

# What You *Really* Need to Know about the Sunshine Act



SLA P&HT 2015 Spring Meeting  
April 21, 2015  
2:00 – 3:00pm

# Panel Agenda

- Introductions
- Sunshine Act Overview
- Spring Meeting Survey Review
- Survey Questions
- Panelist Commentary
- Additional Q&A

# Moderator & Panelists

## **Moderator:**

John Chu

## **Panelists:**

Ian Palmer	Reprints Desk, Inc.
Ben Beit Zuri	Wolters Kluwer
Donna Simcoe	Medical Publication Consultant





But first...a reminder that we  
welcome your interaction!



# Sunshine Act Primer

- OPEN PAYMENTS (Physician Payments Sunshine Act)
- Required by Section 6002 of the Affordable Care Act
- Establish a transparency program to increase public awareness of financial relationships
- Applicable manufacturers must report payments of other transfers of value made to physicians & teaching hospitals to CMS
- CMS lists SIXTEEN different payment types!
- CMS to annually collect, aggregate, publish data
- Extensive & complicated review, dispute, & correction process
- Effluvia of criticism & intense media attention



How should applicable manufacturers or applicable group purchasing organization determine the value of journal reprints provided to covered recipients?

The value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to acquire the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the value of journal reprints.

Key words: Open Payments, Sunshine Act  
(FAQ8370)

# What is the Sunshine Act?

► [View Federal Register Vol 89, No 27](#)

## What is it?

- Signed into law in 2010 as part of the Affordable Care Act, the Physician Payment Sunshine Act requires product manufacturers to track and report transactions of value provided to healthcare professional.



## Timing

- August 1, 2013: Manufacturers are required to begin collecting information about payments and transfers of value to physicians
- March 31, 2014: First report is due covering August - December 2013
- September 30, 2014: 2013 data published on a public website by CMS, subsequent years will be published June 30.



## Journal Reprints

- Reprints are currently classified as a transfer of value to be reported based on purchase unit cost.
- Items worth less than \$10 are not reported unless the sum of all items less than \$10 for a given recipient exceeds \$100.



# Sunshine Act Primer (cont...)



# Sunshine Act Issues



- ? Transfer of Value (Direct or Indirect or Other)
- ? Values Assessment (per unit, copyright, fair market)
- ? Individual & Aggregate
- ? Format (paper, PDF, memory stick)
- ? Exemptions (e.g., CME)
- ? Educational or Promotional
- ? Recipients (licensed to practice in US)  
(Doctors of Medicine, Osteopathy, Dentistry, Podiatry, Optometry, Chiropractic Medicine) *Not Residents!*
- ? Reporting Process
- ? Reporting Entities & Site
- ? Physician Disputes & Resolution (CMS WILL NOT MEDIATE)

# Sunshine Act Future

- H.R 293 – Protect Continuing Physician Education & Patient Care Act (January, 2015 referred to House Subcommittee on Health)
- FDA Draft Guidance: Distributing Scientific & Medical Publications on Risk Information for Approved Prescription Drugs & Biological Products (June 2014)
- New Zealand Medical Journal March 27, 2015 Editorial “Let the sunshine in: Making industry payments to NZ doctors transparent”
- CMS MLN (Medicare Learning Network) Teleconference Presentation, April 2015





# Survey Results

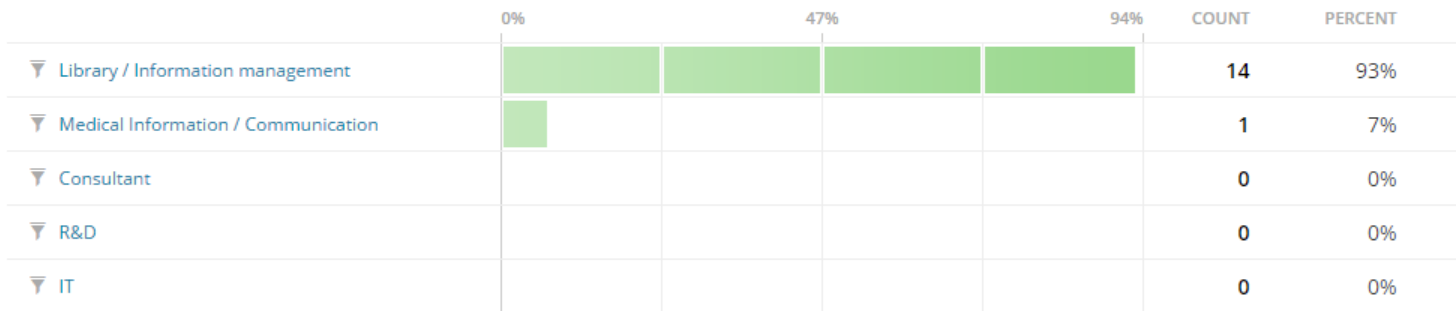
# Demographics

Question  
02

Which best describes your current job role? (Mandatory)

Answers  
**15**  
100%

Skips  
**0**  
0%

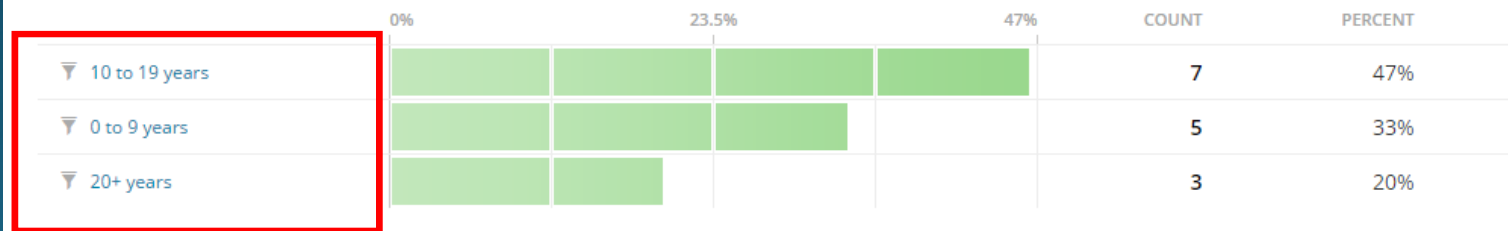


Question  
03

How many years of experience do you have within your current job role?  
(Mandatory)

Answers  
**15**  
100%

Skips  
**0**  
0%



# Implementation Status

Question  
07

Which statement best describes the STATUS of Sunshine Act governance and compliance at your company today? (*Mandatory*)

Answers

15

100%

Skips

0

0%

	0%	40.5%	81%	COUNT	PERCENT
☒ Implemented with widespread communication internally				12	80%
☒ Not applicable				2	13%
☒ In progress				1	7%
☒ Implemented, but not widely communicated internally				0	0%
☒ Not yet started				0	0%



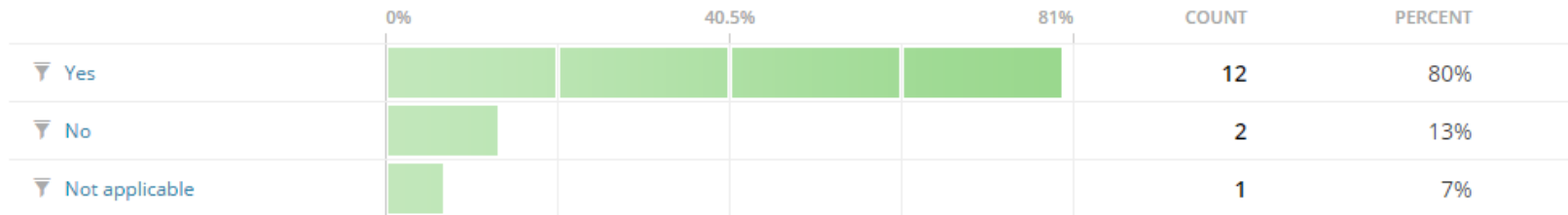
# Workflows & Role Beliefs

Question  
**11**

Have information purchases, dissemination practices, and/or workflows inside your company changed in response Sunshine Act regulation? (*Mandatory*)

Answers  
**15**  
100%

Skips  
**0**  
0%



Question  
**12**

Which statement best represents your belief about the role of information professionals to support Sunshine Act governance and compliance within their respective companies? (*Mandatory*)

Answers  
**15**  
100%

Skips  
**0**  
0%



# Department Role

Question  
**08**

Which best describes your DEPARTMENT's role in supporting Sunshine Act compliance within your company today? (*Mandatory*)

Answers

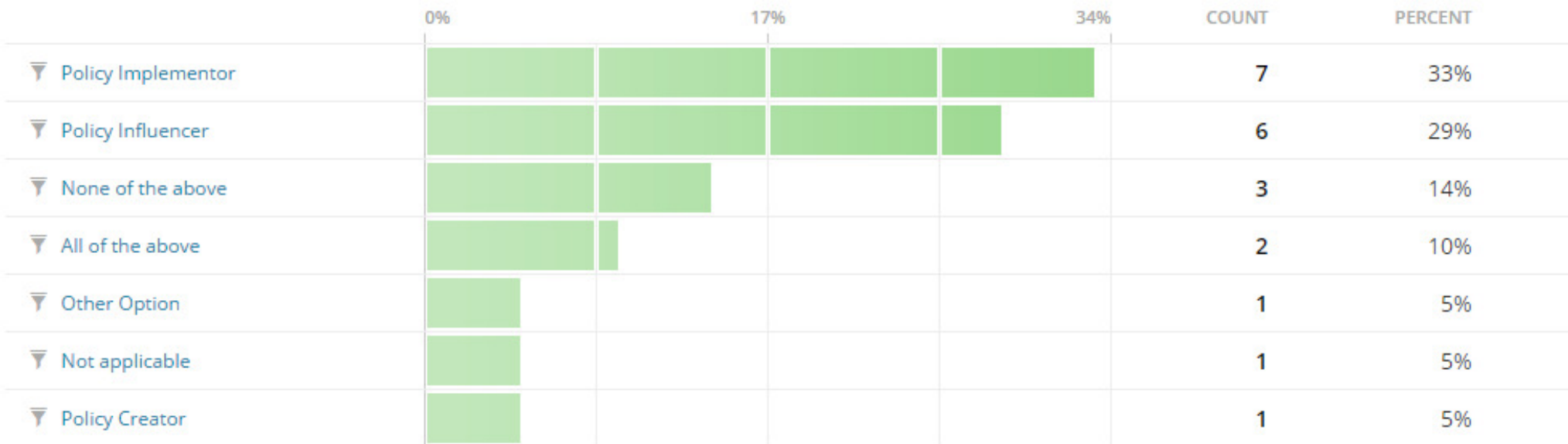
**15**

100%

Skips

**0**

0%



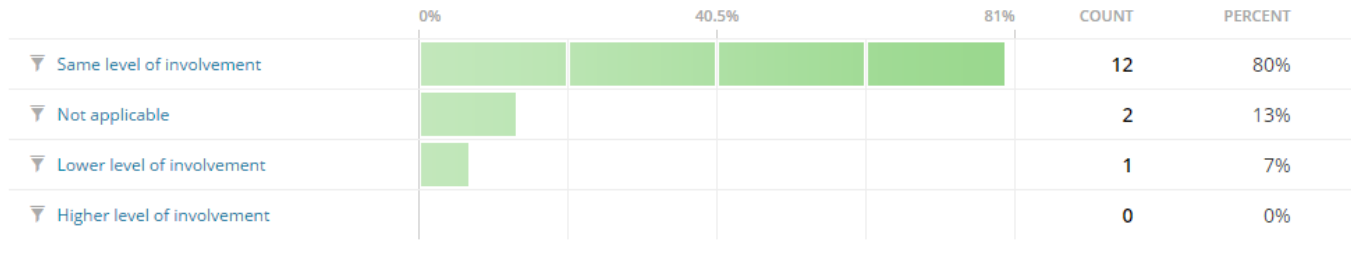
# Department vs Personal Role

Question  
09

How do you expect the role of your DEPARTMENT in supporting Sunshine Act compliance will change within the next 12 months? (Mandatory)

Answers  
**15**  
100%

Skips  
**0**  
0%

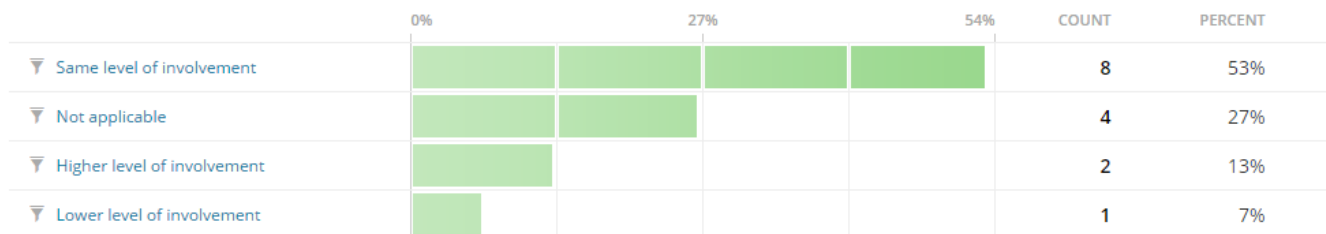


Question  
10

How do you expect YOUR personal role in supporting Sunshine Act compliance will change within the next 12 months? (Mandatory)

Answers  
**15**  
100%

Skips  
**0**  
0%





# Survey Q&A for Audience & Panel Discussion

# Topics of Interest:

## Open Access

### Open Access Commercial Use Licensing Options from WK



OA article link posted on Product Website



Including links in Pharma newsletters, Rep emails to HCPs, Med Affairs email



Add on campaign usage reporting



*Included uses for OA Commercial Fee*



iPad Detail for iPad Sales Reps



Print for non iPad Sales Reps



*Excluded uses for OA Commercial Fee*



Wolters Kluwer  
Health

Lippincott  
Williams & Wilkins

# Topics of Interest (cont...)

- Clinical trials & POs
- Teaching hospitals
- Better identification of which ones are reportable
- Article valuation for non-bulk reprint articles
- Fair market value or exact copyright/delivery fees for reprints shared with HCPs
- Global organizations & standards (eg highest common denominator?)
- Country-specific workflows & processes (eg MedInfo)



# Biggest Info Pro Challenges

- Including Info Pros BEFORE new compliance workflows are defined
  - Explaining how publishing works for compliance colleagues
  - Ongoing relationships with commercial, med-legal w/r/t needed info., copyright & re-use guidance.
  - Staying informed of any guidance or policy or changes
- 
- Setting a value for an article
- 
- Providing the necessary reporting support
  - How to report info. globally & train affiliates (eg licensed in US, but working in S.America)
  - Wrangling reports back from non-info pros
  - Details, tracking & subjective requirements

# Information Professional Support

Question

14

How do YOU think information professionals can best support Sunshine Act compliance within their respective companies?

Answers

9

60%

Skips

6

40%



123,376,475

Provide the needed background information on how we negotiate and procure the content. What our contracts states we can and cannot do. How the document delivery process works now.

Yesterday, 12:37PM



122,822,208

Involve early and proactively

Tuesday, Apr 7th  
9:01AM



122,761,995

Assisting with the tracking process by applying our process knowledge. In my case, I am supporting the team by being another person working on all the information. There are four of us on working on Sunshine year round.

Monday, Apr 6th  
3:26PM



121,755,067

Drive workflows for approving, sharing documents, purchasing copyright permissions, and reporting compliantly

Wednesday, Mar 25th  
10:30AM



121,070,394

Providing benchmarks on cost models, guidance on copyright and reuse; having tools / applications in place to make reporting and compliance part of the user's regular workflow. Partnership with commercial, legal and medical to ensure training and compliance.

Thursday, Mar 19th  
11:28AM



120,966,612

I think we should definitely update our copyright disclaimer on the bottom of all emails to also include Sunshine Act.

Wednesday, Mar 18th  
7:43AM

Comments? Questions? Other Topics?

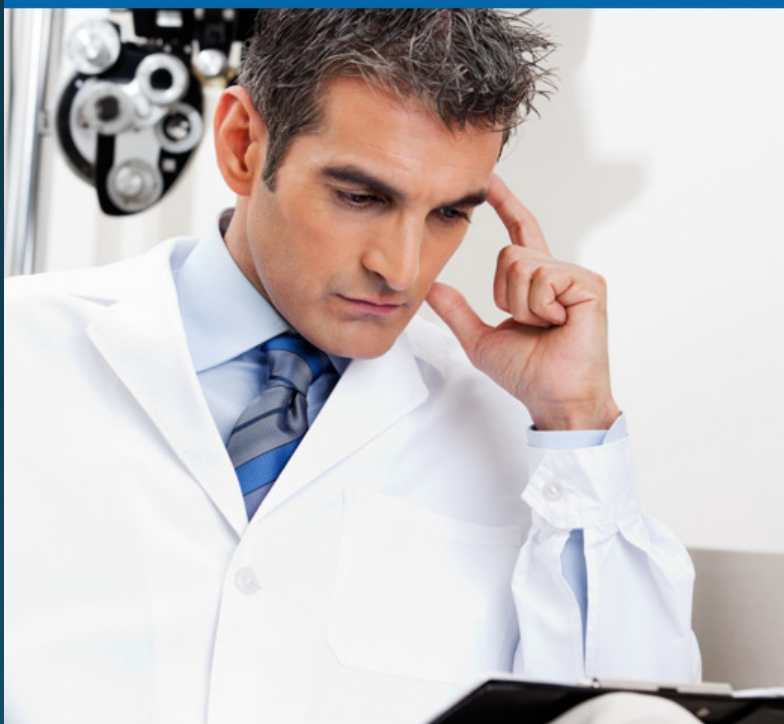




# Panelist Commentary

# Print Reprints

Educate Health Care Professionals about the Clinical Effectiveness of Your Product



## Print Reprint Ruling

The value of a journal reprint can be determined by simply dividing the cost of ordering the reprints from LWW by the number of reprints being ordered.

► [View CMS comments clarifying how to report the value of reprints](#)

- Provide your sales reps with a credible leave-behind with staying power.
- Deliver the clinical report, meta-analysis of data or review article for the physician to read at their convenience.
- Reps can quickly point to key passages.
- All LWW proposals and invoicing will clearly indicate the cost per unit.

Example:

QUANTITY ORDERED	TOTAL PRICE	COST PER UNIT
10,000 Print Reprints	\$50,000	\$5

# Event & Conference Reprint Solutions

Engage Health Care Professionals in  
Learning Mode



## Conferences & Events Ruling

"We believe that at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we will finalize that small incidental items that are under \$10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events **will be exempted from the reporting requirements**, including the need to track them for aggregation purposes."

► [View Fed Reg Vol 89, No 27](#)

- Target specialty groups at society and association meetings.
- Support your brand and conference exhibit experience with print and electronic reprints year-round.
- Display on a tablet or distribute print articles and special collections at your booth.



Wolters Kluwer  
Health

Lippincott  
Williams & Wilkins



# ePrint Advertising

Reach Qualified Health Care Professionals Actively Engaging with their Trusted Journal Content

## 3<sup>rd</sup> Party Distribution Ruling

“Section 1128G(e)(10)(A) of the Act states that the exclusion of indirect payments or other transfers made through a third party is limited to situations “where the applicable manufacturer is unaware of the identity of the covered recipient.”

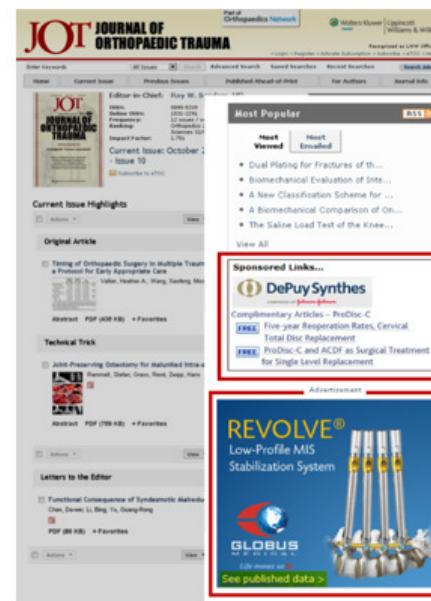
► [View Fed Reg Vol 89, No 27](#)

## iPad Ads



Add ePrint Links

## Text Links & Banners



Add ePrint Links

Add ePrint Links



# Case Study: Literature Tracking

Medical Affairs approached Reprints Desk in March 2013 to create integrated process to track reprint delivery as per Sunshine Act

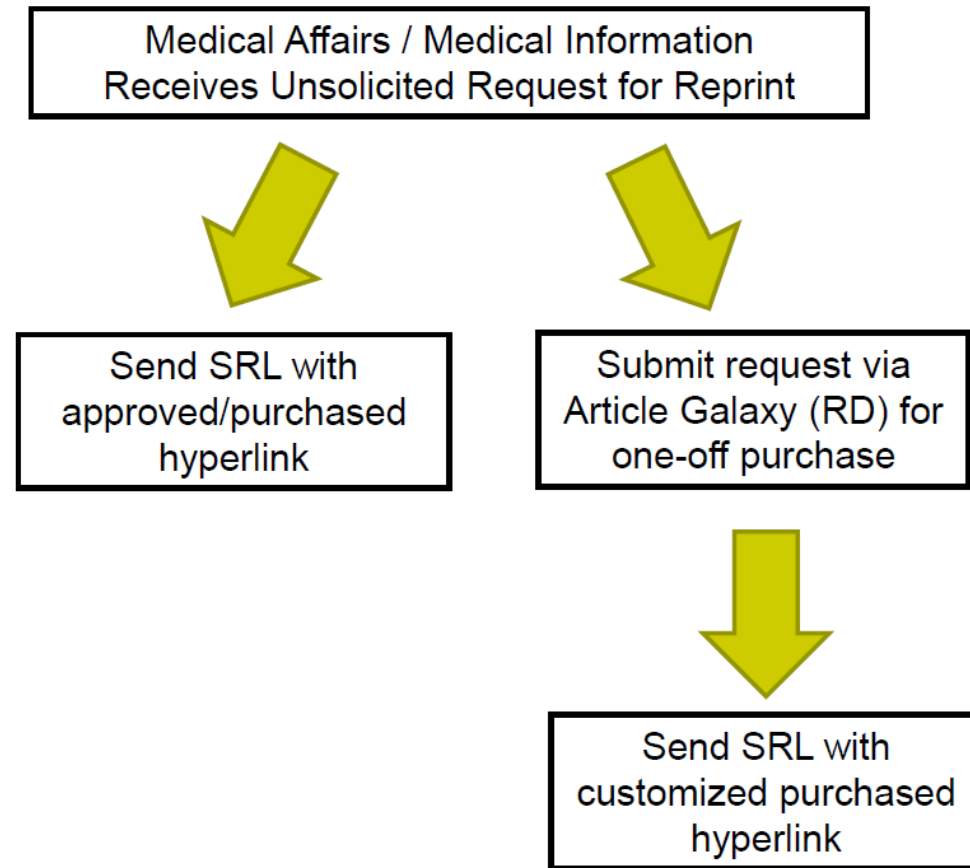
## Bulk ePrints:

All ePrints article purchases converted to ePrint hyperlinks with Sunshine Act landing page for data capture (July 2013)

## "One-off" ePrint:

All ePrint one-off article purchases converted to ePrint hyperlinks with Sunshine Act landing page for data capture (November 2013)

Wish to thank Chung Lu, Medical Information Director for all of his input



# Case Study

## Bulk ePrint

The following information is provided in response to your unsolicited inquiry requesting a reprint of the following journal article:

- Atef A, Fawaz AA. Intravenous paracetamol is highly effective in pain treatment after tonsillectomy in adults. Eur Arch Otorhinolaryngol 2008; 265(3):351-355.

Please be aware that Company reports transfers of value to healthcare professionals, including journal reprints as required by applicable state and federal laws including, without limitation, in accordance with the "Sunshine Act" (Section 6002 of the Patient Protection and Affordable Care Act (PPACA)).

A copyright-secured digital form of the study is provided for your individual use and may be downloaded onto your computer at the following hyperlink:

<http://Company.reprintsdeskdocs.com/#c5d6ec864aa5eec54b2ad2f7145136e8284b89094c51cb22d861b357e2173e45>

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Please note this copy is provided in response to your unsolicited request and is for your individual use only. Dissemination of the hyperlink to any other individual may constitute a violation of U.S. copyright laws.

## "One-off" ePrint

Extra line breaks in this message were removed.

From: Reprints Desk Customer Support <customersupport@reprintsdesk.com>  
To: Chung Lu  
Cc:  
Subject: Reprints Desk article delivery #1994316

Sent: Thu 1/23/2014 10:11 AM

Dear Chung Lu,

The article for OrderID 1994316 is now available to download using the following link. You can download the article yourself or send a link to someone else. The download will be logged in the Sunshine Act report, and the link will then expire.

MSL DOWNLOAD PAGE LINK  
<http://Company.reprintsdeskdocs.com/#3a1ba0c2b03c96a62b71bfd0de53bdd87fec84854f7ecb54e4a6d996c9e1b>

Please note that Acrobat Reader is required to view this document

ARTICLE DETAILS  
Title: Clinical Pharmacology of Intravenous Paracetamol in Perinatal Medicine  
Author: Allegaert, Karel  
Publication: World Journal of Anesthesiology  
Year: 2013

If you have any questions please contact us at +1(310)477-0354, or [customersupport@reprintsdesk.com](mailto:customersupport@reprintsdesk.com). Please refer to the OrderID number when making inquiries about this order.

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The Reprints Desk - One Stop Reprint Solutions  
(883-1)

# Case Study (bulk ePrints)

## Submit the form below to access the article

Company reports payments and other transfers of value to healthcare professionals as required by applicable state and federal laws including, without limitation, in accordance with the "Sunshine Act" (Section 6002 of the Patient Protection and Affordable Care Act (PPACA)). [Learn More](#)

Are you a U.S.  
licensed physician  
(e.g. M.D. or D.O.)?\*

-- Select One --

\* Required

Intravenous paracetamol is highly effective in pain treatment after tonsillectomy in adults.

Atef A; Fawaz AA

Eur Arch Otorhinolaryngol 2008; 265(3): 351-355

Download Article  
(PDF)

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## Submit the form below to access the article

Company reports payments and other transfers of value to healthcare professionals as required by applicable state and federal laws including, without limitation, in accordance with the "Sunshine Act" (Section 6002 of the Patient Protection and Affordable Care Act (PPACA)). [Learn More](#)

Are you a U.S.  
licensed physician  
(e.g. M.D. or D.O.)?\*

Yes

First Name\*

Middle Initial

Last Name\*

State License  
Number\*

State Licensed In\*

-- Select One --

Specialty\*

-- Select One --

\* Required

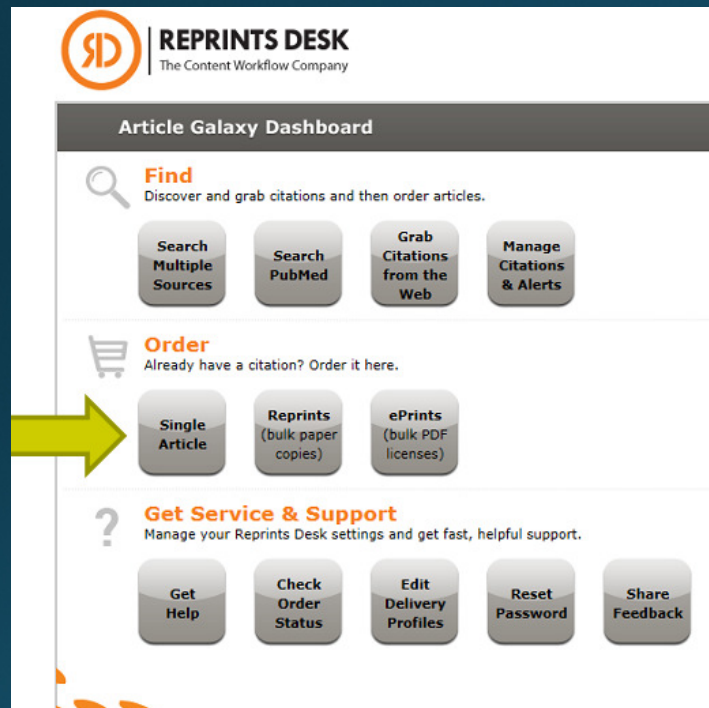
Intravenous paracetamol is highly effective in pain treatment after tonsillectomy in adults.

Atef A; Fawaz AA

Eur Arch Otorhinolaryngol 2008; 265(3): 351-355

Download Article  
(PDF)

# Case Study ("One-off" ePrint)



**SD REPRINTS DESK**  
The Content Workflow Company

### Article Galaxy Dashboard

**Find**  
Discover and grab citations and then order articles.

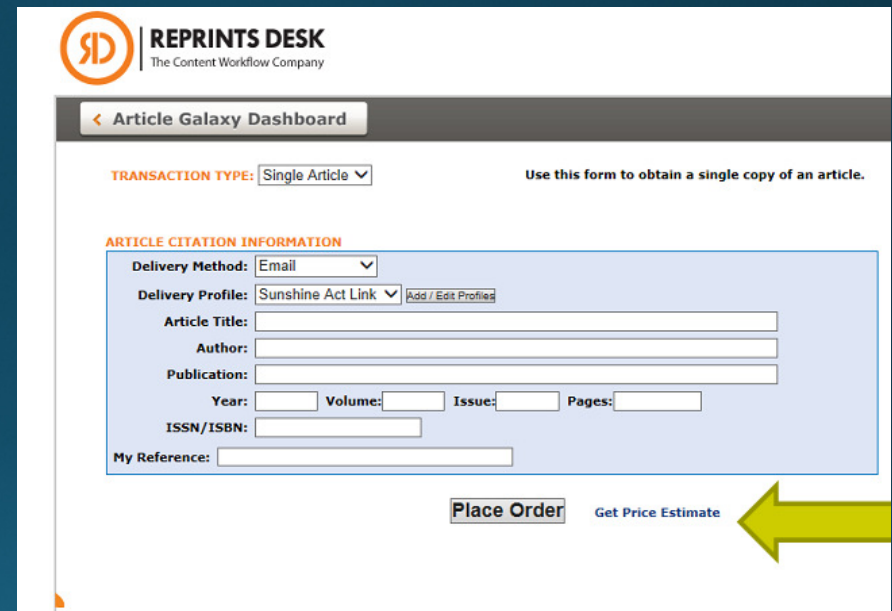
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The Content Workflow Company

### Article Galaxy Dashboard

TRANSACTION TYPE: Single Article ▼   Use this form to obtain a single copy of an article.

**ARTICLE CITATION INFORMATION**

Delivery Method: Email ▼  
Delivery Profile: Sunshine Act Link ▼ [Add / Edit Profiles](#)

Article Title:   
Author:   
Publication:   
Year:  Volume:  Issue:  Pages:   
ISSN/ISBN:   
My Reference:

**Place Order**   [Get Price Estimate](#)



# Case Study

## **Streamlined process**

- Requester provides information
  - Saves employee time to capture Sunshine act information
- Improved turnaround time
  - Reprints Desk handles copyright issues
- Transparent education and disclosures around Sunshine Act
  - Requester provide personal licensure data
- Scalable process
  - bulk orders vs “one-offs”
- Monthly electronic data capture directly fed to Company’s Compliance department

# Final Q&A / Discussion