



संस्कारं जयते  
Ministry of Health & Family Welfare  
Government of India



Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



# 22<sup>nd</sup> Asian Harmonization Working Party Annual Meeting



4-8 December, 2017 | New Delhi





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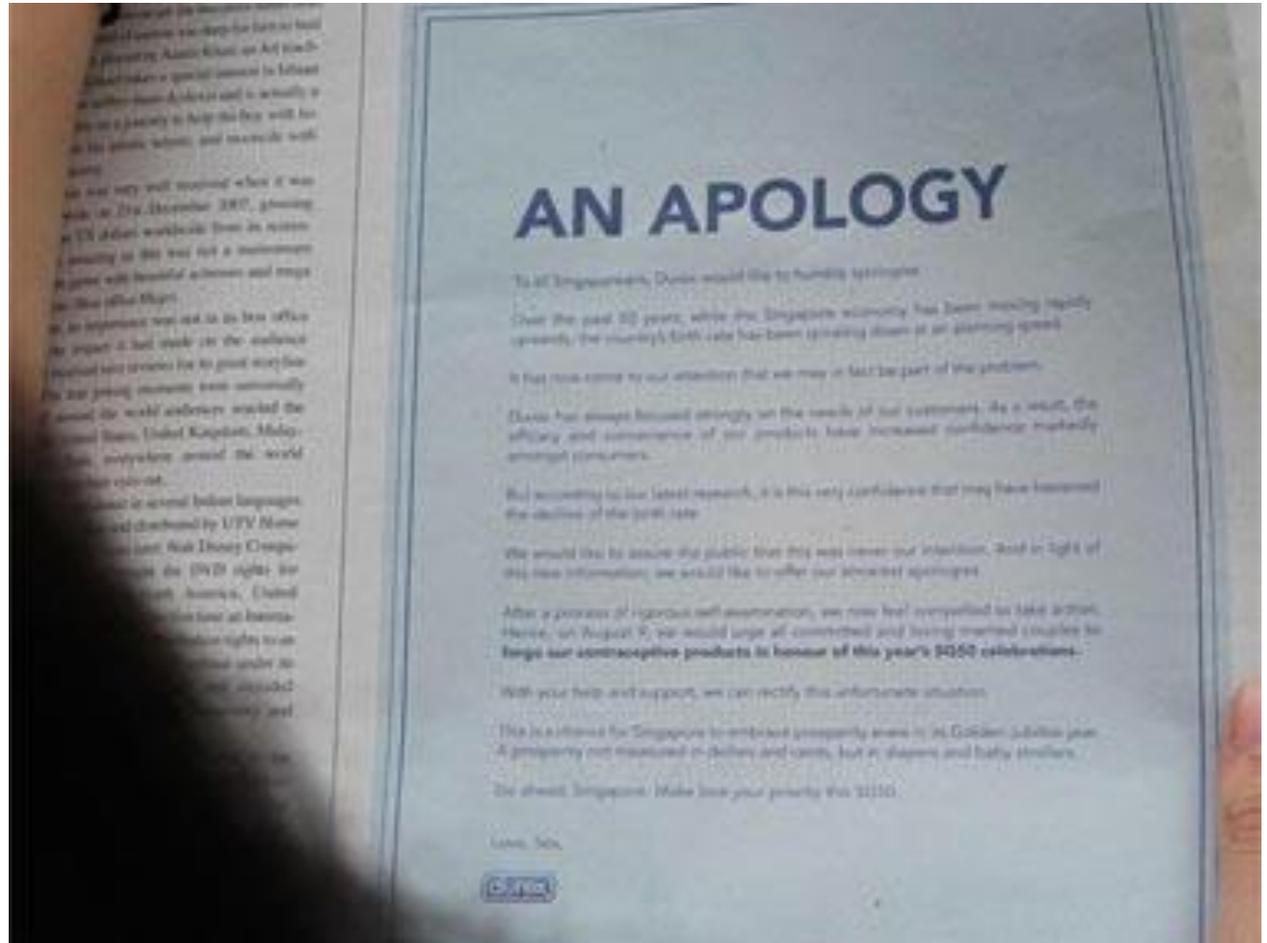
6<sup>th</sup> Dec 2017  
AHWP India Meeting  
New Delhi, India

# Advertisement & Labelling

Alfred Kwek  
Director  
Edwards Lifesciences



# An Apology



# 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.***

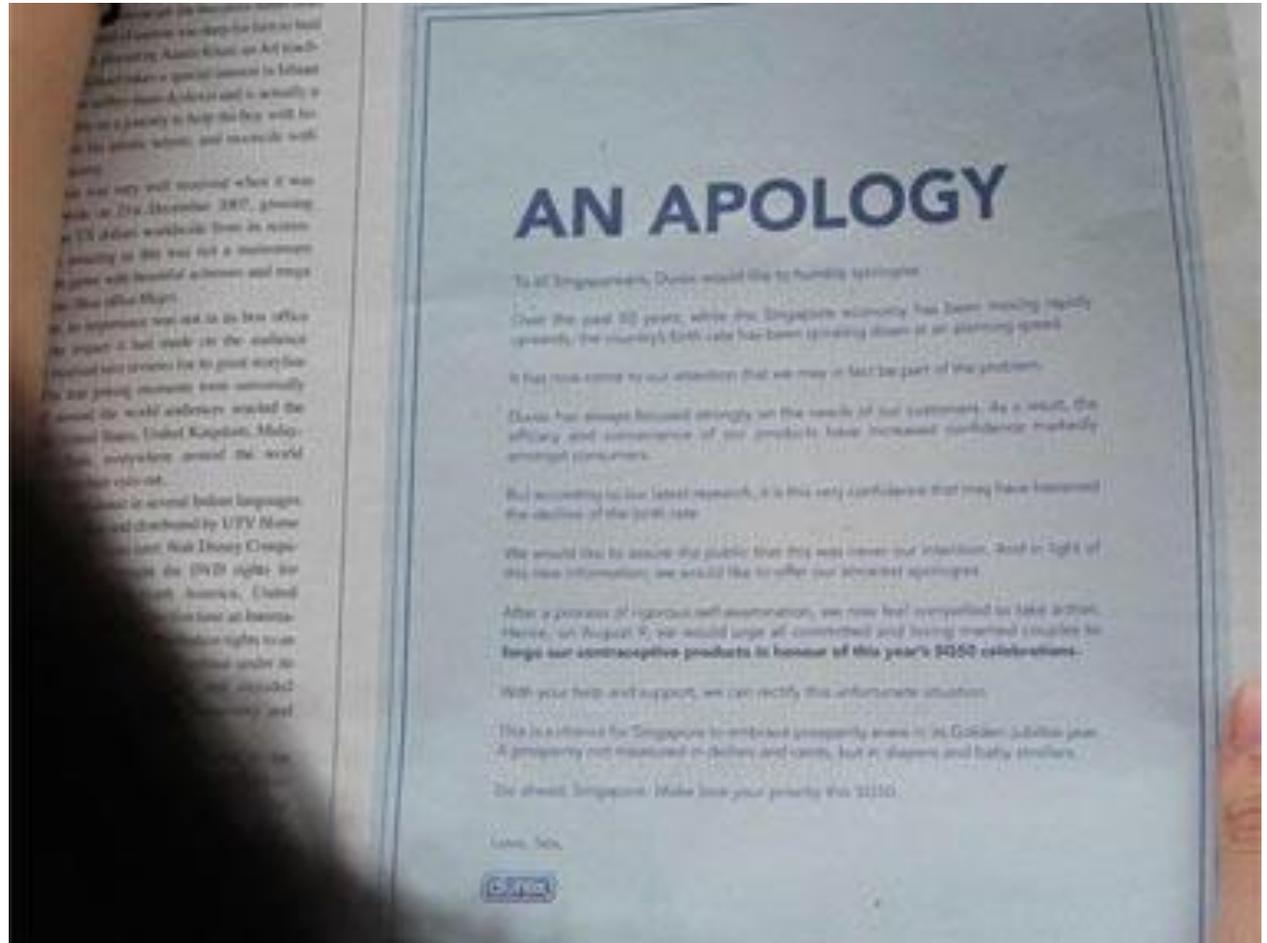
*With your help and support, we can rectify this unfortunate situation.*

*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.



# Best Global Brands 2017 Rankings by Interbrand

01  <b>+3%</b> 184,154 \$m	02  <b>+6%</b> 141,703 \$m	03  <b>+10%</b> 79,999 \$m	04  <b>-5%</b> 69,733 \$m	05  TOP GROWING <b>+29%</b> 64,796 \$m	06  <b>+9%</b> 56,249 \$m	07  <b>-6%</b> 50,291 \$m	08  TOP GROWING <b>+48%</b> 48,188 \$m
09  <b>+10%</b> 47,829 \$m	10  <b>-11%</b> 46,829 \$m	11  <b>+3%</b> 44,208 \$m	12  <b>+5%</b> 41,533 \$m	13  <b>0%</b> 41,521 \$m	14  <b>+5%</b> 40,772 \$m	15  <b>+7%</b> 39,459 \$m	16  <b>+3%</b> 31,930 \$m
17  <b>+3%</b> 27,466 \$m	18  <b>+8%</b> 27,021 \$m	19  <b>-4%</b> 22,919 \$m	20  <b>+3%</b> 22,696 \$m	21  <b>+6%</b> 22,635 \$m	22  <b>+1%</b> 20,491 \$m	23  <b>-10%</b> 20,488 \$m	24  <b>+11%</b> 18,573 \$m
25  <b>+4%</b> 18,472 \$m	26  <b>-9%</b> 18,200 \$m	27  <b>-3%</b> 17,787 \$m	28  <b>+2%</b> 16,416 \$m	29  <b>+7%</b> 16,387 \$m	30  <b>+11%</b> 15,749 \$m	31  <b>+2%</b> 15,375 \$m	32  <b>+11%</b> 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.

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

Posted Jan 27, 2016 by [Lucas Matney](#)

24/25



## #2 – @taylorswift

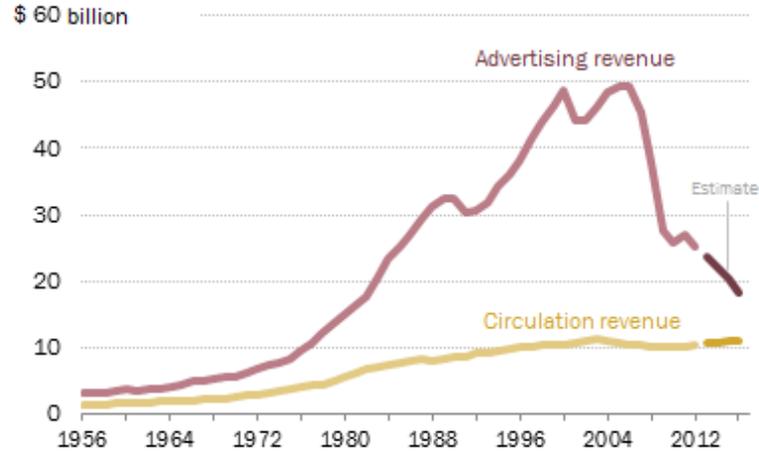
[Taylor Swift](#)

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.

## 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

## 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 <sup>1</sup>	38.3	39.2	39.1	39.3	38.7	38.7	37.8	37.5	36.4	36.3	35.9
Audio <sup>1</sup>	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 <sup>2</sup>	7.1	7.1	7.0	7.0	7.1	7.0	7.0	6.9	6.9	6.8	6.8
Consumer Magazines <sup>2</sup>	6.7	6.3	6.0	5.5	5.0	4.5	4.1	3.7	3.3	3.0	2.7
Newspapers <sup>2</sup>	22.4	20.6	19.4	17.6	16.0	14.4	13.3	12.2	11.4	10.7	10.1

<sup>1</sup>Does not include online or mobile advertising.

<sup>2</sup>Print only.

Sources: McKinsey & Company, Wilkofsky Gruen Associates

## Global spending by digital/non-digital status<sup>1</sup> (US \$ millions)

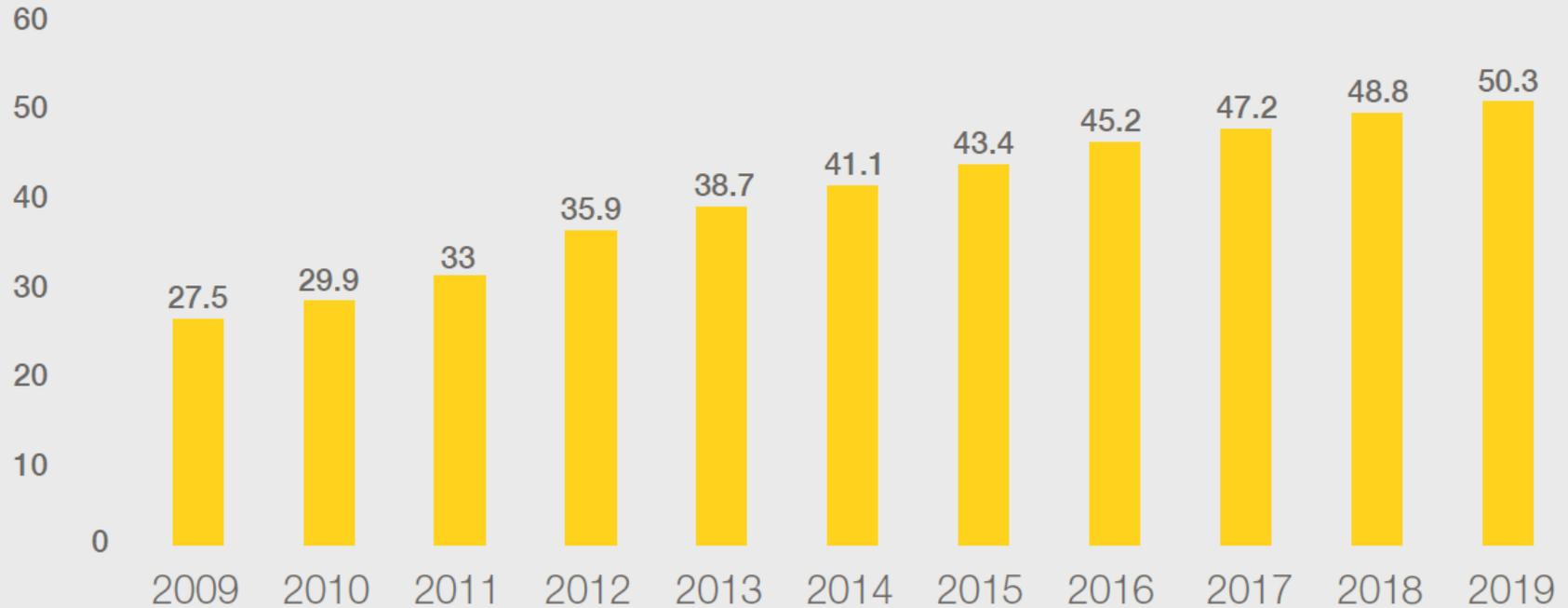
Status	2009	2010	2011	2012	2013	2014p	2009– 2014p CAGR	2015	2016	2017	2018	2019	2014– 2019 CAGR
Digital <sup>2</sup>	332,850	384,560	450,155	519,431	588,232	659,513	14.7	729,859	804,714	881,299	959,040	1,035,973	9.5
Non-digital	875,620	901,966	914,778	926,646	933,188	944,438	1.5	951,455	974,822	987,257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

<sup>1</sup>At average 2014 exchange rates.

<sup>2</sup>Consists of digital advertising, broadband, OTT transactional and subscription digital video, satellite 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.

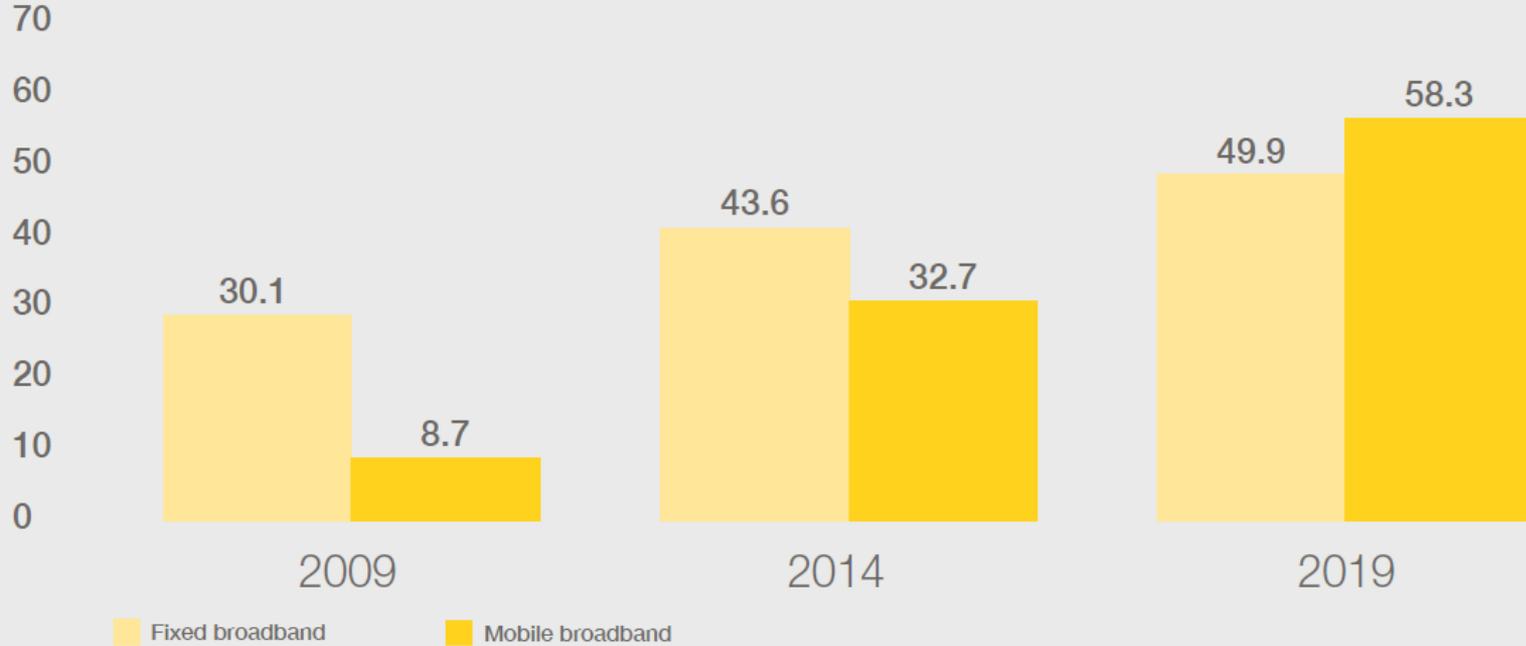
Sources: McKinsey & Company, Wilkofsky Gruen Associates

## Digital share of total spending (percent)



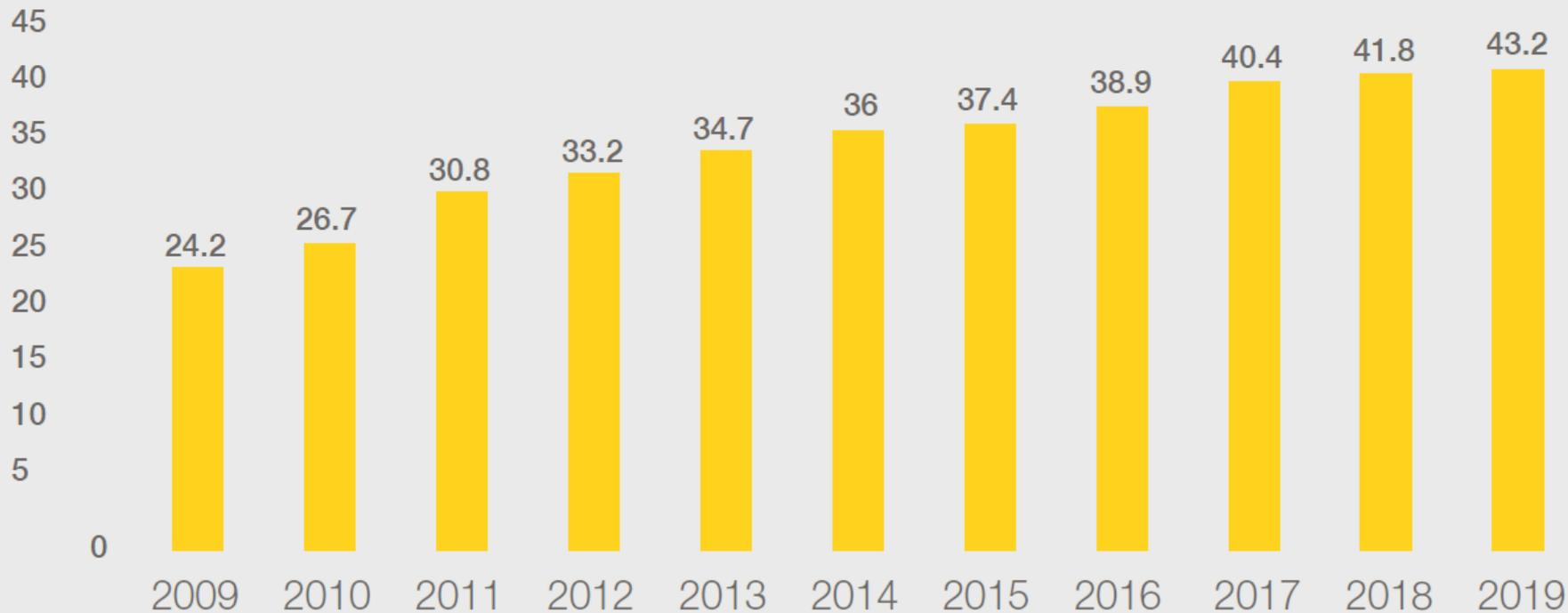
Sources: McKinsey & Company, Wilkofsky Gruen Associates

## Global broadband penetration (percent)



Sources: McKinsey & Company, Wilkofsky Gruen Associates

## Mobile share of digital spending (percent)



Sources: McKinsey & Company, Wilkofsky Gruen Associates



# 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

# 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 artificial-intelligence 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



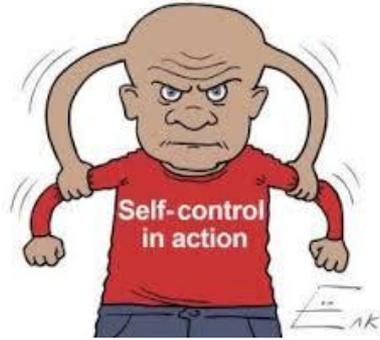
A mix of things that are proven and unproven ..... too technologically complex... how is the consumer to know?

The logo for "The Manufacturer" is displayed in a light gray rectangular box. The word "THE" is in a smaller, red, sans-serif font, and "Manufacturer" is in a larger, bold, black, sans-serif font.

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)?

# Science and Marketing Clash in the “Jungle” of Advertising



# 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?

The logo for "THE Manufacturer" is displayed in a white box. "THE" is in a smaller, bold, black font, and "Manufacturer" is in a larger, bold, black font.

- **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 over-the-counter) can be advertised to consumers?

- Based on Professional Use Only?
- Based on Prohibition of Certain Disease States?



Key Stage Two History:  
Stone Age to Iron Age

# Possible Controls

USFDA 510k - K163510

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
<b>Indications for Use</b>	
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) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
<b>CONTINUE ON A SEPARATE PAGE IF NEEDED.</b>	

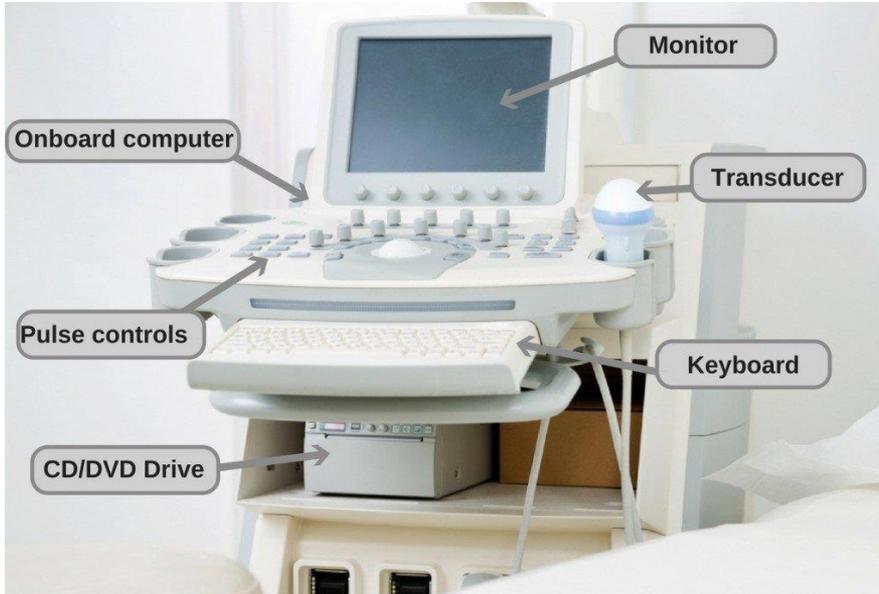
**Professional Use Only cannot be  
Advertised except to healthcare  
professionals**

## 1<sup>st</sup> Schedule Diseases and Conditions

1. Blindness
2. Cancer
3. Cataract
4. Drug addiction
5. Deafness
6. Diabetes
7. Epilepsy or fits
8. Hypertension
9. Insanity
10. Kidney diseases
11. Leprosy
12. Menstrual disorders
13. Paralysis
14. Tuberculosis
15. Sexual function
16. Infertility
17. Impotency
18. 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

## PART V

### 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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