



# TOP-TEN COMPLIANCE TIPS FOR HEALTHCARE PRODUCT COMMUNICATIONS COMPANIES

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# Top Ten Compliance Tips for Healthcare Product Communications

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**10. You're not selling widgets – act like it.**

# Top Ten Compliance Tips for Healthcare Product Communications

## 10. You're not selling widgets – act like it.

- Drugs and devices have tremendous power to heal, cure, and harm – tactics and strategies to make sales for the sake of sales should never be seen as appropriate.
- The legal/regulatory/policy elements of our healthcare system are premised on science, rational medical decision-making, and economics – healthcare product communications should serve as a trusted source of reliable information and advice on all these fronts.
- Data – and the *fair* representation of *all* the data – is the order of the day.

# Top Ten Compliance Tips for Healthcare Product Communications

**9. Don't throw your clients under the bus!**

10. You're not selling widgets – act like it.

# Top Ten Compliance Tips for Healthcare Product Communications

## 9. Don't throw your clients under the bus!

- Your industry, and your clients' industry, are highly competitive, and your clients demand a lot – extreme creativity, aggressiveness, and results – but don't push your clients past the leading edge to the “bleeding edge!”
- Be conscious of the varying degrees of legal sophistication and internal controls among various clients
  - don't assume a client will push back on an overly-aggressive initial approach, even if you think it makes you look good in their eyes.
  - In other words, where a client doesn't seem to fully “get it” from a compliance/risk perspective, you do them no favor by “hitting the gas.”

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# Top Ten Compliance Tips for Healthcare Product Communications

## 8. Don't let your clients throw themselves (and you) under the bus.

- Be conscious of the varying degrees of risk-tolerance and financial motivations among various clients.
  - Resist the pressure to be an enabler of wilful non-compliance or foolish risk-taking.
  - While clients are generally responsible for the legal consequences of their ads, your reputation is on the line, and you could find yourself in legal jeopardy to boot.
    - Under FTC policy and enforcement cases, “an advertising agency may be liable for a deceptive advertisement if the agency was an active participant in the preparation of the advertisement and if it knew or should have known that the advertisement was deceptive....An ad agency does not have to substantiate independently the claims or scientifically reexamine the advertiser’s substantiation. However, it cannot ignore obvious shortcomings or facial flaws in an advertiser’s substantiation.”



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## **7. Don't plant any documentary land mines!**

8. Don't let your clients throw themselves (and you) under the bus.
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## 7. Don't plant any documentary land mines!

- E-mails and other internal communications have a nasty habit of showing up in court and in the press – get a company-wide grip on this ASAP!
  - In an Anti-kickback prosecution, emails showed that
    - “the company hired a dental hygienist as a sales representative to allegedly, ‘have sexual relations with doctors in exchange for...prescriptions.’ A manager...said the former dental hygienist was, ‘dumb as rocks, but that she was sleeping with another doctor and getting a lot of prescriptions out of him.’”
  - A sales training manual featured in a personal injury lawsuit stated:
    - “[Injury] is an obstacle to sales”
    - “Only use the verbatim if a physician asks about [injury] and if not, Sell, Sell, Sell!”
    - “[Company] has struggled with [injury] safety issues” and the medication was “misperceived to be the least safe” of its class

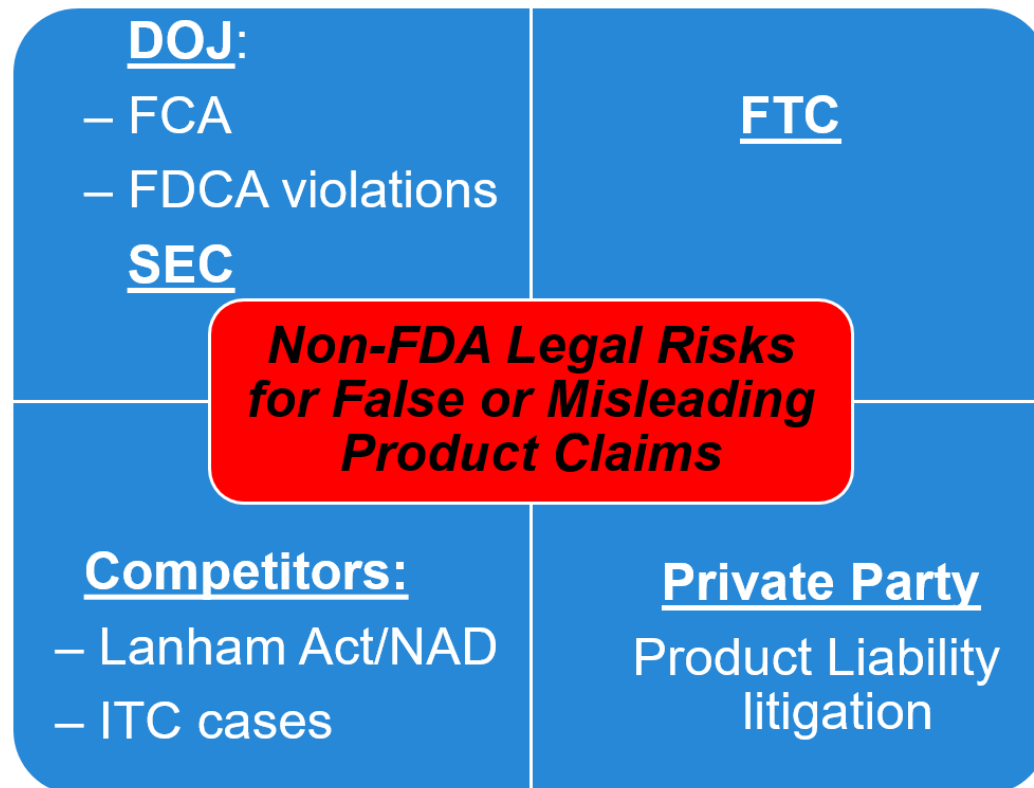
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## **6. Remember that FDA is not the only Sherriff in town**

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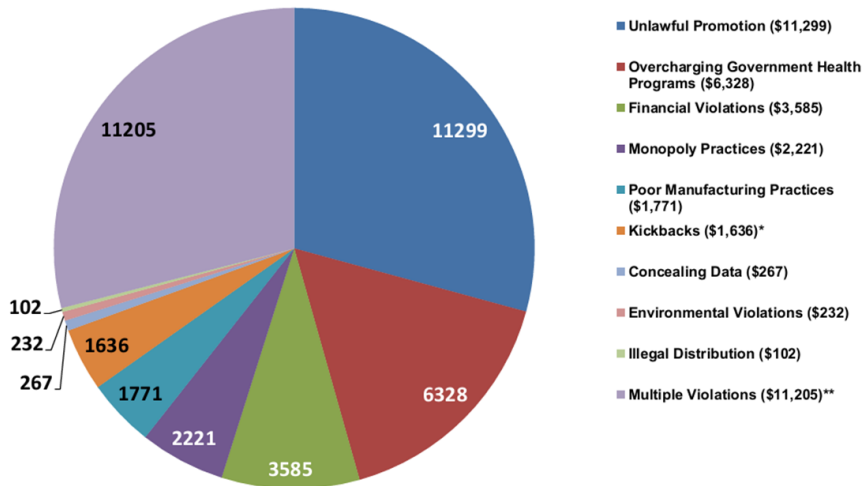
## 6. Remember that FDA is not the only Sheriff in town



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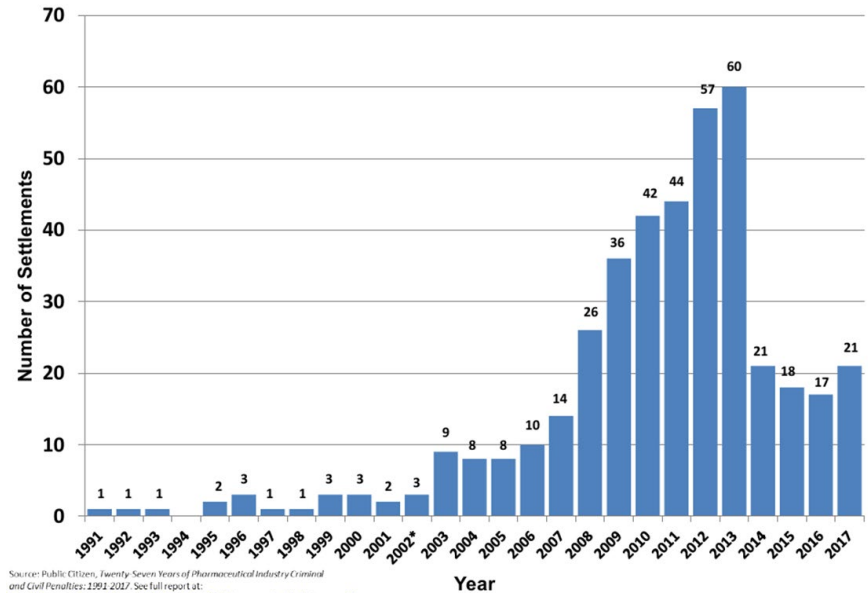
## 6. Remember that FDA is not the only Sherriff in town

Figure 16. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991 –2017



Source: Public Citizen, *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991-2017*. See full report at: <https://www.citizen.org/our-work/health-and-safety/pharmaceutical-industry-penalties>

Figure 1. Number of Pharmaceutical Industry Settlements, 1991 – 2017



Source: Public Citizen, *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991-2017*. See full report at: <https://www.citizen.org/our-work/health-and-safety/pharmaceutical-industry-penalties>

# Top Ten Compliance Tips for Healthcare Product Communications

## **5. Stay close to the approved-use lane**

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## 5. Stay close to the approved-use lane

- FDA's "**Consistent With Labeling Guidance**" offers flexibility, within limits:
  - With respect to disseminated information not in the approved labeling but “that is determined [by FDA] to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use.”
  - But even if “consistent,” the information as presented may still be false or misleading and subject to enforcement.
    - No “different” indications, patient population, use instructions, dosing or route of administration
    - No increased risk
    - Labeling must still be adequate for the usage suggested

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## 5. Stay close to the approved-use lane

- FDA's "**Communications With Payors Guidance**" addresses HCEI to specific audiences, not traditional advertising and promotion
  - "HCEI is defined in section 502(a) as 'any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences...of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.'"



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## 5. Stay close to the approved-use lane

- FDA's "**Communications With Payors Guidance**" addresses HCEI to specific audiences, not traditional advertising and promotion
  - "HCEI can be provided to 'a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement.' This audience includes public and private sector payors, formulary committees...drug information centers, technology assessment committees, pharmacy benefit managers, third party administrators, and other multidisciplinary entities that, on behalf of health care organizations, review scientific and/or technology assessments to make drug or device selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis."

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## 5. Stay close to the approved-use lane

- FDA's "**Communications With Payors Guidance**" addresses HCEI to specific audiences, not traditional advertising and promotion
  - “This guidance **does not apply** to dissemination of HCEI to other audiences, such as health care providers who are making individual patient prescribing decisions or consumers (e.g., dissemination directed toward prescribers or consumers via a public website).”
  - “If a firm disseminates to an appropriate audience HCEI...that relates to an approved indication and is based on competent and reliable scientific evidence (CARSE), as each of these elements is described in this guidance), FDA does not intend to consider such *information false or misleading.*”

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## 5. Stay close to the approved-use lane

- FDA off-label enforcement is actually the least of your clients' off-label concerns
  - False Claims Act prosecutions involving off-label promotion have netted the government tens of Billions of dollars from industry.
  - Manufacturers typically must agree to a Corporate Integrity Agreement (CIA) which imposes significant internal operational and promotional strategy constraints for multiple years.
  - Product liability lawsuits often seek to attack perceived unapproved marketing.

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## **4. ISI is your friend – show it the love!**

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## 4. **ISI is your friend – show it the love!**

- The overwhelming majority of FDA enforcement letters for drug promotion involve inadequate risk disclosures.
- Failure to adequately disclose risk can implicate product liability legal risks.
- Sales and marketing teams often have an irrational fear of disclosing risk information, and may seek to slice, dice, and obfuscate in response to those fears.
- Don't be afraid to get into the weeds on the safety data and claims.

# Top Ten Compliance Tips for Healthcare Product Communications

## 4. **ISI is your friend – show it the love!**

- Ad Agency executives quoted in NYT (2017):
  - “It’s counterintuitive, but everything in our research suggests that hearing about the risks increases consumers’ belief in the advertising.”
  - “What is seemingly a negative to people who don’t have a condition or disease is a positive to people who suffer from it because they’re thinking, ‘Well, of course it has side effects. It’s fighting a really serious illness.’ They’ll say, ‘I’m in a life-or-death situation and I want a drug that’s really strong. I expect there to be risk to get the rewards.’ ”

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## 4. **ISI is your friend – show it the love!**

- But if your clients still fear disclosing risks, consider this perspective:
  - “At some point, the side effects become white noise....There’s a huge amount of information compressed into a 60-second commercial, more so than any other industry. You have the benefits of the drug, you have the specific patient population the drug is intended to treat. You have the dosing mechanism. Is it oral or is it an injection? Where is it administered? How frequently do you need to take it? And, of course, you have all the side effects. And we know that consumers are multitasking across multiple devices while they’re watching TV. So comprehending all that information is a tall order for consumers.”

# Top Ten Compliance Tips for Healthcare Product Communications

## **3. Focus on the Intended Audience.**

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# Top Ten Compliance Tips for Healthcare Product Communications

## 3. Focus on the Intended Audience

- FDA promotional policies reflect its widely differing views of different audiences, so there are different sets of rules for material presented to different audiences
  - Communications With Payors Guidance
  - Consistent With Labeling Guidance (general promotion)
  - DTC rules for efficacy claims and risk disclosure – potentially changing
  - Journal articles and CME events
  - Investor-facing communications
- **Don't fall into the trap of believing that a compliant communication to one audience is compliant if given to another audience!**

# Top Ten Compliance Tips for Healthcare Product Communications

## 3. Focus on the Intended Audience – Payors

- FDA promotional policies reflect its widely differing views of different audiences:
  - “Payors are a sophisticated audience with a range of expertise in multiple disciplines, as well as established procedures for carefully considering evidence about medical products. Generally, payors possess financial resources and motivation to closely scrutinize information about medical products as part of their decision-making process, including an evaluation of the limitations and reliability of that information. Payors seek a range of information on effectiveness, safety, and cost-effectiveness of approved/cleared medical products, including information from firms, to help support their product selection, formulary management, and/or coverage and reimbursement decisions on a population basis. Often, this information differs from – and can be provided in addition to – the information FDA reviews in making approval/clearance decisions.”

# Top Ten Compliance Tips for Healthcare Product Communications

## 3. Focus on the Intended Audience – Doctors

- FDA promotional policies reflect the Agency's widely differing views of different audiences:
  - OPDP studied “prescribers' critical appraisal knowledge and skills about understanding of statistical methods, biases in studies, and relevance and validity of evidence....Results indicated that physicians' extant knowledge and skills were in the low to middle of the possible score ranges...Critical appraisal knowledge and skills are limited among physicians.”
  - Another OPDP study concluded that: “Overall, physicians demonstrated low to moderate knowledge when probed on specific clinical trial terms found in prescription drug promotional materials, despite prior exposure to clinical trial data from promotional materials and other publications, medical training inclusive of various statistics courses, and a general reported comfort in interpreting and applying clinical trial data.”

# Top Ten Compliance Tips for Healthcare Product Communications

## 3. Focus on the Intended Audience – Patients

- FDA promotional policies reflect the Agency's widely differing views of different audiences:



# Top Ten Compliance Tips for Healthcare Product Communications

## **2. Show me the substantiation!**

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## 2. Show me the substantiation!

- Every claim on draft promotional materials should be thoroughly annotated and references provided for review.
- For information potentially covered by the CWL Guidance or the Payors Guidance, formal analysis of compliance is highly recommended
- Review committees should have:
  - multi-disciplinary membership with relevant expertise, and independence from marketing function, in order to fairly judge how the evidence fits the claims;
  - established SOPs to include: adequate timing for review; documentation of deliberations and changes; formal approval sign-off; appeal process for resolving impasses.

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