

Enforcement and Compliance in Current Times

MAPS Compliance Focus Area Working Group



>> NOW SPEAKING: **Jenny McVey, PhD**

Compliance Risk Management, Novo Nordisk

Introductions



Emily Hodge

Presenter

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Partner, Government
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Heather Golding

Presenter

Sobi, Inc.

Vice Present, Legal and
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Ed Chekan, MD

Medical Affairs Consultant



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Housekeeping

Questions for Presenters:

Please submit questions throughout the presentation using the Q&A button in your control panel.

Evaluations:

The control panel includes a webinar evaluation. Please complete that evaluation so that we can work to ensure the highest quality presentations.

On-demand Availability of Webinar:

This webinar, as with all previous ones, will be available on-demand next week in the Community Portal for MAPS members.



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Disclaimer

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

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Webinar Objectives

At the end of today's webinar, participants will have a better understanding of:

- **Enforcement trends** relating to speaker programs
- Key risks associated with the **shift from in-person to virtual activities** due to the pandemic
- Compliance **considerations** for conducting promotional and educational activities virtually

Enforcement Trends: Speaker Programs

Key Speaker: Emily Hodge

Enforcement Trends: Speaker Programs

Government scrutiny of speaker programs continues



Specific areas of focus from recent settlements include:

- Selection of speakers (e.g., top prescribers)
- Fees paid to speakers
- Free, expensive dinners and entertainment
- Sham speaker programs
- Improper promotional activity



Enforcement Trends: Speaker Programs

Big Pharma company entered a \$591.4 million settlement with DOJ in July 2020:

- **Kickbacks provided:** speaker fees, meals, alcohol, and entertainment
- **Inappropriate venues:** high-end restaurants, questionable educational value
- **Repeat HCP Attendees and Speakers:** same HCPs attending multiple programs, switching role of speaker and attendee
- **ROI analytics performed**

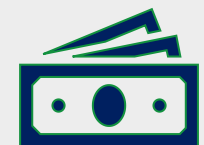
Compliance program was inadequate to prevent this conduct



Enforcement Trends: Speaker Programs

The Big Pharma company entered into a CIA as part of the settlement with the following stringent terms:

- **No more restaurants** and no alcohol served
- Live programs **limited to 18 months** after receiving FDA approval
- Sales reps may **not recommend HCPs** to serve as speakers
- For virtual- speakers and attendees **cannot be in the same location**
- **\$100,000 cap on total payments** to all speakers per product/indication
- **\$10,000 cap on total payments to each speaker** for programs per product/indication



Polling Question 1

Has your company made any revisions to its policies and practices based on this settlement?



1. Yes
2. No
3. We are still considering whether to make changes

Enforcement Trends: Speaker Programs – Other Recent Cases

Mid-Sized Med Device Company

Oct 2020: Settled for \$18 mil; CIA

- Significant fees paid
- Lavish trips, sporting events, dinners, and golf outings
- Analyzed the ROI
- Ignored warnings from former CCO

Mid-Sized Pharma Company

Oct 2020: Settled for \$8.3 bil

- Induced HCPs to prescribe its opioid drugs via kickbacks
- Commercial personnel selected speakers
- Speakers included questionable HCPs

Big Pharma Company

Jan 2020: Settled for \$54 mil

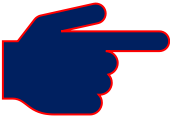
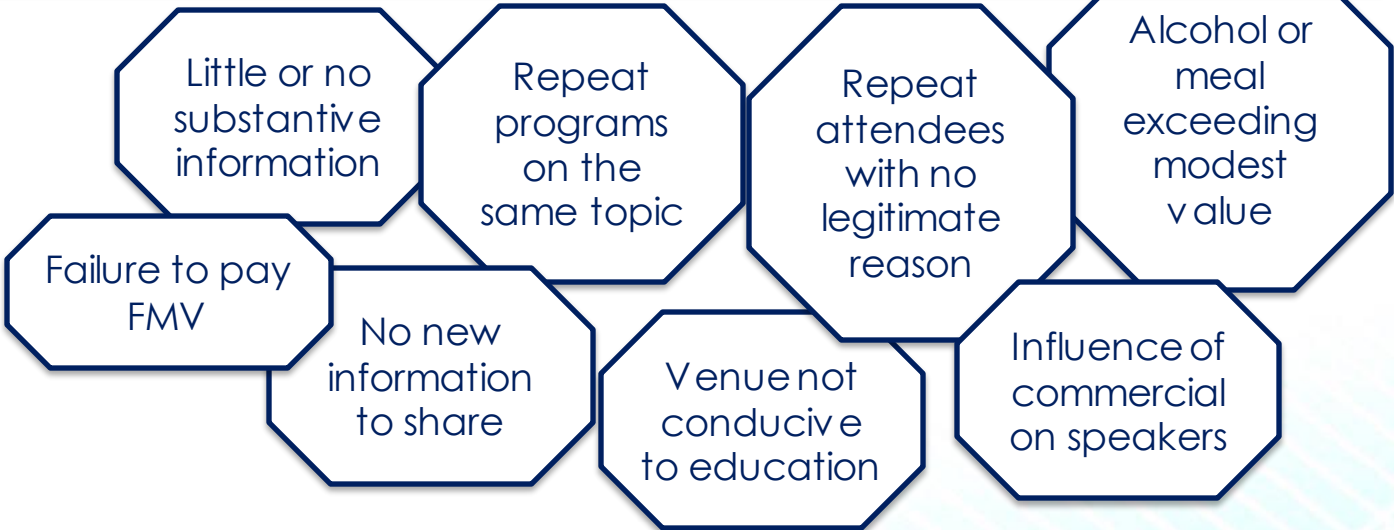
- HCPs hired to conduct “sham” speaker programs
- Speaker programs were conducted repeatedly with the same attendees

November 2020 OIG Special Fraud Alert



‘Significant concerns’ regarding paid speaker programs and **‘skeptical about the educational value’**

‘Suspect characteristics’



Companies should **‘assess the need for in-person programs [...] and consider alternative less-risky means for conveying information to HCPs’**

Virtual Activities and Compliance Considerations in the COVID Environment

Key Speakers:

Emily Hodge, Heather Golding, Ed Chekan

Polling Question 2



Many companies have shifted to conducting promotional and educational opportunities virtually as opposed to in person as a result of the pandemic – Which of the below best describes the current practices at your company?

Promotional and educational activities are:

1. Exclusively virtual
2. Partly in-person and partly virtual
3. Exclusively in person

Virtual Activities in the COVID Environment

II. DETECTING, DETERRING, AND PUNISHING WRONGDOING

In addition to ensuring that the justice system can continue functioning during the current national crisis, it is essential that the Department of Justice remain vigilant in detecting, investigating, and prosecuting wrongdoing related to the crisis. In particular, there have been reports of individuals and businesses selling fake cures for COVID-19 online and engaging in other forms of fraud, reports of phishing emails from entities posing as the World Health Organization or the Centers for Disease Control and Prevention, and reports of malware being inserted onto mobile apps designed to track the spread of the virus. The pandemic is dangerous enough without wrongdoers seeking to profit from public panic and this sort of conduct cannot be tolerated. Every U.S. Attorney's Office is thus hereby directed to prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic.

*Office of the Attorney General, March 16, 2020 Memorandum for All United States Attorneys,
Covid-19 - Department of Justice Priorities*

Virtual Activities in the COVID Environment

The landscape has changed:

- Shift to **virtual** promotional and educational activities
- **No “Coronavirus defense”** – continued need for compliance of codes of conduct and government regulations
- Government agencies have made it clear that **they will scrutinize misconduct**
- **Increase in whistleblower suits** likely given increased layoffs and furloughs

Compliance Considerations

Shift to conducting activities virtually raises unique compliance challenges:



- Difficulty monitoring
- Existing **contracts with HCPs should be examined** and may require revisions (including to compensation)



- **Challenges documenting and tracking** food and beverage consumption



- Medical Affairs and Commercial participation in virtual congresses
- **Communications** with Patient Advocacy Organizations

Virtual Activities in the COVID Environment

When conducting promotional and educational activities consider:

- Continue to follow processes designed to ensure that programs **comply with relevant regulations and guidance**
- **Re-assess** changes to practices over time
- Stay as close to **existing policies and practices** as possible to reduce risk

The transition back to in-person activities should be done in a way that minimizes health and safety risks associated with COVID-19

Safety Considerations: The Lab

Facility Safety Considerations:

- PPE pack
 - Hand sanitizer, PPE, garments, etc.
 - Handbook - Document of safety expectations for participation in lab, signed by each participant
 - Note pad, pens, etc. Notes scanned and emailed to participant, discard pens/paper
- Boundary Markings: floor taped with traffic patterns, standing areas, etc.
- Group size management: small numbers as per local health department guidelines
- Overnight/in-between sterilization of lab space

Personal Safety Considerations:

- App development
- All participants and faculty
- Download app onto phone.
- App acts as a COVID Screener
- Temperature checks & results recording
- Symptom Tracker – day of, 5 days later, 14 days later

Minimizes health and safety risks associated with COVID-19

Polling Question 3



In your opinion, should companies provide meals to attendees at virtual speaker programs?

- 1. Yes**
- 2. No**
- 3. It should be determined case by case**

Compliance Considerations

More important than ever to conduct monitoring – virtual environment may make it more difficult to do so



Track and document deviations from policies and **tailor deviations** to meet the current circumstances

Review systems used for virtual activities and ensure that **guidelines are implemented**



Review and **update monitoring plans** to account for the shift from live to **virtual activities**



Remind employees about the **importance of careful communications**

Key Takeaways

Government's scrutiny of the industry continues



- Speaker programs continue to be a focus in enforcement actions

COVID-19 is changing the way life sciences companies conduct business



- Government scrutiny of COVID-19-related activity is likely
- **Shift to virtual activities** may require additional safeguards and monitoring
- Activities should **continue** to be conducted in compliance with existing policies and government regulations/guidance
- **Deviations** from existing policies should be documented and tailored to the circumstances

Thank you!
Questions?