stanford University and the Veterans Affairs Palo Alto Research Committee approved the study.

We categorized patients according to the presence or absence of 2 advance directive components: a treatment-limiting advance directive (TLD), defined as documentation of patient goals—and the care that is actually delivered. This gap is noteworthy because advance directives have increased in other segments of the population over the same period.

We estimated the difference between the change in end-of-life care between 2000 and 2010 among patients with 1 or both advance directive components and the change in end-of-life care over the same period among patients with neither advance directive component using modified Poisson regression. The models accounted for demographics, clinical characteristics, regional spending, and correlation of patients within nursing homes.

Results | There was little difference in the frequency of TLDs and surrogates in 2000 vs 2010 (Figure). In both years, 63% of patients had neither advance directive component and fewer than 10% had both. Over the same period, the proportion of patients receiving an intensive procedure in the last month of life increased from 16% to 22% (P < .001) and the proportion admitted to an ICU in the last month of life increased from 34% to 47% (P < .001).

Compared with patients who lacked a TLD and surrogate, the adjusted difference in the proportion of patients receiving an intensive procedure in 2000 vs 2010 did not differ for those with a TLD or surrogate alone, whereas it was 7 percentage points smaller among those with a TLD and surrogate (Table). There was no difference across these groups in the proportion of patients admitted to the ICU in the last month of life in 2000 vs 2010.

Discussion | The most striking finding from our study of nursing home residents receiving dialysis is the large and persistent gap that exists between what is widely considered standard of care for patients with serious illness—elicitation and documentation of patient goals—and the care that is actually delivered. This gap is noteworthy because advance directives have increased in other segments of the population over the same period.

Hospitalization may be the most effective way to care for some chronically ill patients, while for others it is the path of least resistance that leads to an unintended escalation in care.

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**Table**

<table>
<thead>
<tr>
<th>Patients, %</th>
<th>2000</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Treatment-Limiting Directive or Surrogate</td>
<td>30</td>
<td>24</td>
</tr>
<tr>
<td>Surrogate Alone</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Treatment-Limiting Directive Alone</td>
<td>47</td>
<td>51</td>
</tr>
<tr>
<td>Treatment-Limiting Directive and Surrogate</td>
<td>10</td>
<td>14</td>
</tr>
</tbody>
</table>

*Figure. Prevalence of Advance Directives Among 153,285 Nursing Home Residents Receiving Dialysis, 2000 vs 2010*

*P value = .95 for comparison across groups.*

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