

**Thank you for joining ISMPP U today!**

*The program will begin  
promptly at 12:00 noon EST.*

## Questions & Answers

*To ask a question, please type your query into the 'Q&A' chat box at the bottom left of your screen. Every attempt will be made to answer each question as it is received.*

# Program Overview



- **Interactive discussion on the role of review articles and sponsored supplements**
- **Views from an expert panel representing the pharmaceutical industry, publication houses and journal editors**
- **Key areas of focus: current concerns, ideal practice and future trends**
- **Questions can be put forward for discussion during the session**



# PUBLICATION PLANNING

## A Publisher's Perspective

Craig Smith

Senior Editor, Manager Supplement Division

Elsevier

AUGUST 19, 2009

# An Industry In Transition

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- PRINT
- PRINT & ELECTRONIC
- ELECTRONIC /INTERACTIVE
- ELECTRONIC TO EXPERIENTIAL ?

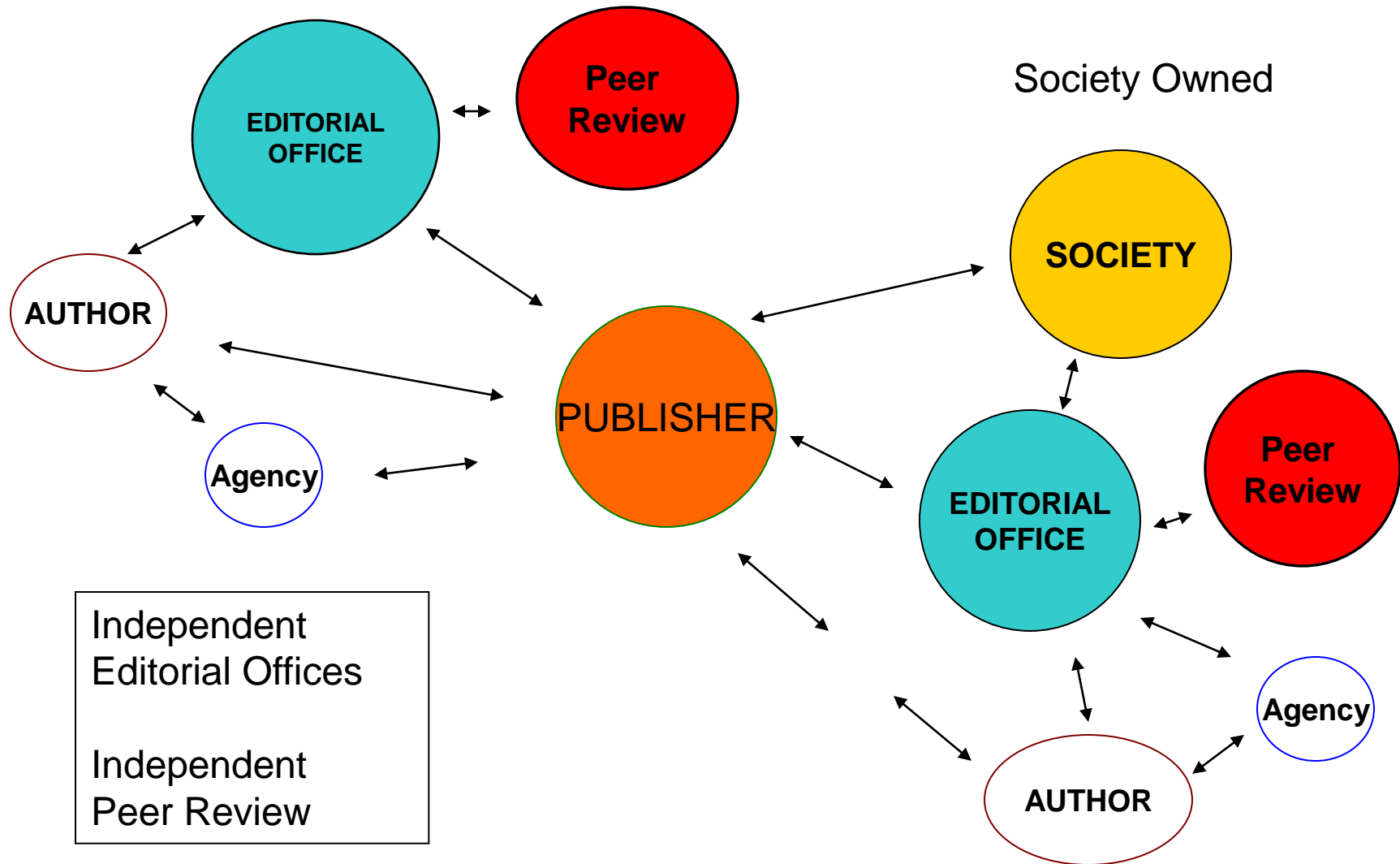
Impact on Publication Planning?

# PUT YOURSELF IN THE CHAIR OF THE EDITOR IN CHIEF

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- Is the Content Useful?
- Is the Content Relevant?
- Is it Educational?
- Is the Science “Clean” or does it have “*Spin?*”
- Will this Content Enhance my Journal?

# WHO DECIDES?



# CHOOSING A JOURNAL

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1. AUTHOR / CLIENT CHOICE
2. CIRCULATION – ELECTRONIC
  - A. Metrics Available
3. CIRCULATION - PRINT
4. REPUTATION (Word of Mouth – Society?)
5. READERSHIP SURVEY
  - A. Advertising or reprints department
6. IMPACT FACTOR
7. TIME FROM SUBMISSION TO PRINT

# ENGAGE THE JOURNAL

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- FROM EDITORIAL OFFICE OR PUBLISHER
  - INDUSTRY SPONSORED RESEARCH PAPERS ACCEPTED? – LET THE EDITORIAL OFFICE KNOW IF THIS NEEDS TO BE PUBLISHED WITHIN 12 MONTHS AS REQUIRED BY FDAAA.
  - UNSOLICITED INDUSTRY SPONSORED REVIEW PAPERS ACCEPTED?
  - RAPID REVIEW POSSIBLE?
  - THEME ISSUES?
  - PRE-PUBLICATION ONLINE POSTING?
  - SPONSORED SUPPLEMENTS ACCEPTED?
- ENGAGE JOURNALS IN ESTABLISHING LEARNING GAPS AND NEEDS ASSESSMENTS
  - surveys – Online or Print
  - Statements of Needs by Editorial Offices
  - Statements of Needs by Societies

# WHAT IS THE CONTENT?

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- **DATA DRIVEN**
  - Initial Publication of Clinical Data
  - Target Audience: Research Community
  - Impact Factor may be important
- **CLINICALLY DRIVEN**
  - Practical “How to” for the Practicing Clinician; Consider additional video components
  - Clinically Oriented Peer Reviewed Journals
- **ISSUE DRIVEN**
  - Rapid Response to Market Conditions; Editorials, letters, comments
  - Rapid Publications; Open Access
  - Circulation and Target Audience More Important

# SUBMIT WITH PROPER DISCLOSURE

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- AUTHOR DISCLOSURES
  - Criteria for authorship: International Committee of Medical Journal Editors (<http://www.icmje.org/#author>)
- ACKNOWLEDGE ANY INDUSTRY SPONSORSHIP
- ACKNOWLEDGE WRITING ASSISTANCE BY NAME AND ANY FINANCIAL ARRANGEMENT WITH SPONSOR
- IN COVER LETTER DISCUSS LEVEL OF WRITING ASSISTANCE OFFERED: Copy Editing, Referencing, Fact Checking, Graphic Services, etc.

# SPONSORED OPTIONS

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- JOURNAL SUPPLEMENTS

- Peer Reviewed, Fully Indexed, Separately Bound; Mailed With Regular Issue, Posted On Journal Website, CME or Non-CME
- Obtain approvals from Pharma Regulatory regarding any off-label discussion

- MULTIMEDIA PROJECTS

- JOURNAL BRANDED WEBCASTS
- KOL VIDEO OR AUDIO INTERVIEWS
- PODCASTS
- VIDEOCASTS

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# THANK YOU

Craig Smith  
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# **Reviews and Supplements: Pharmaceutical Industry Perspective**

**Elizabeth Crane**

**Sr. Manager, Medical Publications**



# “Ideal” Practice for Reviews and Supplements

## First choice:

Independent review without any sponsor involvement in content development or decision to publish

## Second choice:

Independent review with multiple sponsors (industry, societies, government, etc) who had no involvement in content development or decision to publish

**Are there other options that are compliant (US)?**



**To sponsor or not to sponsor...  
that is the question**



# Current concerns

## Perceptions (US) of sponsored reviews/supplements:

- Expensive?
- Difficult to get accepted (reviews)?
- “Pay to Publish” indicates lower quality publication (supplements)?
  - Quality of peer review?
- Supplement issues are not always indexed?
- Potentially biased and/or promotional?
- Compliance issues with distribution (supplements)?
- Does anyone read them?

# Sponsored Reviews: Trends

Documented scientific unmet need

- Gaps in literature, unaddressed questions, outdated material

Systematic rather than narrative reviews

- Transparent methodology

Disease state vs individual drug focus

Process to maximize author independence and minimize sponsor influence

- Fewer reviews with fewer reviewers; scientific accuracy-based, courtesy reviews

# Sponsor Involvement: Invited Reviews?

Scientific experts are often invited to write reviews

Experts, in turn, may request support from sponsor and/or professional writer:

- Bibliography or literature search
- Editorial support under direction of author(s)

Before proceeding...

- Does this project require support from sponsor? If so, then...
- Request that author discuss acceptability of support and types of support with journal editor

Any sponsor and writing support, as well as funding, must be disclosed in final publication

# Supplements: Trends

Documented, scientific unmet need

Content generally not original research articles, sometimes works well for series of papers from patient registry

Prefer journals that utilize multiple peer-reviewers

Many additional features and exposure available, but perceived as potentially promotional and non-compliant

- Consult Legal and Regulatory

Process maximizes author independence and minimizes sponsor influence

- Fewer reviews with fewer reviewers; scientific, accuracy-based courtesy review

Any sponsor and writing support, as well as funding, must be disclosed in final publication

# Moving forward...

Need continued discussion with editors and publishers to reach consensus on:

- Consistent requirements for acceptable sponsored review types, format and level of support
- Format and detail of sponsor support disclosures
- Regulatory and legal thresholds that must be met for US companies

# Thank You

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# Next ISMPP U



**DATE: September 16<sup>th</sup>**

**TIME: 12 Noon EST**

**TOPIC: Watch your mailbox..to be announced soon!**

## Thank you for attending!

*We hope you enjoyed today's presentation. Please take a moment to offer your valuable feedback, as it will help us to develop future educational offerings.*

[http://www.surveymonkey.com/s.aspx?sm=2tp858nawbqAFVilw\\_2fL\\_2f0g\\_3d\\_3d](http://www.surveymonkey.com/s.aspx?sm=2tp858nawbqAFVilw_2fL_2f0g_3d_3d)