

11TH ANNUAL MEETING OF ISMPP



***The Sunshine Act, Medical  
Publications, and Authors:  
Results of the ISMPP Survey***

Presented at the 11<sup>th</sup> annual meeting of ISMPP  
April 28, 2015



# Panelists: ISMPP Sunshine Act Taskforce

- **Angela Cairns, BSc, CMPP**
  - *Senior Vice President, Global Compliance Team Leader, Ashfield Healthcare Communications*
- **Renu Juneja, PhD**
  - *Head, Medical Communications, Medimmune*
- **Robert J Matheis, PhD, CMPP**
  - *Executive Director, Global Scientific Communications, Celgene Corporation*
  - *Chair, ISMPP Sunshine Act Task Force*
  - *Past President, ISMPP (2011-2012)*
- **Kim Pepitone, BA, CMPP**
  - *Scientific Director, Cactus Communications*
  - *Vice Chair, ISMPP Sunshine Act Task Force*
  - *Adjunct Assistant Professor, University of the Sciences in Philadelphia*



# Disclaimer

- The opinions expressed herein are those of the speakers and do not necessarily reflect those of their respective employers or of ISMPP



# Three Potential Reporting Scenarios

No	Yes	Maybe...
<p><b><i>Proposed rationale:</i></b> The value is to the applicable manufacturers as it helps them meet ethical obligations to publish their data in a timely manner; there is no value to covered recipients</p>	<p><b><i>Proposed rationale:</i></b> There is value to CR authors in the form of support for work that the CRs would have had to either perform or secure for themselves if the AM had not provided the support</p>	<p><b><i>Proposed rationale:</i></b> It depends on the circumstance; eg, if the CR approached the AM for support</p>



**ISMPP SURVEY APRIL 2015**  
***SUNSHINE AND AUTHORS:***  
***IS THERE AN EFFECT?***



# ISMPP Survey Description

- 24-question survey
- Distributed to 110 discrete ISMMP members in the position of senior-level medical publication professionals in industry companies
- Conducted via email March-April 2015
- Objective
  - Gain additional understanding of potential impact of Sunshine on authors/publications
- Similar to survey conducted in 2014



# ISMPP Survey Results

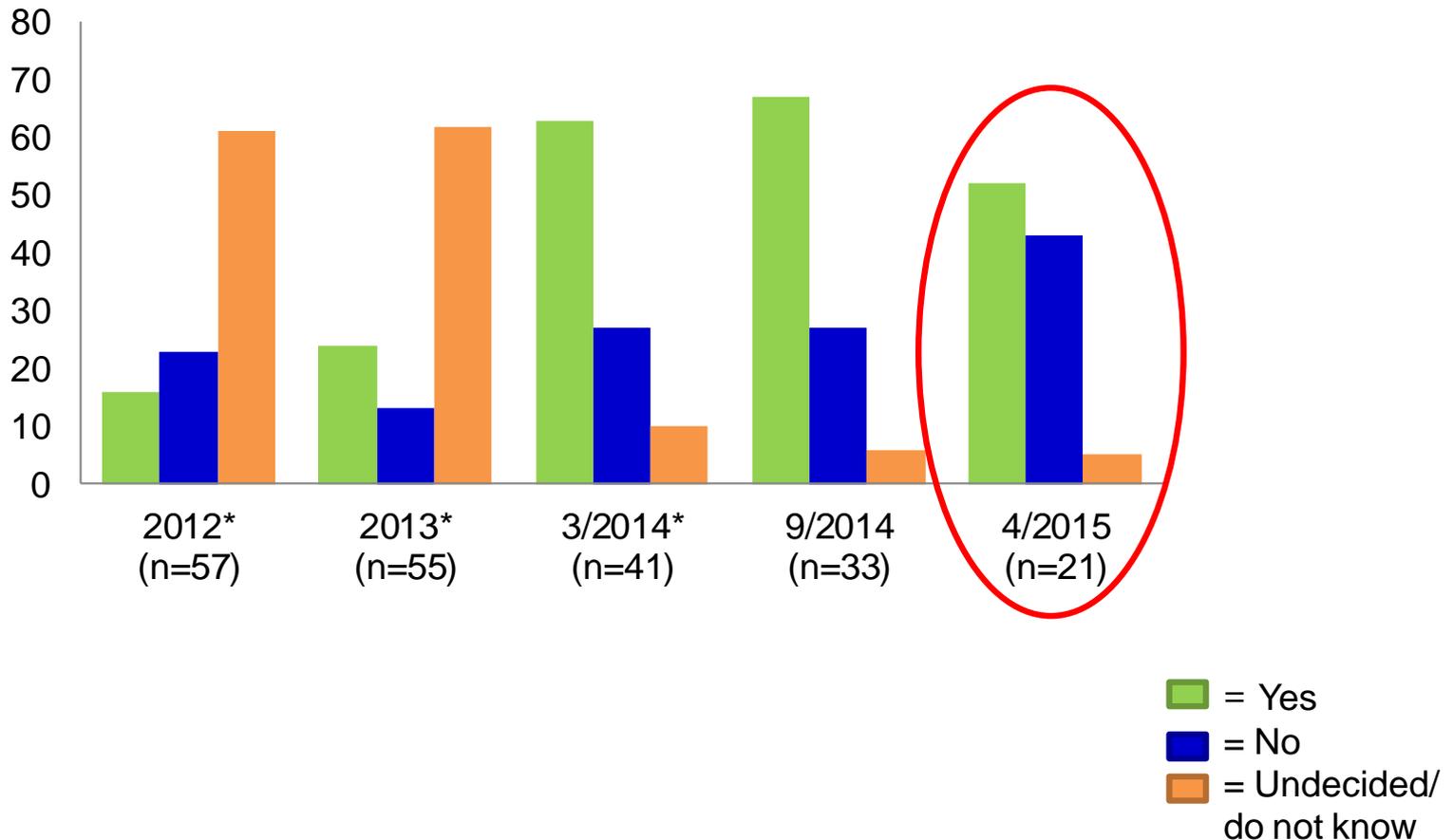
- Response rate: 25 (23%)
- Majority global (88%)
- 38% > 50,000 employees
- 52% report publications support as a TOV



# In YOUR OPINION, should publication support be reported as a TOV?

- Yes
- No
- Undecided

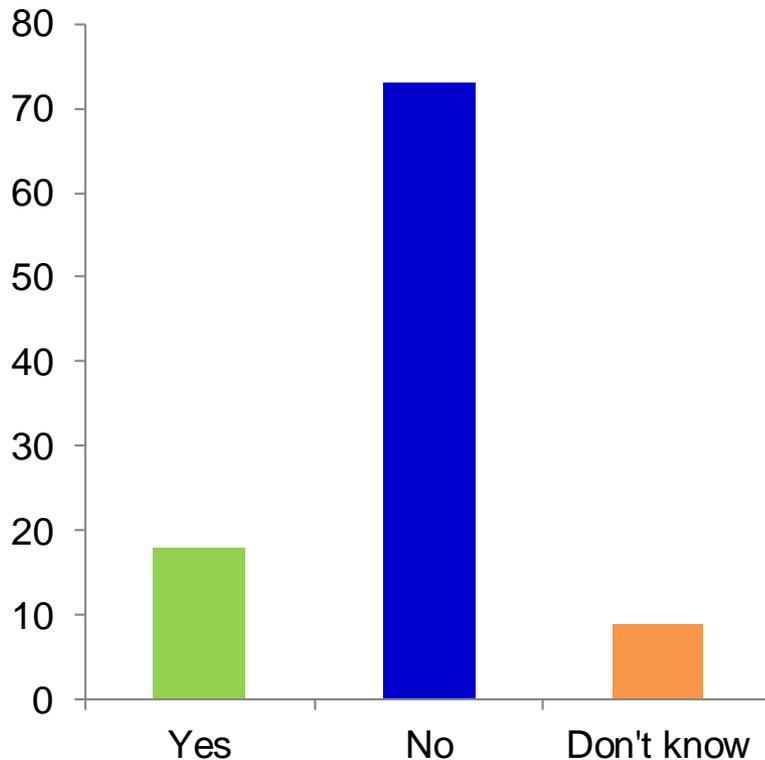
# Does your company consider publications support a reportable TOV?



\*Results for all industry respondents who answered this question; blinded survey; likely multiple respondents per company

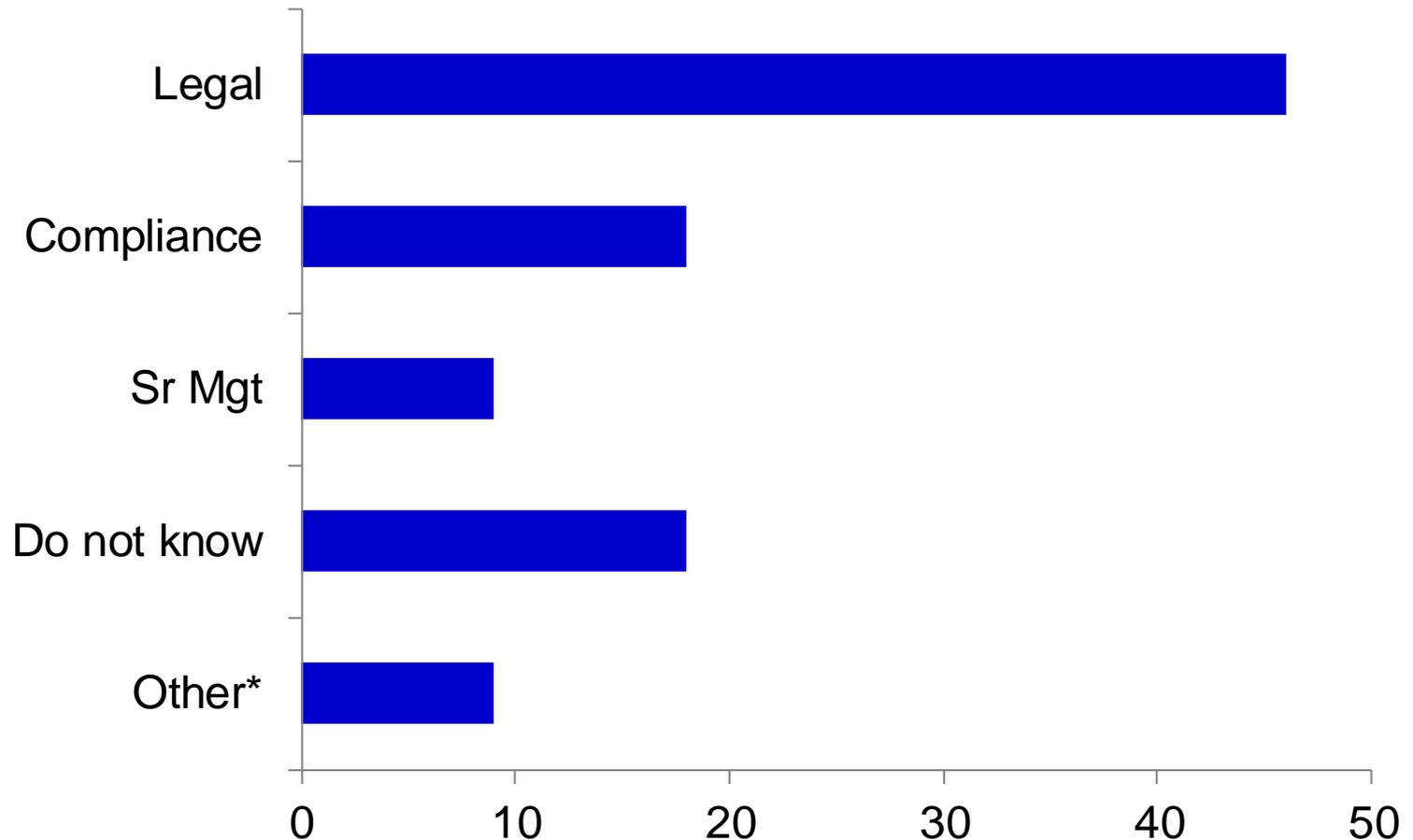
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# Has your company's position on reporting changed over time? (n=11)



'My company is committed to adapting to changes in the ever-evolving international environment. Medical writing and editorial support are now reported as transfer of values, in agreement with the SUNSHINE ACT and more recently in agreement with EFPIA requirements.'

# Who in your company was responsible for the decision [to report support as TOV]? (n=11)



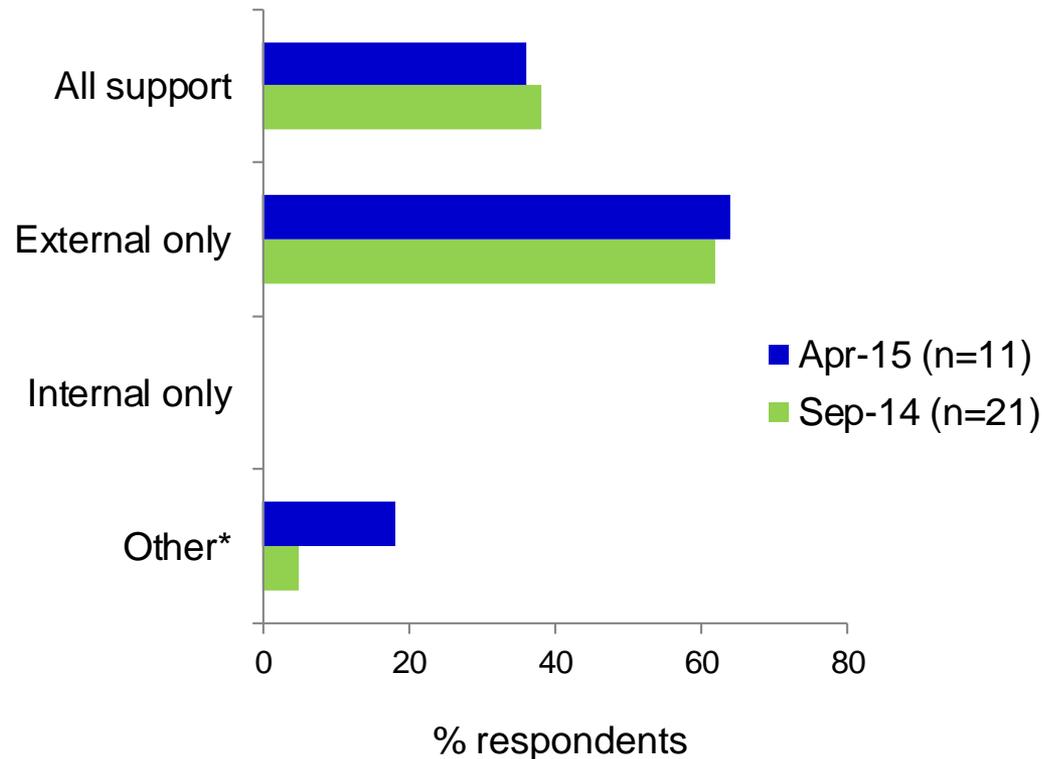
\*Combination of publication leaders, legal and compliance  
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# Has your company actively communicated its policy on reporting of publications support to authors? and if yes, by whom? (yes=9; 2=no)

- If yes, by whom?
  - All 'yes' mentioned member of publication team
    - Publication team lead
    - Combination publication team lead and agency
    - Company authors, study lead, or publication lead, situation dependent
- If yes, how?
  - Body of standard email communication (67%)
  - Company's publication policy (33%)
  - In research agreement (11%)
  - Separate Sunshine communication (11%)

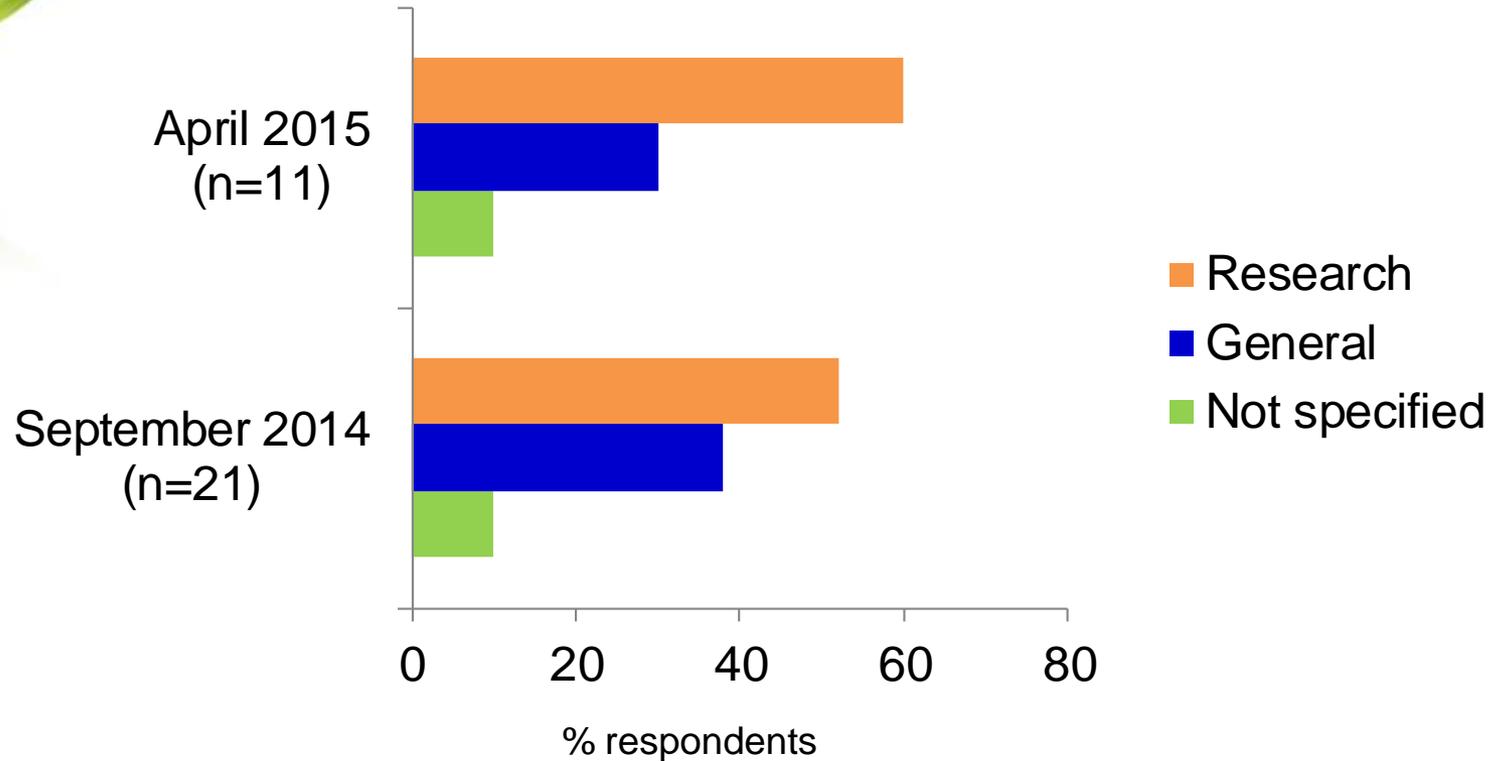
# What is the scope of reportable TOV and how is it calculated?



- Roughly 50/50 split on actual cost vs estimated FMV
  - Results similar to September 2014 survey

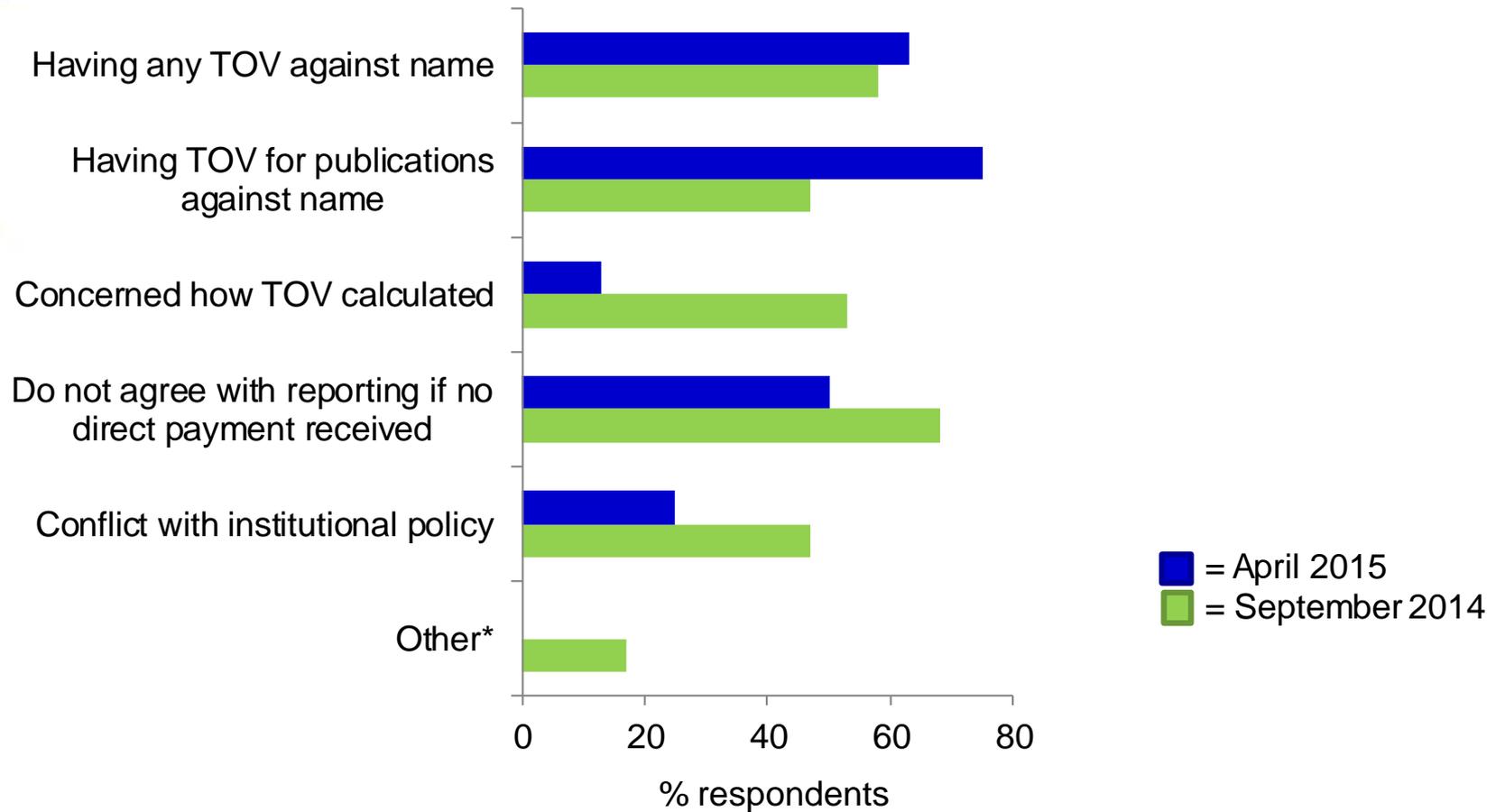
%=>100 due to multiple answers per respondent; \*Includes editorial support and congress and journal fees

# In which category is support for data-driven publications reported?



- Majority respondents report review articles under general category

# What are the main concerns expressed by authors (select all that apply)?



■ = April 2015  
■ = September 2014

# Major impact continues to be on publication timelines

