







22nd Asian Harmonization Working Party Annual Meeting

4-8 December, 2017 I New Delhi









6th Dec 2017 AHWP India Meeting New Delhi, India

Advertisement & Labelling

Alfred Kwek Director Edwards Lifesciences

An Apology

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AN APOLOGY

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But we control to the latest encount, it is this only contained that long have been under

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After a present of representation and an extension, we need to be presented to take action, there are increased by our model angle of constructed and hereign method couples to Target and compressible products in bosons of this year's \$1550 celebrations.

With your help and augport, we can rectly this unfortunate situation.

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CREW!

An Apology

Here 's the complete text of the Durex ad

An apology to all Singaporeans, Durex would like to humbly apologise.

Over the past 50 years, while the Singapore economy has been moving rapidly upwards, the **country's birth rate has been spiraling down at an alarming speed.**

It has now come to our attention that we may in fact be part of the problem.

Durex has always focused strongly on the needs of our customers. As a result, the **efficacy and convenience of our products** have increased confidence markedly amongst consumers.

But according to our latest research, it is this very confidence that may have hastened the decline of the birth rate.

We would like to assure **the public that this was never our intention**. And in light of this new information, we would like to offer our sincerest apologies.

After a process of rigorous self-examination, we now feel compelled to take action. **Hence, on August 9, we would urge all** committed and loving married couples to forgo our contraceptive products in honour of this year's SG50 celebrations.

With your help and support, we can rectify this unfortunate situation.

This is a chance for Singapore to embrace prosperity anew in its Golden Jubilee year. A **prosperity not measured in dollars and** cents, but in diapers and baby strollers.

Go ahead, Singapore. Make love your priority this SG50.

An Apology

While no actual advertisement was actually published in the newspaper, the ad did make its rounds on social media with many lauding the move.

A selection on the large to barrow that the selection of the selection of

the real very well recovered when it was back to 2010 Decrement 2017, process of 224 decrement 2017, process of 224 decrements from its version parally on the weathers for a measure parally of the weather a back second second parally with the second a decrement and respon parally with the second a decrement and respon parally with the second a second second second

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AN APOLOGY

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With your help and apport, we can rectify this unfortunate structure.

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CREW!

Best Global Brands 2017 Rankings by Interbrand

01	02	03	04	05 TOP GROWING	06	07	
ú	Google	Microsoft	<u>Cca Cola</u>	amazon	SAMSUNG	ТОУОТА	f
+3% 184,154 \$m	+6% 141,703 \$m	+10% ^{79,999 \$m}	-5% 69,733 \$m	+29% 64,796 \$m	+9% 56,249 \$m	-6% 50,291 \$m	+48% 48,188 \$m
09	10	11	12	13	14	15	16
\odot	IBM	æ	M.	٥	Disnep	(intel)	cisco
+10% 47,829 \$m	-11% 46,829 \$m	+3% 44,208 \$m	+5% 41,533 \$m	0% 41,521 \$m	+5% 40,772 \$m	+7% 39,459 \$m	+3% 31,930 \$m
17	18	19	20	21	22	23	24
ORACLE'	<u></u>	LOUIS VUITION	HONDA	SAP	papel	HM	ZARA
+3% 27,466 \$m	+8% 27,021 \$m	-4% 22,919 \$m	+3% 22,696 \$m	+6% 22,635 \$m	+1% 20,491 \$m	-10% 20,488 \$m	+11% 18,573 \$m
25	26	27	28	29	30	31	32
TREA	Gillette	ANTERSA ESTALES Y	Pampers.	Ups	J.P.Morgan	Budaveiser	HERMES
+4% 18,472 \$m	-9% 18,200 \$m	-3% 17,787 \$m	+2% 16,416 \$m	+7% 16,387 \$m	+11% 15,749 \$m	+2% 15,375 \$m	+11% 14,210 \$m



https://www.brandwatch.com/blog/top-10-free-social-media-monitoring-tools/

What The 25 Most-Followed Instagram Accounts Show Us About The Platform

Posted Jan 27, 2016 by Lucas Matney



23/25

#3 – @selenagomez

Selena Gomez

62,345,729 followers

Selena's lesson to the world is to look good all the time and have fun while you're doing it. Thanks Selena.

https://techcrunch.com/gallery/what-the-25-most-followed-instagram-accounts-can-tell-us-about-using-social-media/slide/23/

What The 25 Most-Followed Instagram Accounts Show Us About The Platform

Posted Jan 27, 2016 by Lucas Matney



24/25

#2 - @taylorswift

Taylor Swift

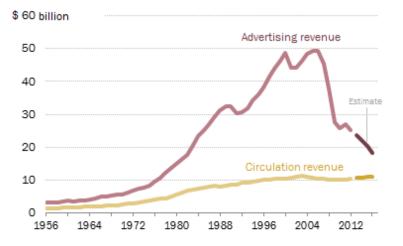
64,032,886 followers

It's important to show who you ride with. Taylor uploads posts with a bunch of fellow celebrities which enhance her street cred and the reputations of those she's pictured with.

https://techcrunch.com/gallery/what-the-25-most-followed-instagram-accounts-can-tell-us-about-using-social-media/slide/24/

Newspapers' circulation revenue climbs steadily even as advertising declines

Total revenue for U.S. newspapers in U.S. dollars



Note: Break in line indicates switch to estimated revenue. There are no data for circulation revenue in 1990.

Source: News Media Alliance, formerly Newspaper Association of America (through 2012); estimate based on Pew Research Center analysis of SEC filings of publicly traded newspaper companies (2013-2016).

PEW RESEARCH CENTER

http://www.pewresearch.org/fact-tank/2017/06/01/circulation-and-revenue-fall-for-newspaper-industry/

Global advertising shares by category (percent)

Category	2009	2010	2011	2012	2013	2014p	2015	2016	2017	2018	2019
Digital	17.2	18.6	20.5	22.7	25.5	28.2	31.0	33.3	35.9	37.5	38.9
Television ¹	38.3	39.2	39.1	39.3	38.7	38.7	37.8	37.5	36.4	36.3	35.9
Audio ¹	7.9	7.8	7.5	7.3	7.1	6.7	6.4	5.9	5.6	5.3	5.0
Cinema	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Out-of-Home ²	7.1	7.1	7.0	7.0	7.1	7.0	7.0	6.9	6.9	6.8	6.8
Consumer Magazines ²	6.7	6.3	6.0	5.5	5.0	4.5	4.1	3.7	3.3	3.0	2.7
Newspapers ²	22.4	20.6	19.4	17.6	16.0	14.4	13.3	12.2	11.4	10.7	10.1

¹Does not include online or mobile advertising.

²Print only.

Sources: McKinsey & Company, Wilkofsky Gruen Associates

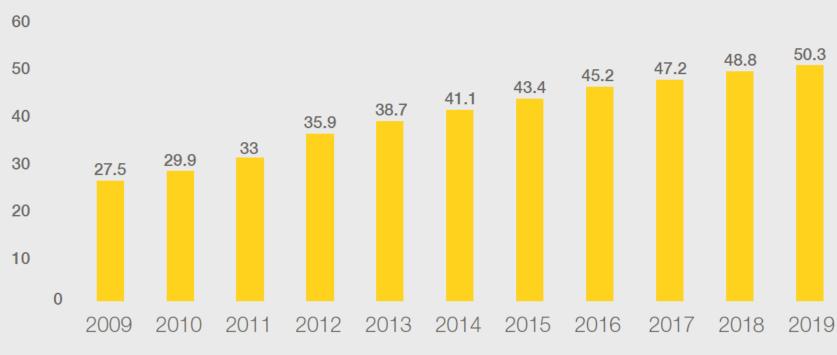
Global spending by digital/non-digital status¹ (US \$ millions)

Status	2009	2010	2011	2012	2013	2014p	2009– 2014p CAGR	2015	2016	2017	2018	2019	2014– 2019 CAGR
Digital ²	332,850	384,560	450,155	519,431	588,232	659,513	14.7	729,859	804,714	881,299	959,040	1,035,973	9.5
Non-digital	875,620	901,966	914,778	926,646	933,188	944,438	1.5	951,455	974,822	987,257	1,007,857	1,025,506	1.7
Total	1,208,470	1,286,526	1,364,933	1,446,077	1,521,420	1,603,951	5.8	1,681,314	1,779,536	1,868,556	1,966,897	2,061,479	5.1

¹At average 2014 exchange rates.

²Consists of digital advertising, broadband, OTT transactional and subscription digital video, satelite radio subscription spending, digital recorded music downloads, digital recorded music streaming subscriptions, digital out-of-home advertising, consumer magazine digital circulation spending, daily newspaper digital circulation spending, electronic consumer books, digital learning materials, online video games, mobile video games. Sources: McKinsey & Company, Wilkofsky Gruen Associates

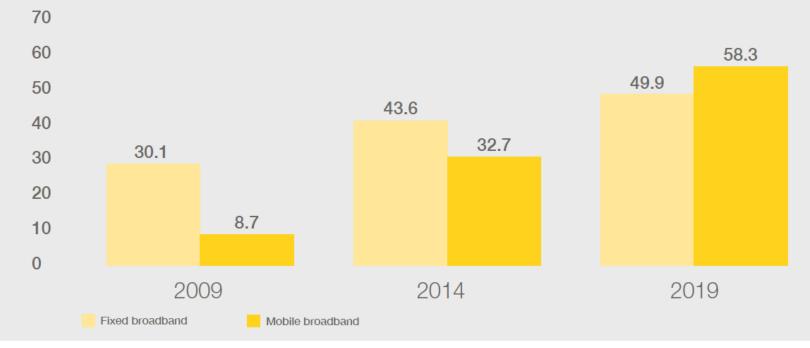
McKinsey & Company, Global Media Report 2015



Digital share of total spending (percent)

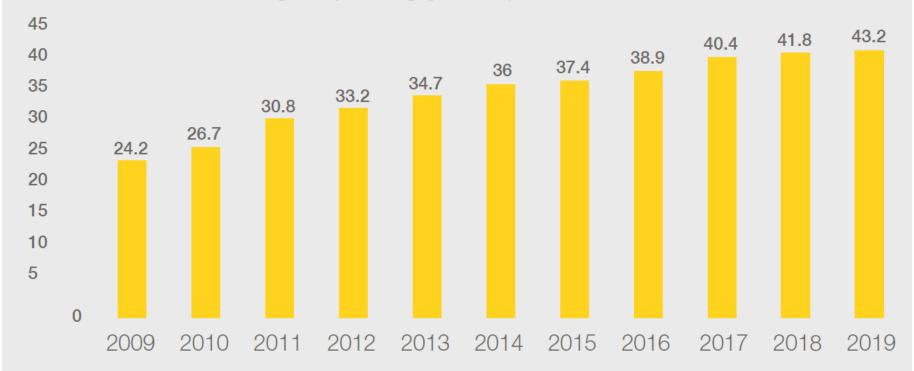
Sources: McKinsey & Company, Wilkofsky Gruen Associates

Global broadband penetration (percent)



Sources: McKinsey & Company, Wilkofsky Gruen Associates

Mobile share of digital spending (percent)



Sources: McKinsey & Company, Wilkofsky Gruen Associates

McKinsey & Company, Global Media Report 2015



Key Assumptions of Traditional Advertising Controls





Self Regulation by Media Owners

Advertise according to Registered Claims

Key Assumptions of Traditional Advertising Controls



Caveat Emptor



Regulating the Manufacturer

Rewriting Life

This Doctor Diagnosed His Own Cancer with an iPhone Ultrasound

Can a smartphone-enabled ultrasound machine become medicine's next stethoscope?

by Antonio Regalado October 27, 2017



https://www.technologyreview.com/s/609195/this-doctor-diagnosed-his-own-cancer-with-an-iphone-ultrasound/

Ultrasound—once practiced only by technicians—has already been spreading among medical specialties as a more routine type of exam. In emergency rooms, doctors use it to quickly look inside a patient's heart, lungs, and stomach without x-rays.

Butterfly, which started in 2011, took 8 years to move the idea for the ultrasound device from concept to market. Instead of vibrating crystals, it uses "**capacitive micro-machined ultrasound transducers**," or CMUTs, tiny ultrasonic emitters layered on a semiconductor chip a little larger than a postage stamp.

The company says it hopes to combine the instrument with artificialintelligence software that could help a novice position the probe, collect the right images, and interpret them. By next year, it believes, its software will let users automatically calculate how much blood a heart is pumping, or detect problems like aortic aneurisms. Work in that direction is described in a video released by the company.

Automating interpretation of fuzzy ultrasound images could eventually turn the technology into something easily used by ambulance crews, in remote regions, or even at home. "The ability to acquire an image and know what you are seeing—I think it's coming,"

"Disruptions" of Key Assumptions



A mix of things that are proven and unproven too technologically complex... how is the consumer to know?



How about the mobile app developer?

How about the interpretation of fuzzy ultrasound images?

"Disruptions" of Key Assumptions



Is there a media owner?

Even if there is, how to hold owner accountable in the digital space?

Native ads, or sponsored content?



To Register or not to Register (to lend credibility or legitimacy to the false or misleading claim)?



First Principles + Creative Control



A mix of things that are proven and unproven too technologically complex... how is the consumer to know?

- Understand underlying technology, instead of simply device product (e.g. wifi vs computer)
- Communicate knowledge on technology



How about the mobile app developer?

How about the interpretation of fuzzy ultrasound images?

- Is there a supply chain, besides the advertisement (which is simply a piece of paper)?
- Is there a physical product? A kit? An accessory?

Whilst advertisement is in the digital space Probe is a physical product Movement of the probe requires a supply chain Sales and distribution of the test kit (e.g. DNA test) requires a supply chain Interpretation of the results (e.g. DNA test), and "treatment" requires a healthcare professional

First Principles + Creative Control



Is there a media owner? Even if there is, how to hold owner accountable in the digital space? Native ads, or sponsored content?

Is Self-regulation still applicable for blogs, sponsored content, etc? Is there a supply chain, besides the advertisement (which is simply a piece of paper)?
Is there a physical product? A kit? An accessory?



To Register or not to Register (to lend credibility or legitimacy)?

- What is the science?
- Who can legitimize your scientific statements?

Direct to Consumer vs Prohibition

What device type (professional use vs overthe-counter) can be advertised to consumers?
Based on Professional Use Only?

Based on Prohibition of Certain Disease States?

Possible Controls

USFDA 510k - K163510

DEPARTMENT OF HEALTH AND HUMAN SERVICES Form Food and Drug Administration Expir

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

Indications for Use

510(k) Number (if known) K163510

Device Name Poseidon Ultrasound System

Indications for Use (Describe)

The Poseidon Ultrasound System is indicated for use by qualified and trained healthcare professionals to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid and arterial studies), Procedural Guidance, Small Organs (including thyroid), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional) and Musculoskeletal(superficial).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED

Professional Use Only cannot be Advertised except to healthcare professionals

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K163510

1st Schedule Diseases and Conditions

11.Leprosy

- 1. Blindness
- 2. Cancer
- 3. Cataract
- 4. Drug addiction
- 5. Deafness
- 6. Diabetes
- Epilepsy or fits
- 8. Hypertension
- 9. Insanity
- 10.Kidney diseases

12.Menstrual disorders13.Paralysis14.Tuberculosis15.Sexual function16.Infertility17.Impotency18.Frigidity

19.Conception and pregnancy

Prohibited Diseases and Conditions

Which is the Accessory Now?



Probe as an Accessory

Probe or Phone as an Accessory?

Future Proof MD Regulation

Definition of a medical device
Definition of an accessory
Regulation of the supply chain
Regulation of the activities - not entities, undertaken

ADVERTISEMENT OF HEALTH PRODUCTS

Advertisement of health products

19.-(1) No person shall --

- (a) advertise any product or cause any product to be advertised as a health product if that product is not a health product; or
- (b) advertise any registered health product or cause any registered health product to be advertised in such a way as to represent the registered health product as being usable for any purpose other than that for which it has been registered.
- (2) Any person who contravenes subsection (1)(a) or (b) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

False or misleading advertisement

- 20.—(1) No person shall advertise any health product or cause any health product to be advertised in a false or misleading way.
- (2) For the purposes of subsection (1), an advertisement of a health product shall be taken to be false or misleading if
 - (a) it falsely describes the health product or gives any false information concerning the health product; or
 - (b) it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the health product.
- (3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

Further requirements for advertisement of health products

- 21.--(1) No person shall advertise any health product or cause any health product to be advertised unless the advertisement complies with and is undertaken in accordance with such requirements as may be prescribed.
- (2) The requirements that may be prescribed for the purposes of subsection (1) include the following:
 - (a) that the advertisement should include or exclude any specified type of information;
 - (b) that the advertisement should not make certain types of claims about the health product;
 - (c) that the advertisement should be distributed or circulated only to certain classes of persons;
 - (d) that the advertisement should not appear in certain types of publications or media; and
 - (e) that the advertisement should be submitted to the Authority for approval before publication.
- (3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.









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