

Impact of Public Disclosure on Operations and Processes



Panelists

- ▶ Carolyn Bruguera , Esq.

Vice President, Consulting Services

- ▶ Elizabeth Schwartz, MBA, CCEP


Director, US External Reporting & Transparency, Health Care Compliance & Privacy for Johnson & Johnson (J&J)

- ▶ Michael O'Connor, MS

Sr. Director, Compliance and Ethics, Alexion Pharmaceuticals

- ▶ Gus Papandrikos, MBA

Head of Compliance Operations, Global Compliance and Risk Management, Shire



Bill Buzzeeo, MS

General Manager – US Compliance, IMS Health

»» Public Disclosure –
Misleading?

Public data can be used without nuance and is often highly misleading

Any payment is “bad” in this context



Dollars for Docs



DONATE

Dollars for Docs

How Industry Dollars Reach Your Doctors

By Lena Groeger, Charles Ornstein, Mike Tigas, and Ryann Grochowski Jones, ProPublica. Updated July 1, 2015

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 2014. | [Related Story: A Pharma Payment A Day Keeps Docs' Finances OK](#) »

Top 50 Companies

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

COMPANY	PAYMENTS
Genentech, Inc.	\$388M
DePuy Synthes Products LLC	\$94.7M
Topera, Inc.	\$93.1M
AstraZeneca Pharmaceuticals LP	\$90.9M
Stryker Corporation	\$90.8M
Medtronic Sofamor Danek USA, Inc.	\$85M
Pfizer Inc.	\$82.1M
Allergan Inc.	\$70.7M
Zimmer Holding Inc	\$70.5M
Arthrex, Inc.	\$58.9M
Smith & Nephew, Inc.	\$56.5M

Highest-Earning Doctors

NAME	PAYMENTS
SUJATA NARAYAN	\$43.9M
KAREN UNDERWOOD	\$28.5M
STEPHEN BURKHART	\$24M
SANJAY YADAV	\$23.1M
KEVIN FOLEY	\$22M

Doctors Paid the Most Often

NAME	PAYMENTS
ANA STANKOVIC	1,711
FARHAD ZANGENEH	1,610
JOHN FRITZ	1,381
ROBERT BUSCH	1,274
RUWANI GUNAWARDANE	1,226

SUJATA NARAYAN

Listed Specialty: **Allopathic & Osteopathic Physicians/Family Medicine**

15025 INNOVATION DR. SAN DIEGO, CA, 921283409

IS THIS YOUR DOCTOR? HERE'S HOW TO TALK TO THEM ABOUT PAYMENTS » SEARCH THIS NAME IN DOLLARS FOR DOCS ARCHIVE »
IS THIS YOU? DO YOU BELIEVE THE DATA CONTAINS ERRORS? [CLICK HERE FOR INFORMATION](#) »

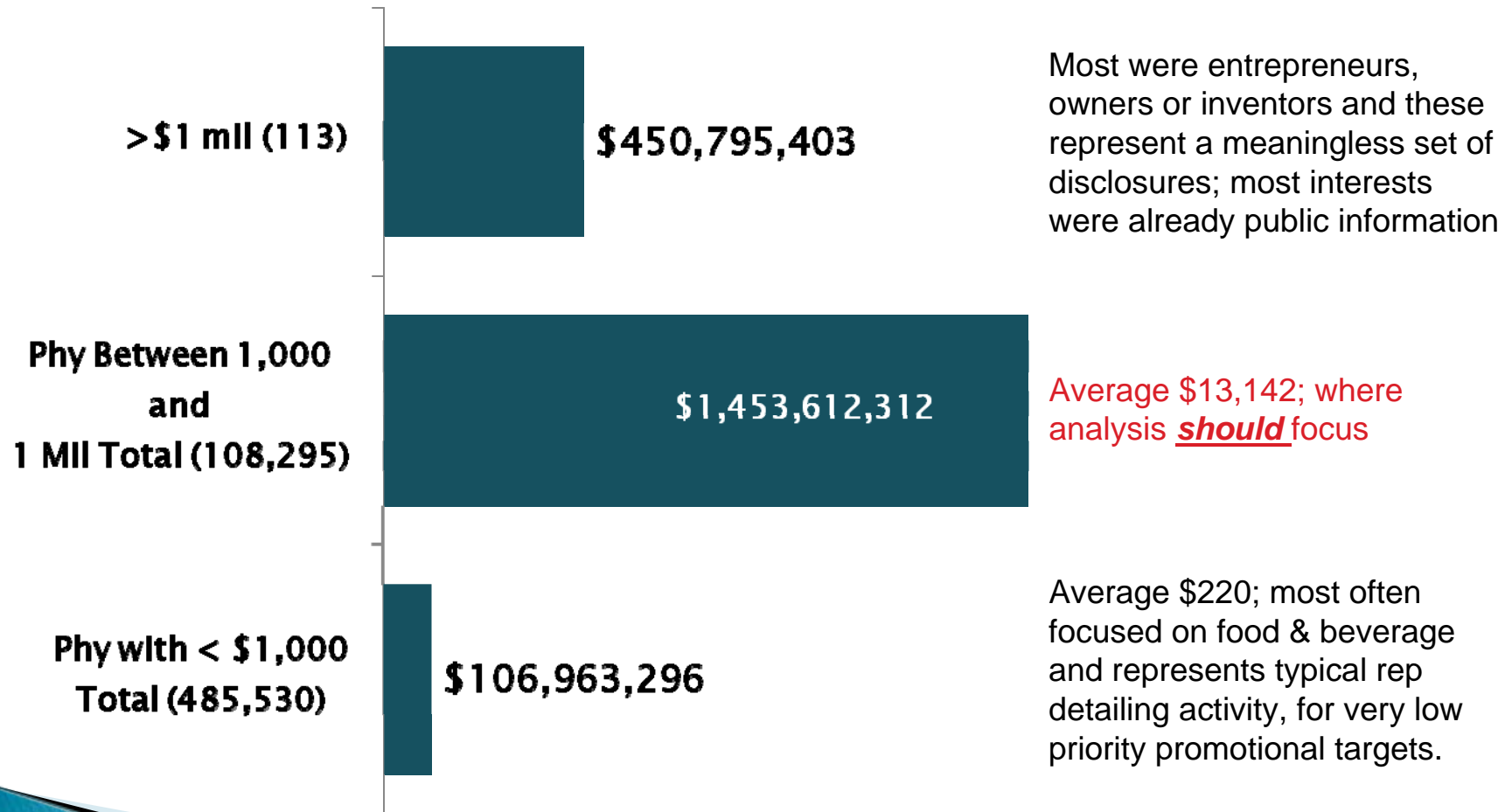
Payments: At a Glance

7	\$43,860,020	4
PAYMENTS	PAYMENT TOTAL	COMPANIES PAID THIS DOCTOR
Rank: 1 out of 6,640 doctors in this specialty and state		

The highest “paid” in the industry is the founder of his company, and received two payments for that role, 5 other payments of food & beverage assumed to be related to just unrelated 5 details by other companies.

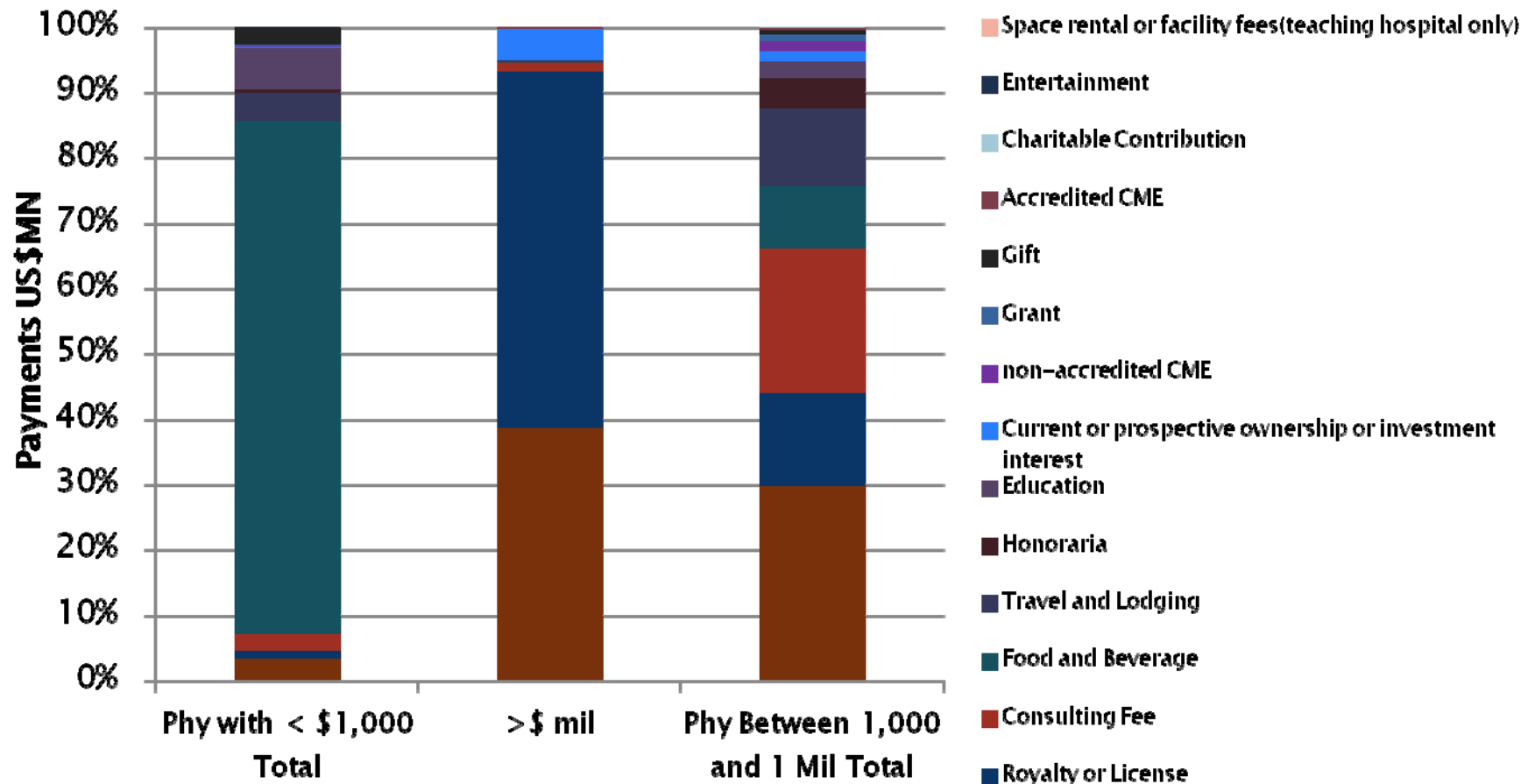
Of the \$2bn in payments to doctors in 2014, 95% went to doctors receiving more than \$1,000 in a year

These segments imply



Low and high-paid doctors unusable data; Middle group demonstrates “useful distribution” for data mining

Very little useful to be gleaned without further granularity and comparisons



Of the top 20 doctors receiving “payments”, the majority are company founders or their families


FIRST NAME	MIDDLE NAME	LAST NAME	SPECIALTY DESCRIPTION	TTL DOLLARS
SUJATA	DAVE	NARAYAN	FAMILY MEDICINE	Topera: Co-founder, family trust, officer (secretary) of the company
KAREN	R	UNDERWOOD	PEDIATRIC CRITICAL CARE MEDICINE	
SANJAY	SINGH	YADAV	CARDIOVASCULAR DISEASE	ST. JUDE MEDICAL, INC. bought Dr Yadav's company CardioMEMS, and this payment corresponds to his share of the sale
GREGORY		PISKUN	GENERAL SURGERY	
KEVIN	THOMAS	FOLEY	NEUROLOGICAL SURGERY	Gregory Piskun, MD, was CEO of Pravel Systems from its inception through acquisition by Covidien in 2008. Payment as royalty past inventions
STEPHEN	SHELBY	BURKHART	ORTHOPEDIC SURGERY	
BRENT	DAVID	LAING	OBSTETRICS & GYNECOLOGY	Kevin Foley – 99% of payments were royalties for device inventions
RODNEY	DEAN	RAABE	DIAGNOSTIC RADIOLOGY	
JOHN	DAVID	GREEN	OBSTETRICS & GYNECOLOGY	Stephen Burkhart is an orthopedic surgeon, primarily paid by Arthrex which is a device company which he invented some devices for and regularly records surgical videos using their devices
SANJIV		NARAYAN	CARDIOVASCULAR DISEASE	
CHARLES	LAZELLE	SAWYERS	MEDICAL ONCOLOGY	
GEORGE	ALBERT	FREY	ORTHOPEDIC SURGERY OF THE SPINE	
TIMOTHY	ALAN M	CHUTER	VASCULAR SURGERY	
ROGER	PAUL	JACKSON	ORTHOPEDIC SURGERY	
WILLIAM	JAY	BINDER	FACIAL PLASTIC SURGERY	
STEPHEN	M	PAPADOPOULOS	NEUROLOGICAL SURGERY	
RICHARD	MAHIR	AWDEH	OPHTHALMOLOGY	
NEAL	SELIM	ELATTRACHE	ORTHOPEDIC SURGERY	
GEORGE	PATRICK	MAXWELL	PLASTIC SURGERY	
DOUGLAS	ALAN	DENNIS	ORTHOPEDIC SURGERY	

Carolyn Bruguera , Esq.

Vice President Consulting Services, R-squared

»» Overview

Current Trends

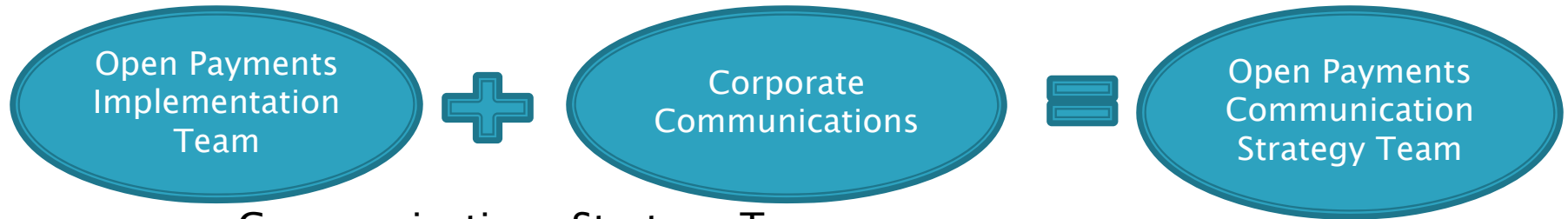
- ▶ End-to-end interactions management
 - Process integration and harmonization
 - Meeting planning through payment & reporting
 - Onboarding due diligence
 - ▶ Globally connected data
 - Local, Regional & World views, workflows, and validations
 - Global customer and vendor master
 - Data protection
 - ▶ Real-time capture and disclosure
 - Consent & revocation
 - Attendance confirmation
 - ToV acknowledgement
 - Opt-out tracking
- 

Elizabeth Schwartz, MBA, CCEP

Director, US External Reporting & Transparency, Health Care
Compliance & Privacy for Johnson & Johnson (J&J)

»» Communication / PR / Media
Training
Testing / Monitoring

Communications / PR / Media



- ▶ **Communications Strategy Team**
 - Multi-functional representation – Compliance, Law Department, Government Affairs, Corporate Communications
 - Address internal and external stakeholder messaging
 - Dedicated resources with aligned priorities
- ▶ **Communications Plan**
 - Determine target audiences and consistent messaging
 - Methods/Channels of Communication
 - Internal employee communication and training materials
 - External Customer Awareness Letters, Leave Behinds, Brochures
 - Engagement with Industry Associations
 - Dedicated call center and email
 - Proactive disclosure/additional context on company website
- ▶ **Managing post publication readiness**
 - Understand the data prior to publication;
 - Media attention and inquiries
 - Customer inquiries/disputes
 - Align internal stakeholders on roles and responsibilities and appropriate response to inquiries
 - Regular inquiries from the media regarding physicians in the news

Training

▶ Training Needs Assessment

- Does Open Payments require training separate from already established compliance trainings?
- Determine target audiences
 - One size fits all or specialized trainings for individual groups
- Methods of Training
 - Live
 - Online modules
 - Tip Sheets, FAQs, Mobile Apps
 - Certifications
- Resources available to develop and deploy training
- Open Payments in steady state
 - Annual training, no training, etc.?
 - Are there gaps that can be addressed with refreshed training?

Testing/Monitoring


- ▶ Assess whether testing and monitoring may be needed for Open Payments
 - Attestation comfort
 - Review data quality and completeness
- ▶ Incorporate Open Payments testing attributes into existing test protocols or create specific testing protocols?
- ▶ Establish regular monitoring
 - Review individual policy exceptions and determine potential impact when data is published
 - Threshold reviews
- ▶ Does the data stratification identify other opportunities to monitor and test?
 - Physicians who receive value across multiple nature of payment categories
 - Employees who have the most reported value transfers for covered recipients
- ▶ Did dispute resolution identify other areas to monitor and test?
 - What are the causes of the dispute?

Michael O'Connor, MS

Sr. Director, Compliance and Ethics, Alexion Pharmaceuticals

»» Approval Processes
Written Procedure

Approval Processes

- ▶ Field Management involvement
 - Approval?
 - How much to share with field force?
 - ▶ Legal and Compliance review
 - Where in process should this occur?
 - Role of Legal Vs Compliance
 - ▶ X Border engagements
 - Who decides what is ok?
 - Feedback from other regions on impact of transparency
 - Data protection
- 

Written procedures

▶ Clear Policy Guidance

- What is allowed and why?
- What is concerning our customers?
- Explain the PR consequences

▶ Process facilitation

- Tightened up processes, particularly around X border
- Roles and responsibilities for senior management, PR, etc...
- Process for dispute resolution

▶ Data driven

- Evaluate disputes, react accordingly via policy and procedures

Gus Papandrikos, MBA

Global Head of Compliance Operations, Shire Pharma

»» Levels and Types of Spend
Systems
Business Practices

Changes in How Companies Spend \$ Post Year 1 Implementation

▶ Meal Management

- \$ per meal
- # of meals allowed



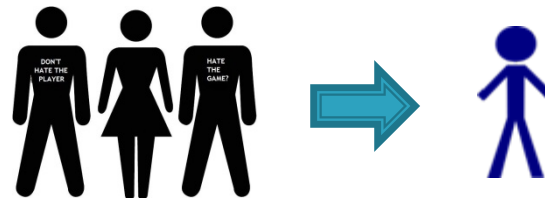
▶ Spend Limits

- Limit \$ – Updated FMV
- Cap management



▶ Restrict Attendance

- 1–2 times per topic



How Have Organizations Updated Systems Based on Year 1 Results

▶ Promotional Programs

- Meal control
- Attendee management
- Speaker management



▶ Reporting Tool

- Validation
- Easy integration
- User friendly



Business Practice Upgrades

▶ Commercial

- Spend Limits
- Process improvements (e.g. sign-in sheets)
- Business Justification



▶ Medical

- Centralize site payment system
- Restrict meals for CME
- Eliminate reprints



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Questions?

