
Managing Speaker Program Compliance Benchmarking and Best Practices

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With You Today

Moderator

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PwC

Panelists

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Agenda

- 1. Enforcement Trends**
- 2. Managing Speaker Program Compliance – Live Polling**
- 3. Looking Ahead**
- 4. Q&A**

Enforcement

Overview of the Novartis Complaint

Novartis Complaint

- US DOJ filed a complaint alleging AKS and FCA violations
- Qui tam action brought on the government's behalf by Oswald Bilotta, a Novartis Sales Representative.
- Seeking treble damages alleging the conduct as willful
- Allegations at a operational level focused on:
 - ✓ Slides
 - ✓ Venue
 - ✓ Honoraria
 - ✓ Attendees
 - ✓ Meals
 - ✓ Discipline
 - ✓ ROI analysis

Specific Programmatic Allegations

- **Presentation:**
 - Failed to present the complete set of slides or all slides in the deck during speaker programs
- **Venue:**
 - Speaker programs occurred in venues that were not modest in nature and included high-end and lavish establishments
 - Locations that were not conducive for scientific presentations / discussions to be made (e.g. fishing trips in Florida and programs at Hooters).
- **Honoraria:**
 - Paying doctors for programs that did not occur;
 - High frequency of HCPs attending and/or presenting the same speaker program presentations.

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Specific Programmatic Allegations

- Attendees:
 - Speaker programs that had few attendees or no attendees
 - Inconsistent and incomplete attendee lists for speaker programs. Signatures on attendance sheet were completed consistently.
- Meals:
 - Meals limits could be avoided by attributing the amounts over the caps to what is termed as “Unmet Minimum”; which was the difference between the restaurant’s minimum spend for an event and the per person charge.

Specific Programmatic Allegations

- **Discipline:**
 - Lack of application of appropriate discipline / corrective action for speaker program infractions:
 - ✓ When abuse was reported, sanctions were categorized by the DOJ as merely a "slap on the wrist" (discipline letters, warnings, etc.)
 - ✓ Some violators were subsequently promoted
- **Return on Investment (ROI) Analysis:**
 - ROI analysis at the speaker level was conducted to identify opportunities to incentivize HCPs. Increased scrutiny by the government on ROI analysis at the HCP level.

Monitoring Program Considerations

Targeted Monitoring

- Increase monitoring focus on brands/products towards the end of their patent lifecycle due to potential increased risk to using programs for improper kick-back / promotion.
- Increase live monitoring to analyze slide deck completion

Speaker Selection

- Identify percentage of accepted speakers nominated by sales representatives as well as a comparison against high prescribers.

Performance Review Process

- Contact appropriate stakeholders to determine how speaker program metrics are used in evaluations.

Speaker Program Budgets

- Sale rep evaluations tied to the use of funds for programs meaning that they were expected to use their full allocated budget versus most effective and well attended programs. This leads to less effective and repeat programs.

Compliance Analytics Considerations

With the level of automation in the speaker program space, there are a number of analytics that can be leveraged to gauge compliance:

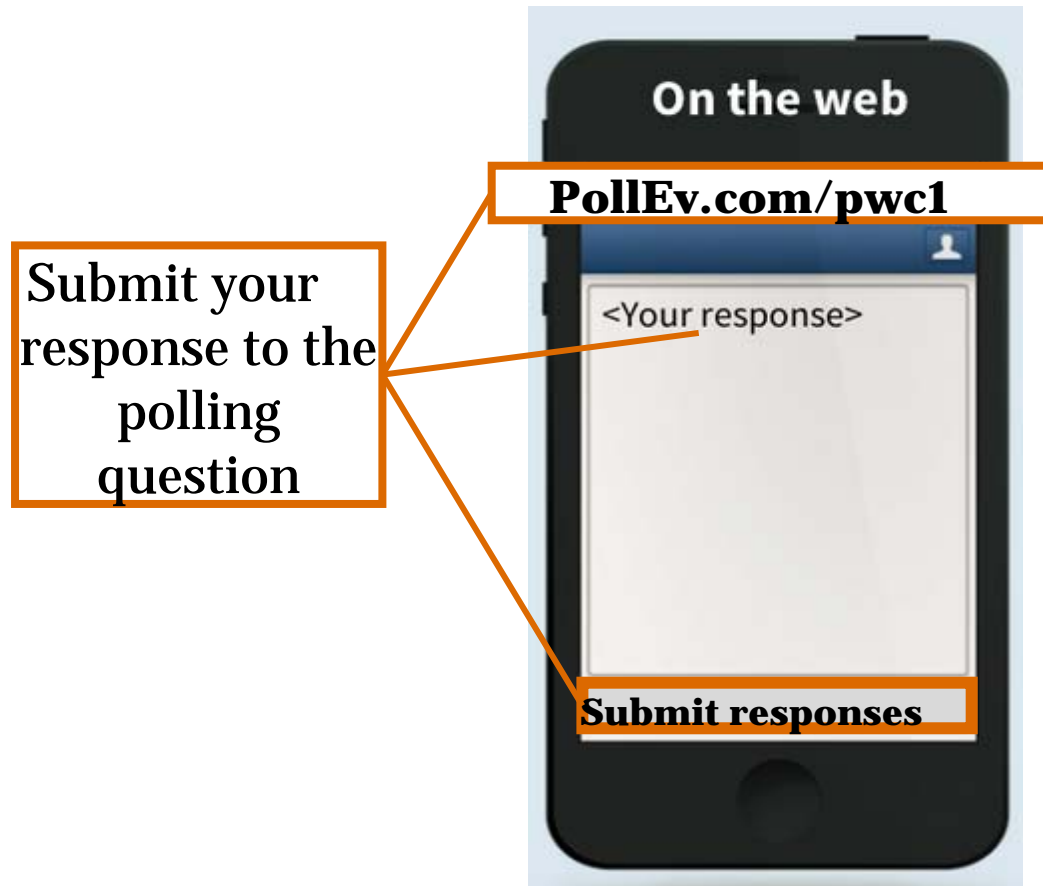


Managing Speaker Program Compliance

Live Polling

Option 1: How To Vote via PollEv.com/pwcl

You may respond at **PollEv.com/pwcl** once the presenter pushes the poll



Option 2: How To Vote via Texting

1. Text **pwcl** to **22333**
(one time only)



2. Text **YOUR ANSWER** to **22333**



TIPS
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1. Standard texting rates only (worst case US \$0.20)
2. We have no access to your phone number
3. Capitalization doesn't matter, but spaces and spelling do

Looking Ahead

Future Challenges

Future Challenges

Non-Traditional 'Speaker Programs'

The evolving commercial landscape has led companies to identify a need for various types of non-traditional 'speaker program-like' events:

- 'Medical' or 'educational' training programs that may be Therapeutic Area- or Disease State-focused (as opposed to product-focused)
- Customer programs for patient education
- Payer programs for HCP and non-HCP payors

New Challenges - Examples

- Defining and approving the business need for new event types
- Determining appropriate audience members for non-HCP participants (i.e. cannot rely on HCP specialty alignment with product) and FMV
- Deciding which internal participants are appropriate (i.e. commercial vs. medical/ clinical)

Q&A

Questions?