



Global Transparency Trends & Challenges

Diva Duong & Brian Sharkey September 2018

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- + Transparency Trends and Approaches
 - Legal Provisions (US, France, Portugal, etc.)
 - Regional Industry Codes (EFPIA, MFE, MedTech Europe, etc.)
 - · Local Industry Code (Australia, Germany, UK, etc.)
- + Key Considerations for Transparency Reporting
 - Issues and Challenges
 - Lessons Learned & Opportunities
- + Data Protection and Consent Management
 - GDPR
 - Local Data Privacy Requirements
- + Conclusion





The Global Life Sciences Industry Continues To Be Challenged By Changing Perceptions And Expectations



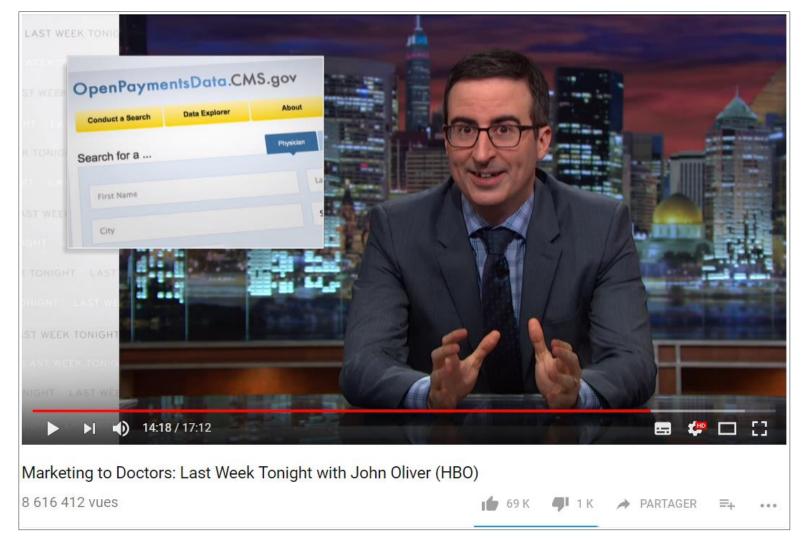
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Marketing To Doctors By John Oliver (HBO)

https://www.youtube.com/watch?v=YQZ2UeOTO3I







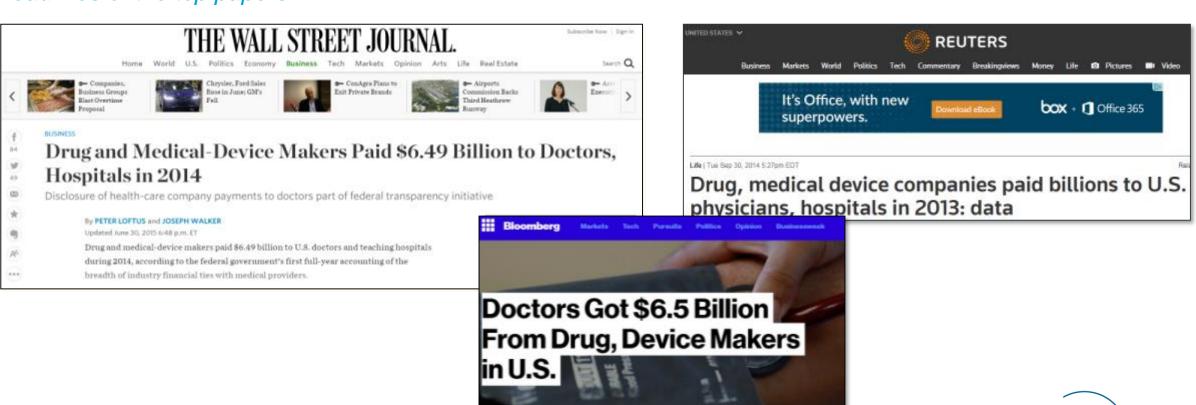
June 2015, immediately after the full 2014 US data disclosure the Transparency subject makes it to the headlines of the top papers

by Zachary Traces and Caroline Chen

ure 30, 2045 - 757 PM CEST (Iprinsolas June 30, 2045 - 4142 PM CEST

companies and the people who prescribe their products

U.S. doctors and teaching hospitals got \$6.49 billion from drug and medical-device makers in 2014, according to new government data on the financial links between the

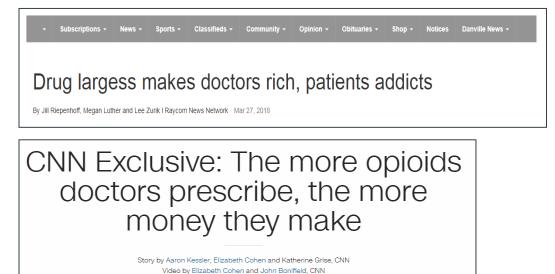




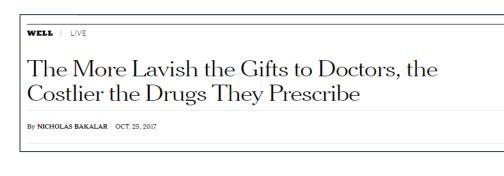


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Recent Media Coverage in the US







Updated 8:45 AM ET, Mon March 12, 2018







June 2016, the press commented on the first disclosure in the United Kingdom



What are they hiding? A THIRD of health workers including top doctors refuse to admit if they've been given lavish perks or payments by drug firms

By PRESS ASSOCIATION and SOPHIE BORLAND, HEALTH EDITOR FOR THE DAILY MAIL







Media Coverage in Australia – Summer 2016, the press commented on the first individual disclosure



© AUGUST 31, 2016 9:00PM

DRUG companies have for the first time revealed how they are paying Australian doctors up to \$19,000 for overseas trips, and more than \$18,000 in speaking and consultancy fees to spruik and critique their medicines.

Doctors shared in \$8.5 million in payments in the six months between October 2015 and April 2016.

One in three doctors refused to allow drug companies to publish how much they received.

Professor Andrew Carr who received more than \$39,000 from drug company Gilead was the doctor who received the most drug company payments in the six months to April 2016.

Gilead has just received a government subsidy for its \$19,000 per patient per month Hepatitis C cure Sovaldi.

Professor Carr was paid \$18,960 in consultancy fees and over \$19,000 in travel and accommodation expenses by Gilead in the six months between October 2015 and April 2016.

Drug companies paying doctors million Australia report reveals

Daniel Burdon and Julia Medew









Drug companies have paid Australian doctors and nurses more than \$64 million since April 2015 to attend educational events and advisory group meetings and to act as consultants to the industry.

A new report that names those doctors and nurses for the first time has revealed thousands of them shared in about \$8.5 million from 35 drug companies during the six months to April this year.





speaking engagements and expenses

Media Coverage in Australia - Summer 2016, the press commented on the first individual disclosure



Professor Andrew Carr. Photo: Sydney Pathology



Professor Merlin Thomas (right) was paid more than \$35,110.



Dr Mark O'Reilly received \$30,635.



Professor Rodney Sinclair was paid \$22,617.



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Sample Of Transparency Trends And Approaches

Detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organizations

North America

- USA (Federal & State Laws)
- Canada (upcoming provincial Laws)
- Mexico (upcoming)

South America

• Brazil (Minas Gerais State Law)



Europe

- EFPIA Code (1)
- MedTech Europe Code (2)
- Medicines for Europe Code (3)
- National Laws

Asia Pacific

- Japan (Code)
- Australia (Code)
- South Korea (Law)
- Philippines (Law)
- Indonesia (Law)

Africa

- Mecomed Code (4) MENA (5) region
- Saudi Arabia (upcoming Law)

Trend: More and more transparency regulations all over the world



- (1): EFPIA European Federation of Pharmaceutical Industries Association HCP/HCO Disclosure Code
- (2) MedTech Europe Code of Ethical Business Practice
- (3) Medicines for Europe Code of Conduct
- (4) Mecomed Medical Devices, Imaging and Diagnostics Trade Association
- (6) MENA Middle East and North Africa



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Transparency Requirements Continue To be More Stringent And Significantly Growing In Life Sciences

COVERAGE

MONITORING

DISCLOSURE

ANALYTICS









More industries and more geographies along with more touch-points

Closely monitor interactions between life science industries and HCP/O

Reinforce accuracy and completeness of the publication of Transfers of Value

Ability to gain insight from aligned data sets

IMPLICATION

Organizations must implement scalable, robust and flexible solutions to deal with diverse requirements

IMPLICATION

Better manage HCP/HCO interactions to minimize risks of unethical behaviours, corruptions, bribery, false claims

IMPLICATION

Publish all interactions with HCP/O ensuring greater transparency and compliance with data privacy regulations

IMPLICATION

Enable manufacturers to gain a 360 view on their spending to HCP/O and potentially benchmark against their competitors





United States – Enforcement Actions

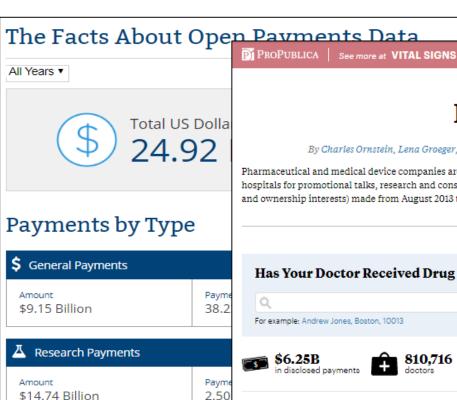
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District N ROPER. ger, defendant, was responsible for the es territory that included Doctor-1 and Doctor-2, who both se as Speakers for Pharma Company-1 during ROPER's tenure as Di ct Manager. served as the SSP assigned to Doctor and Doctor-2 prior to ROPER's promotion to District Manager. Based on my review of publicly available data maintained by the Centers for Medicare and Medicaid Services ("CMS") regarding remuneration provided by pharmaceutical companies to doctors, I know that Doctor-1 and Doctor-2 were both highly compensated by Pharma Company-1 during ROPER's tenure as a result of their participation in the Speaker Program. By way of example, in 2014, Pharma Company-1 reported to CMS that it made payments of approximately \$147,245 in Speaker Program fees to Doctor-1 and payments of approximately \$112,340 in Speaker Program fees to Doctor-2. In 2014, Doctor-1 and Doctor-2 were two of the top recipients of Speaker Program fees from Pharma Company-1 in the entire United States.

kind, to a person to induce such person to purchase, lease, order, and arrange for and recommend purchasing, leasing, and ordering a good, facility, service, and item for which payment may be made in whole and in part under a Federal health care

kind, to a person to induce such person to purchase, lease, order, and arrange for and recommend purchasing, leasing, and ordering a good, facility, service, and item for which payment





Value of Ownership

Amount

\$1.03 Billion

Dollars for Docs

By Charles Ornstein, Lena Groeger, Mike Tigas, and Ryann Grochowski Jones, ProPublica. Updated December 13, 2016

Pharmaceutical and medical device companies are now required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2015. | Related Story: We've Updated Dollars for Docs, Here's What's New. »









1,866

Mhat are the different payment types?

Totals listed below account for all payments from August 2013 to December 2015.

\$128M

Top 50 Companies

3.64

PFIZER INC.

Click on a company to see how its payments break down by drug, device or doctor. Or, see all companies »

‡ COMPANY	PAYMENTS
GENENTECH, INC.	\$727M
DEPUY SYNTHES PRODUCTS LLC	\$167M
STRYKER CORPORATION	\$153M
MEDTRONIC SOFAMOR DANEK USA, INC.	\$147M
ASTRAZENECA PHARMACEUTICALS LP	\$145M

Highest-Earning Doctors

NAME	PAYMENTS	
ROGER JACKSON Orthopaedic Surgery of the Spine	\$54.1M	
SUJATA NARAYAN Family Medicine	\$43.9M	
STEPHEN BURKHART Orthopaedic Surgery	\$43.4M	
KEVIN FOLEY Neurological Surgery	\$39.8M	
KAREN UNDERWOOD Pediatric Critical Care Medicine	\$28.5M	

About the Dollars for Docs Data

f DONATE

Details behind our drug company money database.

Download the Data

The entire data set is available for purchase in the ProPublica Data Store.

Source

The Centers for Medicare and Medicaid Services Open Payments data.

Archive

Search for payments made by 17 drug companies between 2009 and 2013.

Patients, Take Action

We want to know how you've used or might use this information in your day to day lives. Have you talked to your doctor? Do you plan to? Tell us: propub.li/participate-d4d

Reporters, Use Our Data

Have questions about how you can best use Dollars for Docs for your own localized reporting? Contact us at media@propublica.org.

Background Stories

▲ Research Payments	Value of Ownership or Investment Interest
Amount \$379.01 Million*	Amount \$1.03 Billion
Amount \$2.94 Billion	Amount N/A**
Amount \$14.74 Billion	Amount \$1.03 Billion





Common Challenges Before Spend Is Aggregated Or A Report Is Created



What other challenges around transparency reporting are you concerned with?





The Solution: Early And Ongoing...Strengthen Business Processes And Automation Before The Money Is Spent



- 1. Review policies and SOPs for completeness and clarity
- 2. Ensure effective communications and understanding
- 3. Automate workflows that feed into aggregate spend
- 4. Support decision-making before an HCP or third party is contracted:
 - Provide historic spend information
 - Provide current year-to-date aggregate information
 - Look out for duplication
 - Ideally, look at contracting and spending globally and across all functions
 - Check for internal compliance business rules (caps, etc.)
- Ensure contracts are clear, comprehensive and transparent, especially with third party vendors
- 6. Include automated FMV and KOL determination (cross border)

Opportunity to act as a partner to the business





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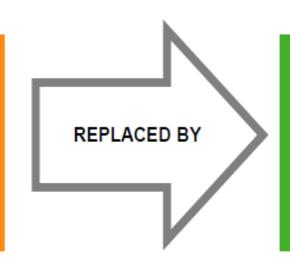




General Data Protection Regulation – GDPR

Directive 95/46/EC

Data protection directive with regard to the processing of personal data and on the free movement of such data transposed to member state laws



GDPR

Regulation directly effective in member states without the need for implementing legislation.

Fully in force from May 25, 2018 in all EU countries



- Stronger rights for individuals
- Greater accountability requirements
- · Increased scope
- Strong sanctions and penalties for non-compliance: top fine is up to 4% worldwide group turnover



GDPR – Key Requirements



Consent to **Process**

Implementation of transactional(1) and universal(2) consent to process

Consent to **Disclose**

Implementation of transactional and universal consent to disclose

Data Segregation

Implementation of data segregation per Country and **Business Unit**

Right of **Erasure**

Implementation of right of erasure on demand

Right of Rectification

Implementation of right of rectification on demand

- Ability to collect and manage consent:
 - Per activity types (e.g., Speaker Programs, Advisory Boards, Symposia, Ad-hoc Consulting, IIS, Sponsorships, Medical Educations, etc.)
 - Per Transaction (i.e., engaging with same HCP/O in a variety of different transactions)
- **Ability to withdraw consent**

- **Compliance with applicable Data Subjects** Rights:
 - Right of Access.
 - Right of Rectification, and
 - Right to be Forgotten

Data Security

Implement technical and organizational security controls to protect personal data against accidental or unlawful destruction or loss, alteration, unauthorized disclosures or breach.





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Questions?















Thank You





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