

Risk Management Tips

Seven Tips to Manage the Risks of Off-Label Promotion

1. **Compensate sales and marketing reps in ways that do not incentivize off-label promotion.**
2. **Regularly train sales reps in the perils of off-label promotion and how to avoid it – provide periodic training, *not* “one-off” efforts. Train reps to spot off-label use and to escalate its reporting inside the company. Document your training efforts.**
3. **“Script” sales rep’s answers to physician questions about off-label use.**
4. **Have sales reps defer and refer questions about off-label use to the Medical Affairs Department.**
5. **Establish Medical Affairs as an independent and scientifically objective department, not reporting or subordinate to Sales and Marketing.**
6. **Check sudden sales spikes to ensure these are not due to off-label promotion.**
7. **Have sales reps document each visit to doctors to build a record of on-label promotion only and in sufficient detail to rebut any allegation of off-label promotion.**



While doctors can prescribe drugs and devices for “off-label” purposes, life science companies cannot legally promote these products for such uses. The zeal to drive sales and capture market share, however, has tempted some companies to engage in off-label promotion. Pushing this envelope can have financially devastating results due to government crackdown or product liability lawsuits. Here are seven risk management tips for avoiding the perils of off-label promotion.

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