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How Corporate And Sales Messaging Affects Public Perceptions Of A Company's Culture

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Today's Road Map:

- **The problem**
- **The challenges**
- **The best practices**
- **Risks still remain, however**



A World Of Change In Business Practices From 1999 To Present

- **Today drug and device companies function very differently**
- **Introduction of AdvaMed Codes of Conduct.**
- **Anti-kickback rules and safe harbors.**
- **Companies introducing tight controls on marketing and sales.**
- **Separation of on-label and off label uses.**



**The reality remains, however:
sales and marketing are an essential component
to every pharma and device company.**



And with that, the argument will be made:

Companies put profits over safety.

Companies put profits over people.

And so the hazards remain

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This Insys Rap Video May Be the Worst Thing to Come out of the Opioid Crisis

Two Insys Therapeutics salesmen created a distasteful rap video to promote sales of Subsys, the drug company's opioid product.

Rectangular Snip

By **Tim Hayes**, Contributing Editor

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Last week, we covered the [conviction of the executives](#) linked to bribing doctors to prescribe highly addictive painkillers. Thanks to a recent *Boston Globe* [article](#), we get to see some of the marketing material behind the product, and it's frightening. Two [Insys Therapeutics](#) salesmen created a music video to push sales of Subsys, the company's powerful fentanyl spray. Likely to the musical pair's dismay the video was played not once but twice for the jury while deliberating the case. "The rap video just makes me sick to my stomach," said one member of the jury.



ENLARGE

Insys jurors horrified at use of rap video to push sales

By MARIA CRAMER — BOSTON GLOBE and JONATHAN SALTZMAN — BOSTON GLOBE
/ MAY 7, 2019






Best Practices for Mitigating Corporate Risk

Keren Tenenbaum

Vice President & Assistant General Counsel,
Head of Legal, Salix and Bausch Health





Best Practices for Internal Communications and Messaging

- **Keep company's values in mind**
- **Assume every internal communication will be made public**
- **Avoid writing on sensitive topics**
- **Avoid writing on legal topics**
- **Discard drafts IF there is no legal hold**
- **If you choose to write, do so carefully**
- **Clarify mistakes or documents that could be misconstrued**
- **When in doubt, contact in house counsel**



Two General Categories of “Bad” Messaging

“Wrong Thinking” documents

- Documents containing statements which are inconsistent with the company’s values, sense of corporate responsibility, or otherwise violate legal or regulatory obligations AND say exactly what the writer meant to say
- Example: Place profits over safety, when marketing and commercial interests, not scientific or safety considerations, drive the clinical trial process, off label promotion, discuss kickbacks, quid pro quo, bribery, price fixing


“Wrong Expression” documents

- Documents containing statements which could be interpreted as inconsistent with the company’s values, sense of corporate responsibility, or otherwise violate legal or regulatory obligations AND do not at all say what the writer meant to say
- While the thinking and intent of the writer may not be wrong, the method of expression or lack of context could lend itself to inaccurate interpretation



Best Practices – Training

- Colleagues should be encouraged to communicate because communication is the key to influencing others and creating powerful teams, relationships and joint forces to achieve successful outcomes.
- Colleagues need to be mindful about communications, especially in writing, as they reflect analysis, motives and decision-making
- Training should address:
 - How to “Write Right” and how to avoid creating “wrong expression” documents
 - How to close loop on bad communications



Best Practices for External Communications and Messaging

- Balance the benefits of marketing strategies with their risks
- Promotional Review Committee should have colleagues with appropriate expertise that are sensitive to reputational risks
- Clear guidance to the field on how to use promotional materials is critical
- How the intended audience interpret the messaging in promotional materials is as important as the intended message
- Addressing Execution risk is as important
- Branding of company values – externally and internally
- Proactive reputational risk management



Some Risk Areas to Consider

- **Sales representative/HCP interactions**
- **Promotional materials**
- **Product sampling**
- **Healthcare professional financial relationships**
- **Pricing**
- **Data generation**
- **Appropriate interactions between commercial and medical affairs**



"Well, sure, it LOOKS like a straightforward plea to buy our product...but for safety we better run it by the legal department."



Best Practices for Mitigating Corporate Risk

Jodie Floyd
Assistant General Counsel
Eli Lilly and Company





Importance of a Culture of Compliance

- **Becomes the lens through which decisions are made and actions are taken**
- **Internal Code of Conduct establishes expectations**
- **Tone must be set from the top down**
- **Training is critical to educate across organization**
- **Expectations must be reinforced**
- **Mechanisms for reporting concerns**
- **Monitoring is essential for continuous improvement**



Policies and Procedures – Clear Expectations

- **Code of Conduct** establishes framework
- **Policies** address topical areas
 - e.g., “Ethical Interactions: Communicating Honestly”
- **Procedures** provide more clarity around specific topics – examples:
 - Key Content for Medical Devices
 - Meetings with HCPs to Promote or to Educate
 - Using Electronic Resources (e.g., text messaging limited to logistical information or pre-approved public-facing messages)



Training

- Code of Conduct – annual/bi-annual computer-based training (CBT)
 - Videos from senior management
 - Vignettes depicting real-life dilemmas
 - Customized to functional areas
- Individual Learning Plans based on roles – e.g., procedures on creating promotional content
- Include in training expectation to *speak up* regarding compliance



Training on Good Documentation Practices

- Think *before* creating documents
- Be professional
- Understand the limitations of your communication
- Assume unintended audiences
- Avoid absolutes
- Ensure your document is accurate
- Assume all documents are attributable to the Company



Reporting of Compliance Concerns

- Provide multiple options for reporting concerns
 - Hotline (internal for employees; external for customers)
 - Supervisor or management
 - Internal Legal function
- Emphasize “no retaliation” policy
- Visible reinforcement of expectation to report concerns
 - “Speak Up” posters
 - Reminders on internal business TV monitors



Monitoring

- Ethics and Compliance monitoring of activities
 - Sales ride-along
 - Advisory Boards
- Report findings of monitoring activities to business
- Corrective actions, if necessary
 - Remedial action plans with implementation schedule
 - e.g., Training/re-training
 - e.g., Revisions to policies/procedures
- Investigate reported compliance concerns and take action if warranted.



Litigation roads often intersect with sales rep: what to remember

Matthew D. Keenan
Partner, Shook, Hardy & Bacon





Trained Sales Representative



Sales Representative Making Calls



Risks Remain: With Every Drug Or Device, There Are Four Sure Things:

- 1. Sooner or later, there will be a claim of personal injury.**
- 2. Litigation pathways will eventually lead to marketing, and then sales documents and witnesses.**
- 3. The individual sale representatives who called on key doctors will be on the short list.**
- 4. Call notes with the hospital, nurses, physicians will be scrutinized. And marketing materials.**



**The Foremost Plaintiff's Journal
Trial Magazine Targets The Sales
Reps**

BY JERVIN A. BROWNE

Switch Sales Rep Testimony ADVANCE

To Your

Whether they are promoting a product to a physician or testifying in a tort case, sales representatives are the face of pharmaceutical and medical device manufacturers. Here's how to use their inside knowledge and training as a powerful deposition tool to gain helpful trial testimony.



Trial Magazine

“The testimony of pharmaceutical and medical device sales representatives can support your trial strategy in many different ways in a product liability case. The key is turning the sales rep’s unique knowledge and commitment to patient safety in your client’s favor.”



Trial Magazine

“It is important to have the defendant’s entire universe of training and marketing materials ... you should obtain sales and commission records to thwart feigned memory loss or claims that the product was of minimal focus ...



Other Challenges With Sales Reps:

Consider relying on the testimony and text messages of a 31 year old, burdened with student debt, looking to make his bonus, while also building relationships with prescribers and implanters, and hoping to transition to a new employer.



Best Practices

- **National sales meetings: substance over fun**
- **Reward teams, not individuals**
- **Sales contests**
- **Bonus include conduct consistent with Code of Conduct**
- **If you are a device company, incorporate conduct codes if present in OR.**
- **Incorporate rewards with employee retention**
- **Avoid pejorative terminology: e.g. ‘converting’ doctors, KOL**
- **Separation agreements require witness cooperation should it be necessary.**

7/13/2019

Schwab Scraps Hawaii Trip for Firm's Top Employees - WSJ

THE WALL STREET JOURNAL.

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<https://www.wsj.com/articles/schwab-scraps-hawaii-trip-for-firms-top-workers-11562975809>

MARKETS

Schwab Scraps Hawaii Trip for Firm's Top Employees

Discount brokerage cites 'reputational risks' associated with award programs



Rather than take members of its Chairman's Club to Hawaii next spring, Charles Schwab will pay \$5,000 after taxes and give them a paid week off. PHOTO: CHRISTOPHER DILTS/BLOOMBERG NEWS

By Anne Tergesen and Jason Zweig

July 12, 2019 7:56 pm ET

Charles Schwab Corp. is scaling back a sales-incentive program designed to reward its top employees with all-expenses-paid trips.

In an email to its staff Friday, the discount brokerage and investment firm said that rather than take members of its Chairman's Club to Hawaii next spring, Schwab will pay \$5,000 after taxes and give them a paid week off.

The program has been running for over 30 years, and the change will save money, according to the email. A Schwab spokesman declined to elaborate on how much.

Under the Chairman's Club, Schwab has each year flown its top 200 or so employees in areas including its call and service centers, branches and operational support departments from around the country to destinations including Hawaii and Florida.

<https://www.wsj.com/articles/schwab-scraps-hawaii-trip-for-firms-top-workers-11562975809>

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Schwab's Reasoning

- **“In the email to employees, the firm said the Chairman’s Club was created in “a different era” and that there are “significant reputational risks” associated with award programs.**
- **“At the same time, our regulators are more closely examining how award programs might skew client service or outcomes,” the firm said in an interview with The Wall Street Journal in 2018 that some sales contests are inappropriate.**



Digital evidence preservation

- **The smart phone**
- **Informal nature of messaging**
- **Most popular form of communicating now, especially with millennials.**
- **Consider recent examples in the news**



Text messaging: plan ahead

-- “In addition to asking for e-mail and cell phone records, you should request inspections of electronic devices.” Trial Magazine.

-- Ameritox, Ltd. v. Millennium Laboratories 2014 WL 12623022 U.S. D.C. M.D. Florida (February 26, 2014). Ameritox sought an order sanctioning Millennium for allegedly destroying emails and text messages related to contacts between its sales representatives and physician clients.

-- another case: “The litigation hold and the requirement to produce relevant text messages, without question, apply to that space on employees cell phones dedicated to the business which is relevant to this litigation.”



Questions, comments?