




Sunshine Act in practice

We're aiming to combine a review of practical experiences of the US Sunshine Act and Open Payments system

Sunshine act plus EU derivations

-  Top line on US sunshine and what I can see our clients are doing about it
-  Top line on EFPIA and clients' reactions to it
-  Some questions that will hopefully fuel the debate this afternoon

Sunshine Act is finally 'live'





POLICY AND MEDICINE

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Physician Payment Sunshine Act

August 21, 2013

→ [Physician Payment Sunshine Act: Listing of Resources for Open Payments](#)



Under the [Physician Payment Sunshine Act Final Rule](#) (Open Payments), beginning today August 1, 2013 applicable manufacturers and group purchasing organizations will be required to report all payments and transfers of value to physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (CMS).

Policy and Medicine has been writing about the [Physician Payment Sunshine Act](#) for a long time. Since CMS announced [the final rule](#), we have published numerous articles. This serves as an ongoing reference to articles related to the Physician

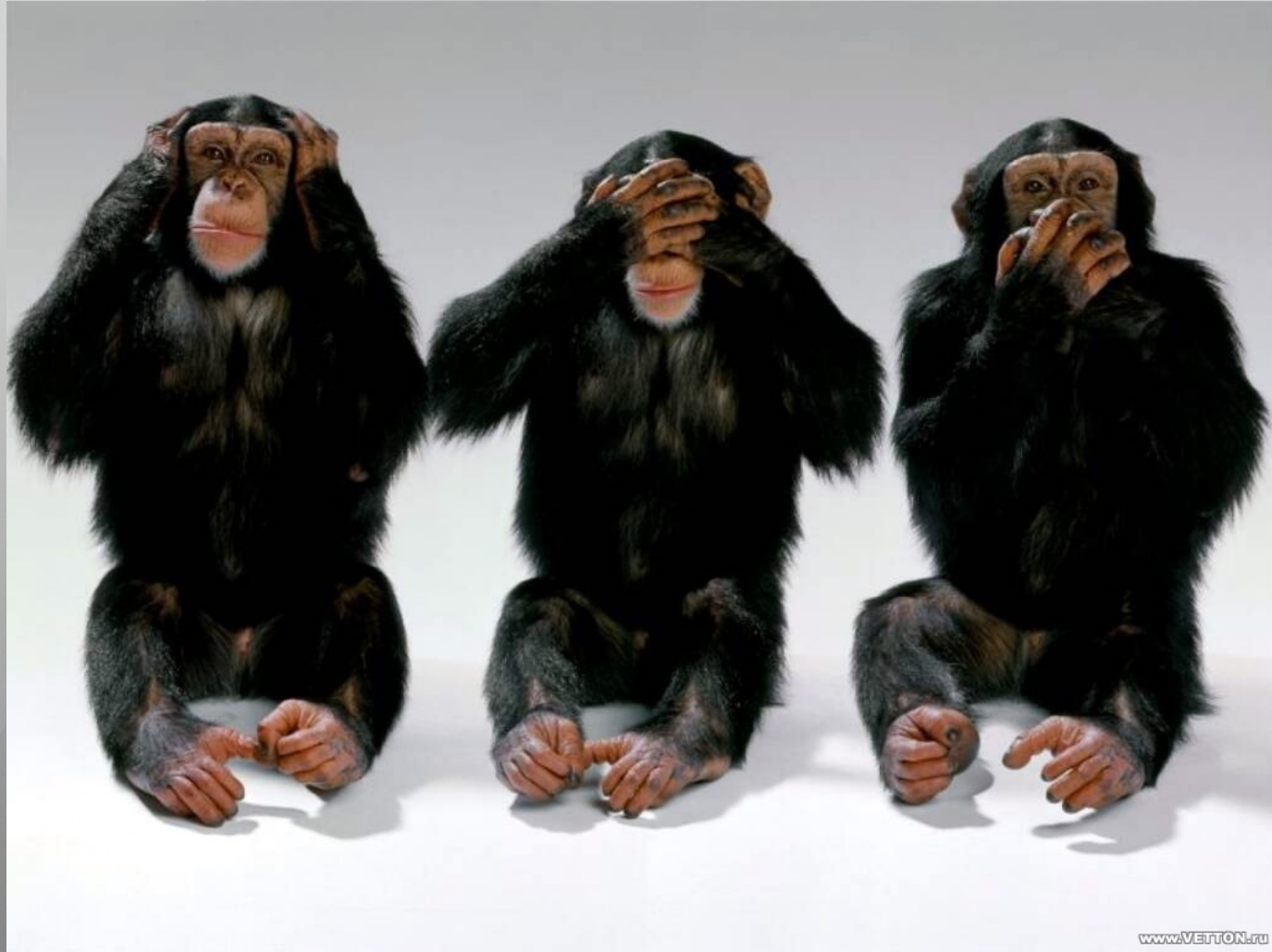
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Physician Payment Sunshine Report Due to CMS
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So here's the irony

- 🌐 Aside from the usual tub-thumping and public proclamations from people like Andrew Witty we are not any the wiser to knowing the practicalities about US or EU Sunshine
- 🌐 Transfer of Value
- 🌐 Physician acceptance – and legality thereof
- 🌐 Public opinion
- 🌐 A bill and set of measures that are supposed to encourage openness and transparency has so far led to an almost media blackout from our clients about what they will actually do

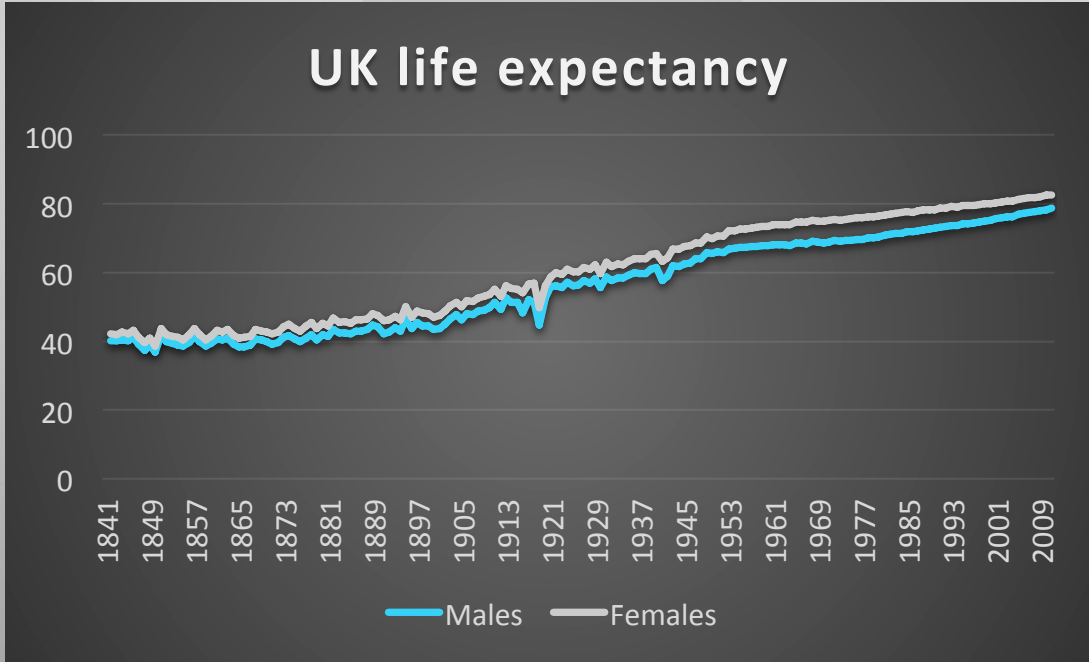
So let's come back to what we do know...

-  US – legal obligations of pharma to collect and disclose information on a range of activities, payments and TOV
 - > Data collection started – August 2013
 - > Data to CMS – end March 2014
 - Although there are already delays apparently
 - > Data available – end September 2014
 - > Fall-out and analysis...

So let's come back to what we do know...

- EU – part legislation, part voluntary via EFPIA and the national codes
- Some countries adopting codes that are more stringent than even US Sunshine
- EFPIA
 - > EFPIA adopt the disclosure code – 2013
 - Local associations adopt the code from end of 2013
 - > Collect information (multi-layered Excel spreadsheet +) from 2015
 - > Publish – 2016
 - > Sit back and relax

So what is exactly at play?



BITTER PILL

£323m amount GSK is accused of using to bribe officials	4 number of months GSK spent probing whistleblower claims
7,000 number of GSK staff based in China	£759m annual revenues from China in 2012







ALL TRIALS REGISTERED

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ALL RESULTS REPORTED

And... what else do we know?

All of our clients are

-  Collecting data - with Excel spreadsheets
-  Talking to some very expensive consultants
-  Recruiting more compliance personnel
-  Amassing armies of interns to shift the paperwork
-  Not (yet) making public statements on the “how”
-  Not (as far as I am aware) telling their KOLs/
consultants/trialists

But there are still many unanswered questions

- Self regulation – does it work?
 - > Will those with an axe to grind have their day?

- Will it remove bad practices?
 - > Don't those who bend the rules always still find a way?

- What will we do with all the data?
 - > And what will it all mean?
 - > When will the caps on spend be created?

But there are still many unanswered questions

- 🌐 Will healthcare professionals cooperate?
 - > Data protection, tax implications
 - > It's voluntary after all




- 🌐 Will we see a decrease in the amount of activity that senior KOLs become involved in?
 - > And will that impact patient care?

- 🌐 Will it reduce the healthcare burden?
 - > Do we care what our physicians are doing as long as we get better?

And... for us in medical communications?

- 🌀 Uncertainty is the order of the day
- 🌀 We probably have our houses in order up to a point
 - > If the client asks us to use reference A or B do we?
- 🌀 Will we end up with 2 tiers?
 - > CME
 - > Promotional
 - > ...and nothing in between
- 🌀 Should there be independent of pharma company writing agencies
- 🌀 Where is our voice

Overall

-  Sunshine – initial reports will be interesting
-  Transparency is here to stay but I would suggest the form it takes will change
-  Pharma needs to put its house in order and be more vocal about the positives and work with governments and communities to improve care

Thanks