Publishing Data on OTC and Consumer Products: Providing the Evidence and Dispelling the Myths

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JOHNSON & JOHNSON
Disclaimer

- David A. Mays is a stockholder and employee of Johnson & Johnson Consumer & Personal Products Worldwide.
- The views and information provided during this presentation should not be interpreted as a position of Johnson & Johnson and are the sole opinion of David A. Mays.
- Representation and discussion of products are for demonstration purposes only.
So…

Why should we care about products that are OTC or just lotions & potions?
Model of Influence Has Shifted Dramatically

**Pyramid of Influence 20th Century**
- Elites
- The Media
- The Masses

**Sphere of Cross-Influence 21st Century**
- Media online and offline
- Employees
- Governments
- Investors
- NGOs
- Consumers
- Retailers
- Influencers
The 4 C’s

Cut
What it looks like...and is it different up close

Color
Always should be in black and white (maybe a bit of color)

Clarity
Clear with minimal imperfections or inclusions

Carat
Value, meaning, and impact
The 4 C’s

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The proliferation of channels means disparate publics are more connected and able to talk freely—and anonymously, if they choose.

- Dispersion of authority
- Democratization of information
- Desire to socialize—share opinions and thoughts
- Discussion of issues not previously part of popular culture
88% I usually turn to my physician to validate info I get online.

88% I usually turn to other sources to validate info I get from my doctor.

Consumer confusion and mistrust regarding the overall safety of personal care products
Ghostwriting Is Called Rife in Medical Journals

Researchers, like politicians, use "spin" in presenting their results, conference hears.

Disclosure of competing interests: A new standardised format that all journals could use.

Health care, under the influence
The Globe and Mail, 26 April 2008
Yet Expert Voices Are Still the Most Trusted

Who’s the Expert?

Megan says:
October 6, 2011 at 6:15 pm

My boyfriend’s mom is a chemist for a company contracted by the big cosmetics companies. We’ve had so many arguments with her since switching to clean products. She still insists the ingredients they use are completely safe. I constantly wonder if she wasn’t paid by those corporations if she would have a different opinion, but there is another part of me that thinks she would know better since she is the chemist. Either way I’m still sticking with the product I know are clean.

accessed October 10, 2011.
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Woe to the scientist who fails to respect the intrinsic affective nature of the human risk perception system and denigrates people whose fears do not match the facts as “irrational.” The attitude that people are too dumb to “get it,” too poorly educated to “get it,” too emotional to “get it,” too easily manipulated by politicians and marketers to be able to make smart decisions for themselves, slaps people in the face with an arrogance that diminishes trust, and reduces the influence the scientist might hope to have. No matter how benignly the science community tries to “educate” the public, if the underlying message of that effort is a paternalistic attitude toward people’s limited abilities to perceive and respond to risk rationally, that effort will fail.
Not Just for Pharma Anymore

“The days when armies of sales reps in the field drove revenues are over”

Shift money from the increasingly ineffective ‘more feet on street’ budget to the increasingly important ‘peer-reviewed publications’ budget

Peer-reviewed publications—More important to sales and marketing than sales representatives?

Peer-reviewed publications are the foundation of medical knowledge; they disseminate advances in medical knowledge. In this article we will provide an overview of the business case for peer-reviewed publications and show how companies can benefit from the practices of their competitors.

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Case Examples of Misleading Impressionism

REVIEW OF 1,4 DIOXANE & FORMALDEHYDE ALONG WITH A LITTLE PRESERVED SCENT…
Examples

- Traces found in products
- Fragrances, scents, & evidence
- Preservation
BOO!!!
Know what's scary?
Toxins in mama and baby products.

The Case...

EWG's Skin Deep®
Cosmetics Database

Have you read your ingredients?
Search below to see.

Search more than 65,000 products...
The Science of Traces

• With the ever decreasing level of detection, zero is a matter of the limit of detection
• Traces of thousands of chemicals can be detected in our food, water, air, and similarly in cosmetic ingredients
• There is a body of scientific analysis called "risk assessment" to determine whether the level present is meaningful
• *No effect levels* are often available
1,4-Dioxane Contained in Food Additives*
Considered Safe at Trace Levels

- Sherbet, Ice cream, Ice milk
- Frozen custard
- Cottage cheese
- Fruit juice drinks
- Barbeque sauces
- Vitamins
- Mineral supplements
- Pickled products
- Dessert toppings and fillings
- Non-dairy creamers
- Shortenings
- Gelatin
- Flavoring oils
- Sweeteners

*May be found in additives such as polyethylene glycols, polysorbates, and ethoxylated mono/di-glycerides used as emulsifiers, stabilizers, or solubilizers. Sapphire Group, 2007.
Long-term Dermal Exposure Does Not Cause Detectable Blood Levels of 1,4-Dioxane

- CDC study measured 1,4-dioxane in blood as biomarker of long-term exposure
  - Human blood samples collected from NHANES 2007-2008 database (N=2053, ≥12 y)
    - High potential for dermal exposure to 1,4-dioxane through normal product use (e.g., dish soaps, shampoos, lotions, cosmetic products)
    - 1,4-dioxane levels measured using microextraction and gas chromatography/mass spectrometry
      - Limit of detection - <0.400 ng/mL (<0.4 ppb)
  - 1,4-dioxane was consistently undetectable, despite high potential for dermal exposure through normal product use

Centers for Disease Control and Prevention (CDC) – U.S.
Formaldehyde is a Product of Metabolism in All Living Organisms

- Commonly found in air, water, plants, animals (including humans), and food
- Exists in humans at ~3 ppm from metabolism

Concentrations of Formaldehyde in Nature

<table>
<thead>
<tr>
<th>Food</th>
<th>Concentration (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pears, apples, tomatoes, and radishes</td>
<td>3.7–60.0</td>
</tr>
<tr>
<td>Cabbage, carrots, and green onions</td>
<td>3.3–26.3</td>
</tr>
<tr>
<td>Meat</td>
<td>5.7–20.0</td>
</tr>
<tr>
<td>Fish</td>
<td>8.8–20.0</td>
</tr>
<tr>
<td>Shellfish</td>
<td>1.0–98.0</td>
</tr>
</tbody>
</table>

Be Careful What You GOOGLE

A Fragrant Illustration…
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Exposure Sources</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>PANTHENOL</td>
<td>Multiple, additive exposure sources</td>
<td>Limited</td>
</tr>
<tr>
<td>GARDENIA TAHITENSIS (TIARE) FLOWER (ORGANIC)</td>
<td>None Identified</td>
<td>None</td>
</tr>
</tbody>
</table>
What’s really in a Name?

GARDENIA TAHITENSIS (TIARE) FLOWER
(ORGANIC)

It is the national flower of French Polynesia and the Cook Islands.

GARDENIA TAHITENSIS FLOWER is classified as: SKIN CONDITIONING
No records were found which contain **all** of the search words. The following records contain at least one of the words.

**The term** *tahitiensis* **was not found.**

Items 1 through 4 of 4

Substance Names are sorted in **relevancy ranked** order.

<table>
<thead>
<tr>
<th>Select Record</th>
<th>Substance Name</th>
<th>Words Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BENZYL ACETATE</td>
<td>gardenia</td>
</tr>
<tr>
<td></td>
<td>140-11-4</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1,2-DIBROMO-3-CHLOROPROPAHE</td>
<td>gardenia</td>
</tr>
<tr>
<td></td>
<td>96-12-8</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>ALPHA-METHYL BENZYL ALCOHOL</td>
<td>gardenia</td>
</tr>
<tr>
<td></td>
<td>98-85-1</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>METHYL ANTHRANILATE</td>
<td>gardenia</td>
</tr>
<tr>
<td></td>
<td>134-20-3</td>
<td></td>
</tr>
</tbody>
</table>
What’s in a Number?

XXXXX Baby Shampoo & Body Wash is a gentle, real castile soap, pure and mild enough to cleanse even delicate baby skin and hair. USDA certified made with organic ingredients, free from synthetic foaming agents and sulfates, with no artificial preservatives, dyes or fragrances. Just pure organic body wash for your pure organic baby!

Saponified Cocos nucifera (organic coconut) oil, Saponified Olea europaea (organic olive) oil, Aloe barbadensis (organic aloe) leaf juice, Vanilla planifolia (organic vanilla) bean extract, Citrus sinensis (organic orange) oil, Kosher vegetable glycerin, Potassium citrate, Butyrospermum parkii (organic shea) butter, Calendula officinalis (organic calendula) extract.
Sounds simple, but really contains...

- If Label Says:

Orange Peel

- Product Contains:

0.2% - 0.5% essential oil, linalyl acetate, alpha-pinene, limonene, linalool, nerol and geraniol, Methyl anthranilate, Bitter Substances, Flavinoids, tangeretin, tetra-o-methylscutellarin, 3-heptametoxyflavone, 5-heptametoxyflavone, 6-heptametoxyflavone, 7-heptametoxyflavone, 8-heptametoxyflavone 3'-heptametoxyflavone, 4'-heptametoxyflavone, nobiletin, sinensetin, auranetin, and 5-hydroxyauranetin, alkaloid synephrine and N-methyltyramine, carotene derived from cryptoxanthin (major), luteoxanthin, mutachrome, auroxanthin, zeaxanthin
Preservation…

- Toxicity
- Formaldehyde
- Paraben
- Phenoxyethanol
In fact, these preservatives protect users from bacteria. Present in quantities so small—typically, less than 1 percent of a product’s total weight—they are added to prevent contamination and to protect consumers from the buildup of dangerous bacteria that can cause eye infections, skin rashes, and even deadly infections such as E. coli and Salmonella.

Parabens, for example, are added to makeup, deodorants, moisturizers, and body creams to prevent bacteria, fungi, and mold. According to the Campaign for Safe Cosmetics, parabens are linked to breast cancer and can cause hormone dysfunction. Yet scientists have refuted the claims, arguing that concentrations of parabens in cosmetics are too small to have an adverse effect, and are at levels in our body thousands to millions of times lower than naturally produced estrogens.

Available online: http://cei.org/sites/default/files/Dana%20Joel%20Gattuso%20-%20The%20True%20Story%20of%20Cosmetics.pdf
Reality…

Competitive Product Same Microbial Growth As Test Product With No Added Preservative

3 days post inoculation
Further Reality

Results: 1 to 20 of 349

   Lundov MD, Zachariae C.
   PMID: 19099548 [PubMed - indexed for MEDLINE]
   Related citations

2. Recalls of foods and cosmetics due to microbial contamination reported to the U.S. Food and Drug Administration.
   Wong S, Street D, Delgado SI, Klontz KC.
   PMID: 10945589 [PubMed - indexed for MEDLINE]
   Related citations

3. Microbiological study of cosmetic products during their use by consumers: health risk and efficacy of preservative systems.
   Campana R, Scesa C, Patrone V, Vittoria E, Baffone W.
   PMID: 16910936 [PubMed - indexed for MEDLINE]
   Related citations

4. Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy.
   Lundov MD, Moesby L, Zachariae C, Johansen JD.
   Contact Dermatitis. 2009 Feb;60(2):70-8.
   PMID: 19207376 [PubMed - indexed for MEDLINE]
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Edelman Health Engagement Barometer 2008.
Available at: http://www.edelman.com/image/insights/content/edelmanhealthengagementbarometerpresentation.pdf
“The days when armies of sales reps in the field drove revenues are over”

Peer-reviewed publications—More important to sales and marketing than sales representatives?

Peer-reviewed publications are the foundation of our knowledge; they disseminate advances in medical knowledge to all who need to know. In this paper, we will provide evidence that peer-reviewed publications are an essential component of the business model of many companies. We will show that without peer-reviewed publications, companies will not be able to compete in today’s marketplace. We will also show that companies that do not invest in peer-reviewed publications will lose market share.

Shift money from the increasingly ineffective ‘more feet on street’ budget to the increasingly important ‘peer-reviewed publications’ budget.

Woe to the scientist who fails to respect the intrinsic affective nature of the human risk perception system and denigrates people whose fears do not match the facts as “irrational.” The attitude that people are too dumb to “get it,” too poorly educated to “get it,” too emotional to “get it,” too easily manipulated by politicians and marketers to be able to make smart decisions for themselves, slaps people in the face with an arrogance that diminishes trust, and reduces the influence the scientist might hope to have. No matter how benignly the science community tries to “educate” the public, if the underlying message of that effort is a paternalistic attitude toward people’s limited abilities to perceive and respond to risk rationally, that effort will fail.
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“I’m not bad, I’m just drawn that way.”

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Jessica Rabbit, Who Framed Roger Rabbit, Touchstone Pictures, 1988
Questions…