

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

David A. Mays, PharmD, MBA

**Director, Global Scientific Engagement - Baby
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...

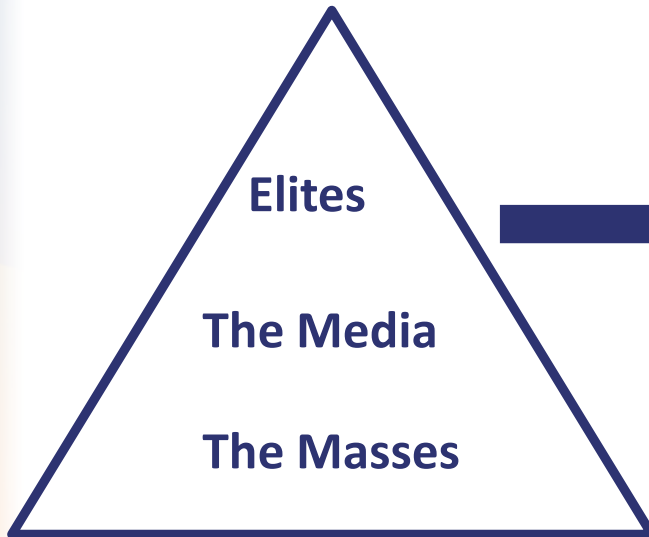
Why should we care about products that are OTC or just lotions & potions?



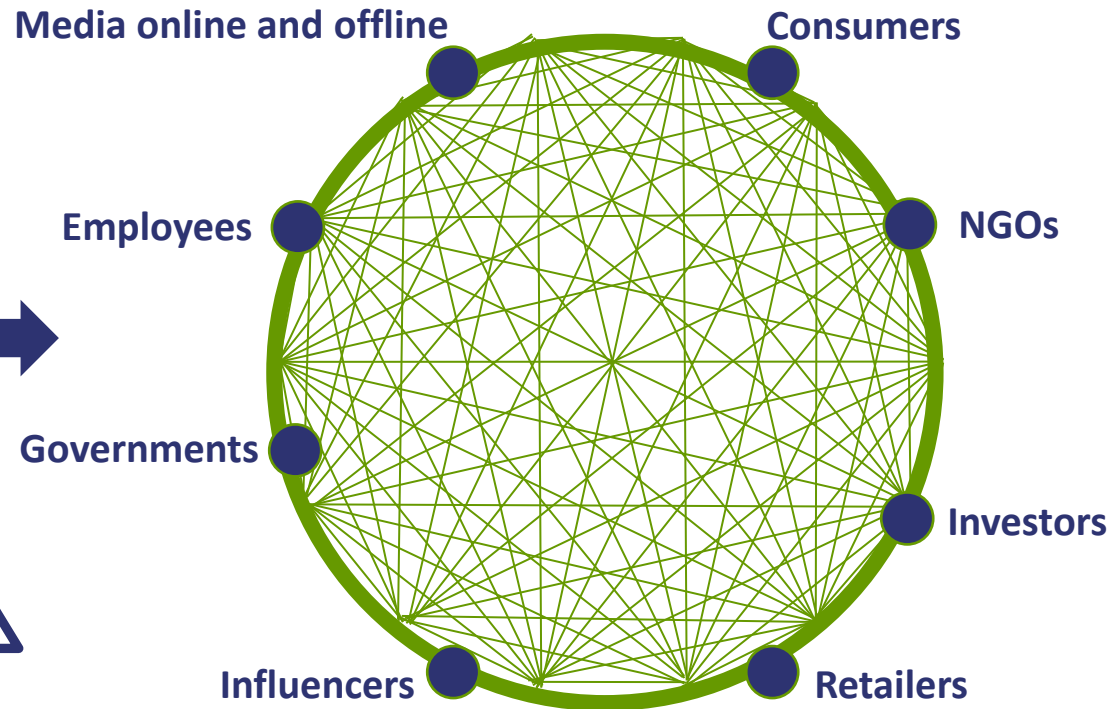
Cut

Model of Influence Has Shifted Dramatically

Pyramid of Influence
20th Century



Sphere of Cross-Influence
21st Century



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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Digital Revolution

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

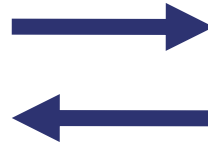
Cut

New Second Opinion



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.





Cut

**Consumer confusion and mistrust
regarding the overall safety of personal
care products**

Cut

Ghostwriting Is Called Rife in Medical Journals

September 2009 - NY Times, 10

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

BMJ, 15th September 2009

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

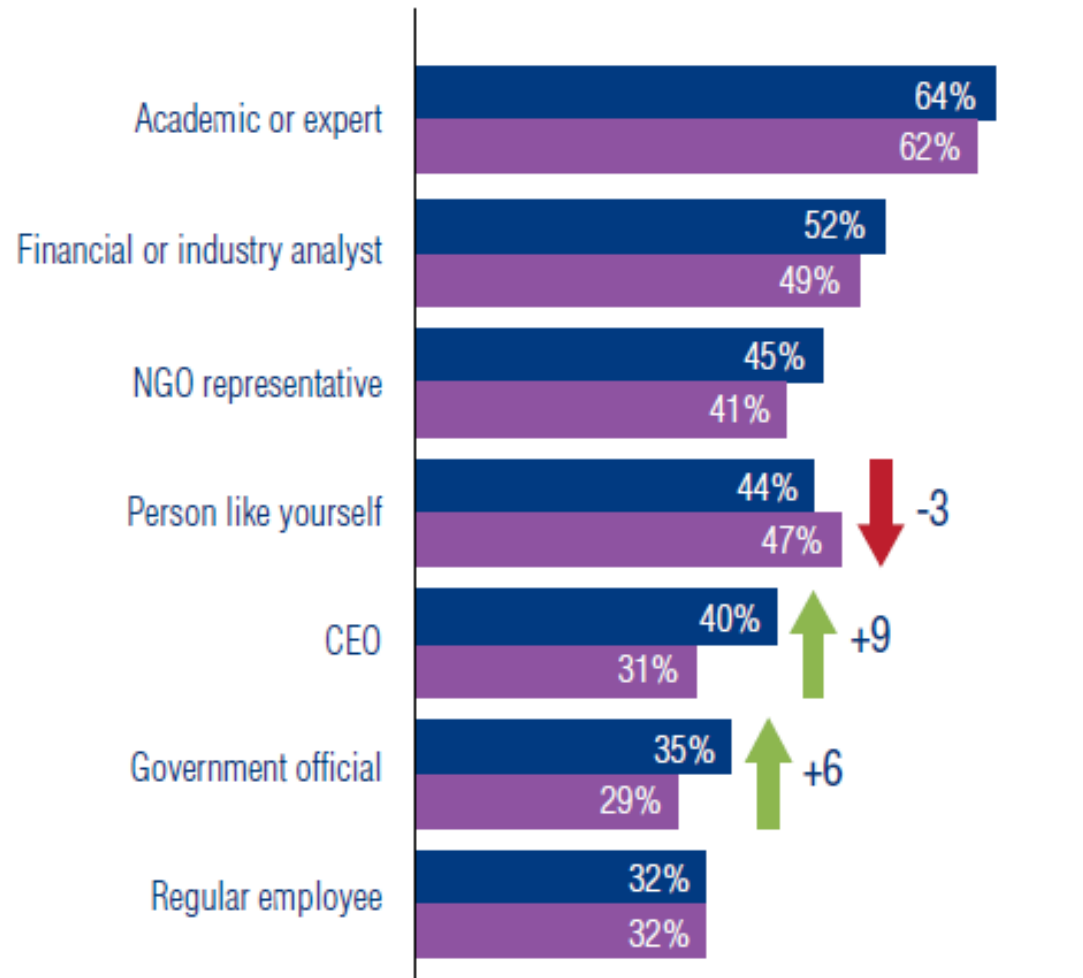
BMJ, 12TH OCTOBER 2009

Health care, under the influence

The Globe and Mail, 26 April 2008

Yet Expert Voices Are Still the Most Trusted

If you heard information about a company from one of these people, how credible would the information be?



Informed publics ages 25 to 64 in 20 countries
"Extremely credible" and "very credible" responses only

■ 2010 ■ 2009

Cut

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.

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Risk Perception in Toxicology—Part I Moving beyond Scientific Instincts to Understand Risk Perception

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

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as their ethical and scientific, objectives. Indeed, viewed publications, and the professional medica who make them happen, can allow companies to each of these objectives in a complementary mann

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

Peer-reviewed publications are the foundation c cal knowledge; they disseminate advances in m

“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

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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



1 2 3
BOO!!!
Know what's scary?

Toxins in mama
and baby products.

No More Toxic Tub

Getting Contaminants Out Of
Children's Bath & Personal Care Products



The Case...

Home Sun Makeup Skin Care Hair Eye Care Nails Fragrance Babies & Moms Oral Care Men's FAQ

 **EWG's Skin Deep[®]**
Cosmetics Database

Have you read
your ingredients?

Search below to see.

Search more than 65,000 products...

GO

Safe Cosmetics
EWG.org

EWG.org
Safe Cosmetics

EWG.org

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 (eg, 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

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

Food	Concentration (ppm)
Pears, apples, tomatoes, and radishes	3.7–60.0
Cabbage, carrots, and green onions	3.3–26.3
Meat	5.7–20.0
Fish	8.8–20.0
Shellfish	1.0–98.0

Heck H, et al. *Regul Toxicol Pharmacol*. 2004;40:92-106.

Feron V, et al. *Mutat Res*. 1991;259:363-385.

Butterworth. Available at: http://www.consumeraffairs.com/news04/2009/03/toxic_baths02.html. Accessed

Clarity

Be Careful What You GOOGLE



=



A Fragrant Illustration...

Clarity

Is a Number a Number?

<u>PANTHENOL</u>	Multiple, additive exposure sources	 Data: Limited
<u>GARDENIA TAHITENSIS (TIARE) FLOWER (ORGANIC)</u>	<i>None Identified</i>	 Data: None



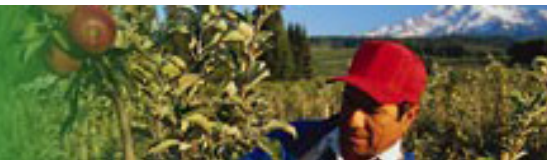
Clarity

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



HSDB Search Results

For chemicals, add synonyms and CAS numbers to search: Yes No

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](#).

Select Record	Substance Name	Words Found
1 <input type="checkbox"/>	BENZYL ACETATE 140-11-4	gardenia
2 <input type="checkbox"/>	1,2-DIBROMO-3-CHLOROPROPANE 96-12-8	gardenia
3 <input type="checkbox"/>	ALPHA-METHYLBENZYL ALCOHOL 98-85-1	gardenia
4 <input type="checkbox"/>	METHYL ANTHRANILATE 134-20-3	gardenia

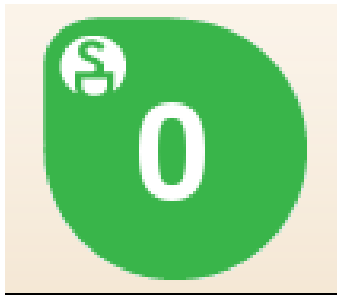
1

10

6

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, Butyrospermun parkii (organic shea) butter, Calendula officinalis (organic calendula) extract

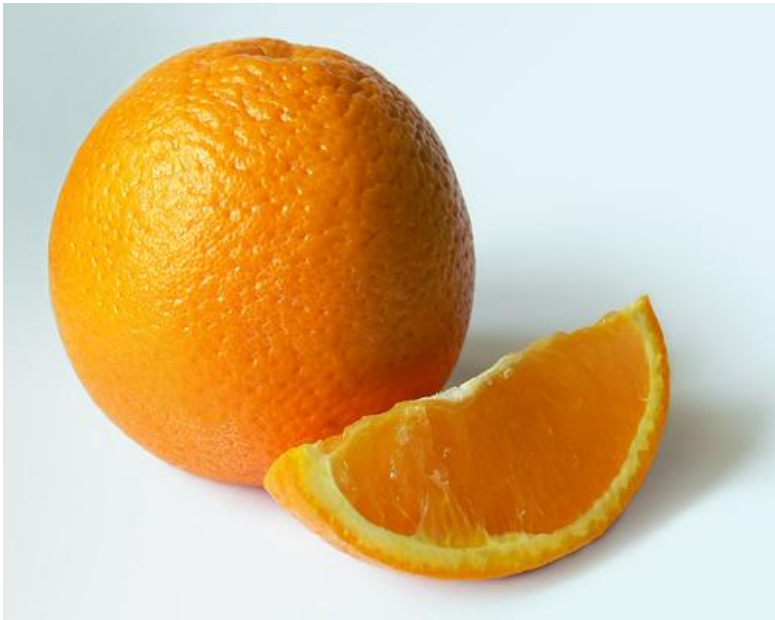
Data: Limited

Sounds simple, but really contains...

- If Label Says:

- Product Contains:

Orange Peel



Google Images - www.impactlab.com/.../10/orange-peel-bsp.jpg

0.2% - 0.5% essential oil, linalyl acetate, alpha-pinene, limonene, linalool, nerol and geraniol, Methyl anthranilate, Bitter Substances, Flavonoids, tangeretin, tetra-o-methylscutellarin, 3-heptamethoxyflavone, 5-heptamethoxyflavone, 6-heptamethoxyflavone 7-heptamethoxyflavone, 8-heptamethoxyflavone 3'-heptamethoxyflavone, 4'-heptamethoxyflavone, 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

The True Story of Cosmetics

Exposing the Risks of the
Smear Campaign

By *Dana Joel Gattuso*

OCTOBER 2011

Reality ??

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



A

B

C

Further Reality

Results: 1 to 20 of 349

<< First < Prev Page 1

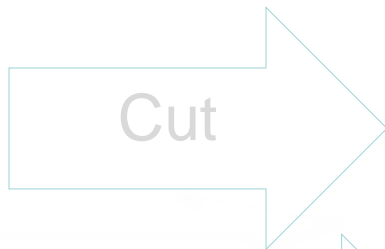
- [Recalls of microbiologically contaminated cosmetics in EU from 2005 to May 2008.](#)
 1. Lundov MD, Zachariae C.
Int J Cosmet Sci. 2008 Dec;30(6):471-4.
PMID: 19099548 [PubMed - indexed for MEDLINE]
[Related citations](#)

- [Recalls of foods and cosmetics due to microbial contamination reported to the U.S. Food and Drug Administration.](#)
 2. Wong S, Street D, Delgado SI, Klontz KC.
J Food Prot. 2000 Aug;63(8):1113-6. Review.
PMID: 10945589 [PubMed - indexed for MEDLINE]
[Related citations](#)

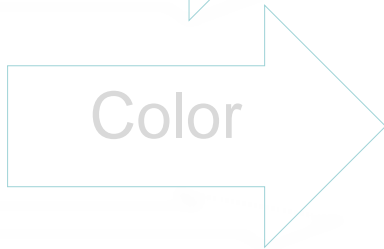
- [Microbiological study of cosmetic products during their use by consumers: health risk and efficacy of preservative systems.](#)
 3. Campana R, Scesa C, Patrone V, Vittoria E, Baffone W.
Lett Appl Microbiol. 2006 Sep;43(3):301-6.
PMID: 16910936 [PubMed - indexed for MEDLINE]
[Related citations](#)

- [Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy.](#)
 4. Lundov MD, Moesby L, Zachariae C, Johansen JD.
Contact Dermatitis. 2009 Feb;60(2):70-8.
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[Related citations](#)

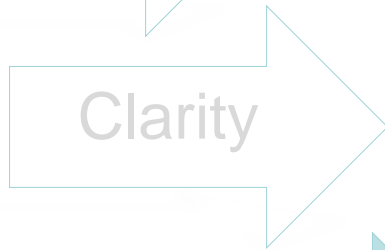
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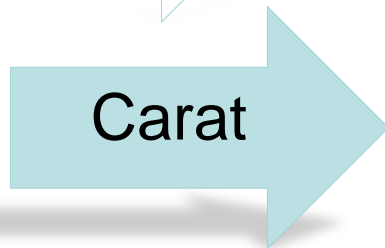
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Value, meaning, and impact

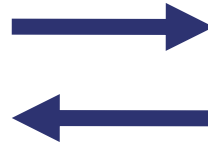
Carat

Answers



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.



Carat

Value, Meaning, & Impact

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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...

