Sunshine Act in practice

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

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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

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Sunshine Act is finally ‘live’

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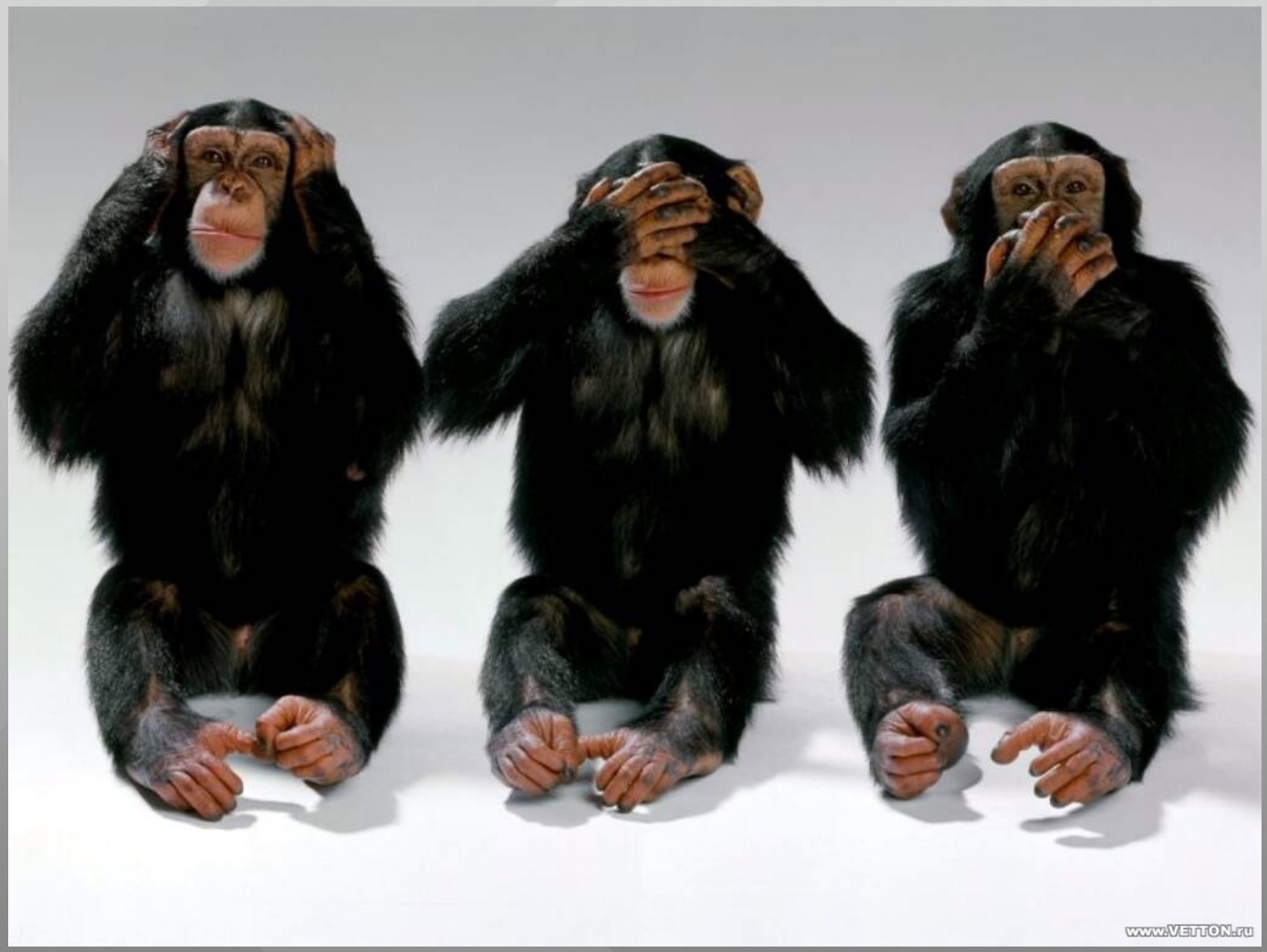

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So here's the irony

- 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

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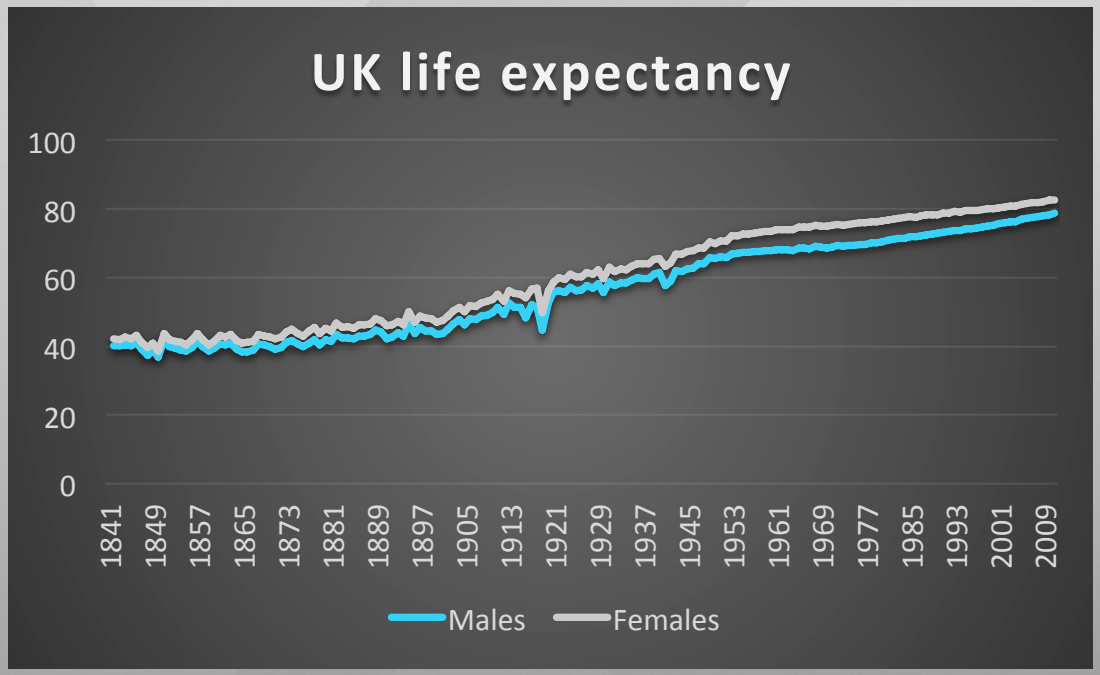
So let's come back to what we do know…

- 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 that 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?



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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

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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

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