KING & SPALDING

Other Agencies and Considerations

October 11, 2022

INTRODUCTION TO ADVERTISING AND PROMOTION FOR MEDICAL PRODUCTS

Food and Drug Law Institute

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Agenda

Federal Trade Commission (FTC) Authority

National Advertising Division (NAD)

Lanham Act

State Actions and Consumer Class Actions

Interactions with SEC

False Claims Act, Qui tam Actions, and Anti-Kickback Statute

Industry Codes of Conduct

Sunshine Act

Privacy

FDLI
Food and Drug Law Institute

Federal Trade Commission (FTC)

FTC Jurisdiction

Food and Drug Administration

- Regulates **labeling**
  - All FDA-regulated products
- Regulates **advertising** of:
  - Prescription drugs
  - Restricted medical devices
  - Biologics
  - Vaccines
  - Tobacco

Federal Trade Commission

- Regulates **advertising** of:
  - OTC drugs
  - Unrestricted medical devices
  - Foods, including dietary supplements
  - Cosmetics
  - Tobacco
  - Consumer packaged goods

Federal Trade Commission

FTC Act

- §5: Prohibits unfair or deceptive acts or practices in or affecting commerce
- §12: Pertains to FDA regulated products and prohibits "*false advertising*" that is "*misleading in a material respect*"

Enforcement actions: administrative or federal

- Injunctive relief
- Equitable monetary relief
- Corrective advertising
- Compliance monitoring provisions

FTC Basic Principles

Enforcement Policy Statement on Deceptively Formatted Advertisements

- ✓ Advertising must be truthful and not misleading
- ✓ Representation or omission likely to mislead the consumer
- ✓ Acting reasonably under the circumstances
  - The reasonable consumer standard
- ✓ Misrepresentation must be material
  - Claims about health or safety are presumed material

https://www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf

Substantiation

FTC Policy Statement Regarding Advertising Substantiation

- Before disseminating an ad, advertiser must have a "*reasonable basis*" for all express and implied claims
- For health-related claims, a reasonable basis consists of "*competent and reliable scientific evidence*"

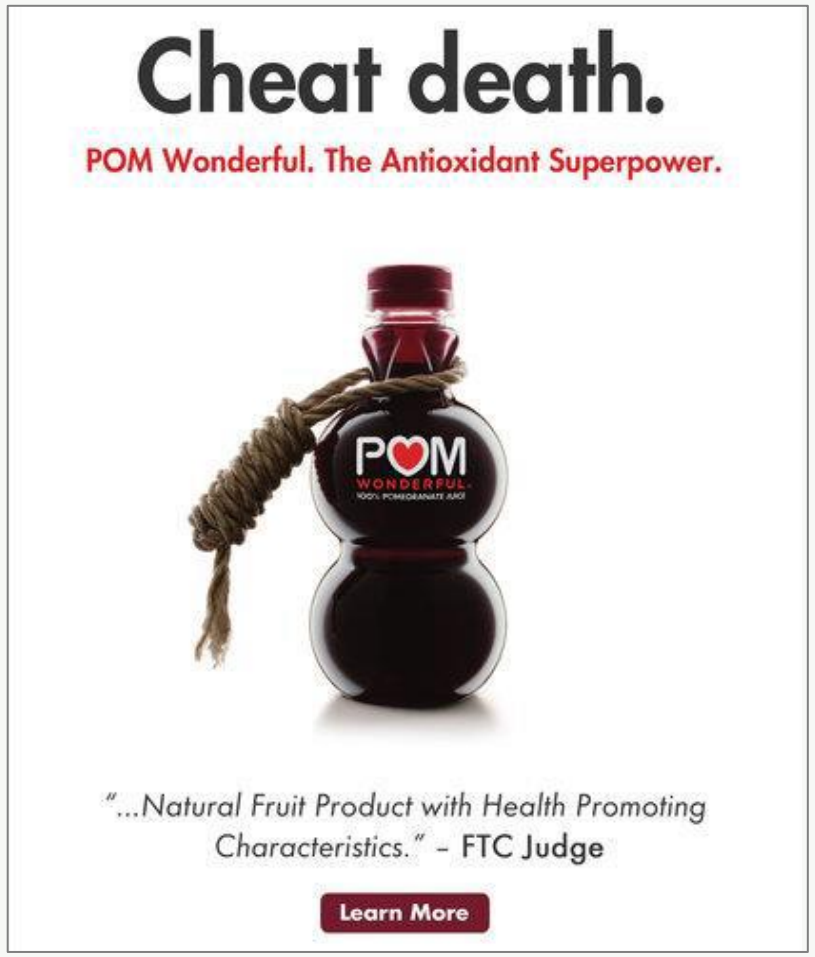
https://www.ftc.gov/legal-library/browse/ftc-policy-statement-regarding-advertising-substantiation

Substantiation

Competent and Reliable Scientific Evidence (CARSE)

- Required for Health & Safety Claims
  - "tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results"
- Sliding scale based on the nature of the claim and the type of data experts in a field would rely on to determine whether a claim is unfair and deceptive
- Different from other FDA substantiation standards
  - Substantial evidence
  - Valid scientific evidence
  - Scientifically appropriate and statistically sound (SASS)

POM Wonderful



- FTC brought case in 2010
- FDA Warning Letter
- Claims that POM treats heart disease, prostate cancer, ED
  - "Backed by $25 million in bullet-proof medical research"
- Court: POM's claims were not supported by CARSE
  - Criticized POM for advertising only positive aspects of studies, and ignoring/downplaying negative or contradictory results
  - POM was making "establishment claims" by invoking medical symbols, references to publications in medical journals
  - POM's future disease claims must be supported by at least one RCT and other health benefit claims by competent scientific evidence

FTC Guidance Updates: Influencer Marketing & Native Advertising

"FTC's Guides Concerning the Use of Endorsements and Testimonials in Advertising" (2009)

FTC "Dot Com Disclosures" Guidance (2013)

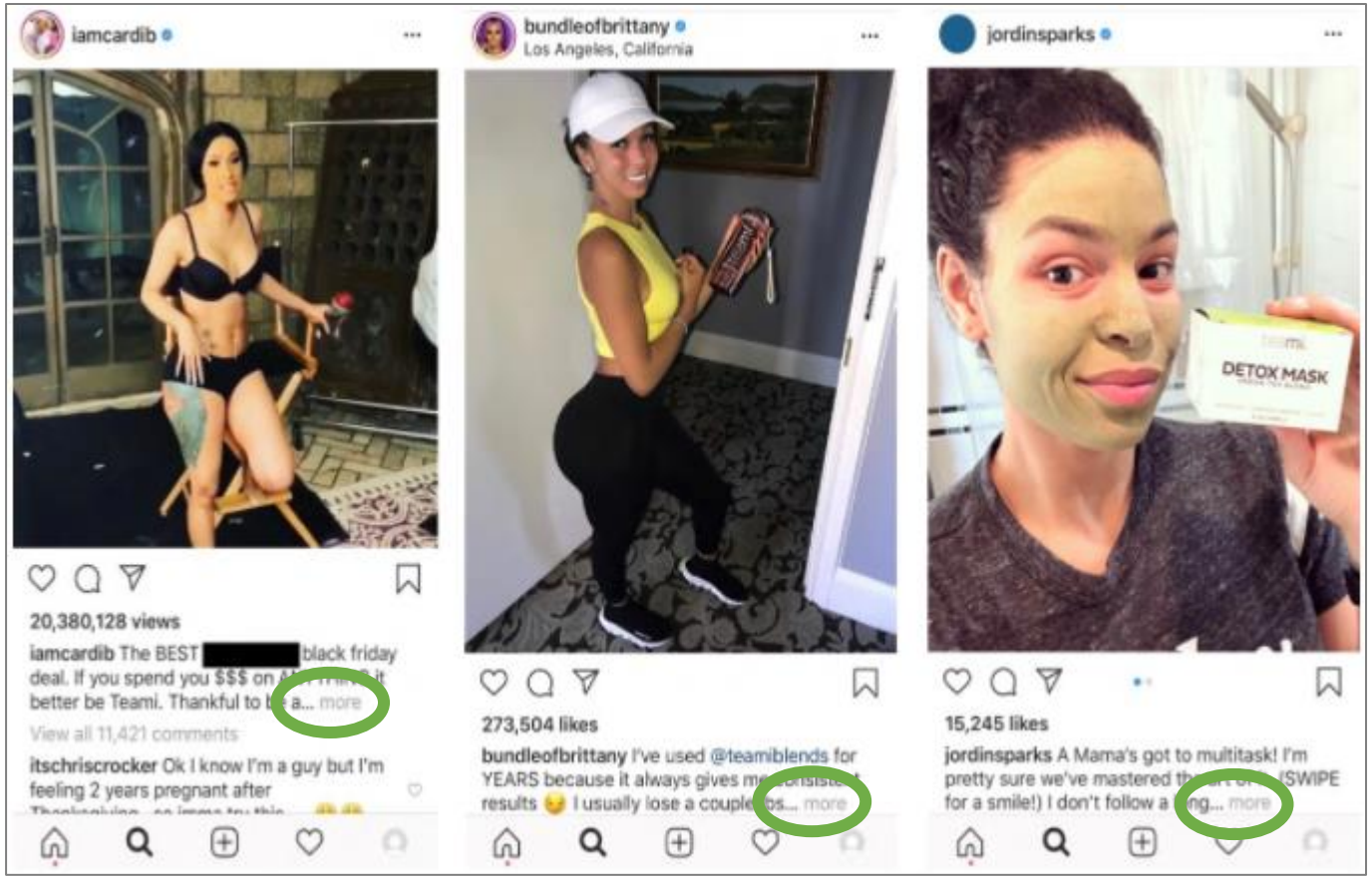
FAQs: "The FTC's Endorsement Guides What People Are Asking" (Updated 2017)

FTC Tweet Chat on Social Media Influencers (September 2017)

Disclosures 101 for Social Media Influencers (November 2019)

FTC Enforcement: Teami (March 2020)

teami



- Misleading weight loss claims for Teami's 30 Day Detox Pack through website and paid influencers' Instagram posts
- Disclosure that the endorsements were paid were not visible unless users clicked the "… more" option

FTC and FDA Coordination

- Complementary and consistent actions
- FTC defers to FDA on content, purity, safety determinations
- FTC relies on FDA's scientific expertise
- Joint Warning Letters

Joint Enforcement Examples

- COVID-19
- Biologics/Biosimilars
- Dietary Supplements
- Flavored e-liquid tobacco

National Advertising Division (NAD)

National Advertising Division

- Investigative self-regulatory body formed to:
  - Protect the integrity/credibility of advertising by ensuring that claims are truthful and accurate
  - Preserve “fair play” between competitors
  - Discourage unnecessary government involvement in advertising
- Quicker, cheaper, less formal than Lanham Act or FTC proceeding
- Oversees FDA-regulated products
- BBB National Advertising Review Council
  - Initiates own inquiries and judges competitive challenges
    - National Advertising Division (NAD)
    - Children’s Advertising Review Unit (CARU)
    - Electronic Retailing Self-Reg Program (ERSP)

BBB National Programs

https://bbbprograms.org/programs/all-programs

NAD Process

- NAD opens inquiry or competitor/consumer initiates challenge
  - Voluntary: challenged advertiser can decline to participate
- Challenged advertiser has burden of proving claims are substantiated
- Decisions published with detailed analysis and factual support
  - Claims are substantiated; or
  - Recommendation that claims be modified or discontinued
- May refer to FTC
- Right to appeal to National Advertising Review Board (NARB)

NAD and Medical Devices

NAD's Questions about Medical Devices:

1. Are you advertising?
2. Is your advertising limited to its FDA clearance and, if not, have you supported all express and implied messaged reasonably communicated?
3. Do you possess competent and reliable scientific evidence that fits your claim?

https://bbbprograms.org/media-center/blog-details/insights/2021/07/29/avoid-misleading-messages-when-advertising-medical-devices

NAD – Zantac 360 Claims

Johnson & Johnson Consumer, Inc., manufacturer of competing Pepcid products, challenged Sanofi claims for Zantac (same active ingredient, famotidine):

- Zantac 360 "contains the #1 doctor recommended medicine approved to both prevent and relieve heartburn."
- "With the #1 doctor recommended heartburn medicine."
- "#1 Doctor Recommended."

NAD recommended discontinuing claims

Sanofi plans to appeal

- Revised claims

NAD – SmileDirectClub

Procter & Gamble Company, maker of a variety of Crest Whitestrips products, challenged SDC claims:

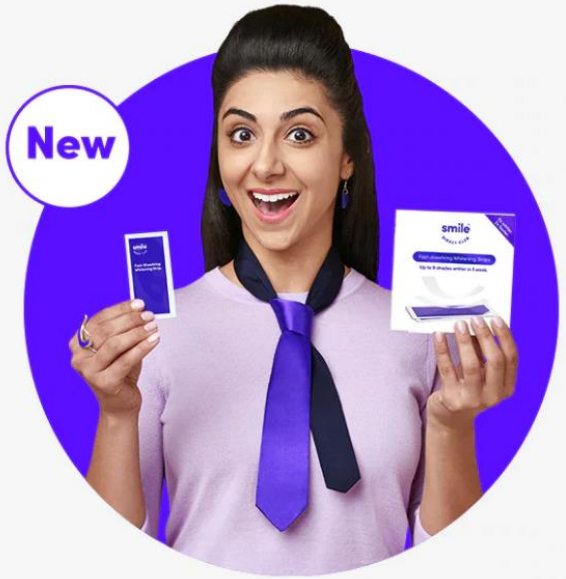
- Get teeth "2X whiter than Crest Classic White Whitestrips"
- Whiten teeth "2X faster than Crest Classic White Whitestrips"

NAD recommended discontinuing claims

- Revised claims after NAD decision

2X brighter, 2X faster.

Whiten your teeth in just 15–20 minutes once a day. That's 2x faster than the leading Whitestrips.[2] Plus the strips fully dissolve, leaving no mess.



Lanham Act

Lanham Act

Prohibits false or misleading representation in commercial advertising or promotion that "misrepresents the nature, characteristics, qualities, or geographic origin of. . . goods, services, or commercial activities" §43(a) (15 U.S.C. §1125(a))

- No cause of action to consumers, only to business competitors
- Interim injunctive relief available

Elements

✓ False or misleading statement in advertising about its own or another's products

✓ Statement deceives or has a tendency to deceive

✓ Deception was material (i.e., likely to influence the purchasing decision)

✓ Defendant caused its goods to enter interstate commerce

✓ Plaintiff was or is likely to be injured as a result

Lanham Act Example

POM challenged Minute Maid Pomegranate Blueberry Juice Blend, along with three other juice products in different suits.

Minute Maid labeled according to FDA regulations allowing for naming specific juices even if the juice is not predominant in the blend as a percentage of volume

Supreme Court held:

- FDCA does not preempt Lanham Act claims
- Although FDA regulations may permit a statement in labeling, it is not a ceiling to regulation of food & beverage labeling
- Caveat for drug labeling – the court distinguished FDA pre-approval of prescription drug labeling versus FDA's after-the-fact enforcement authority for food and beverage labeling

POM WONDERFUL®

v.

Coca-Cola®

POM Wonderful LLC v. Coca-Cola, 573 U.S. 102 (2014)

State Actions and Consumer Class Actions

State Actions and Consumer Class Actions

State Actions

- State laws analogous to federal AKS and FCA
- State agencies or prosecutors can bring actions

Private Actions

- Lanham Act
- Product liability
  - Based on failure to warn
  - FDA regulatory violations

Consumer Class Actions

- Consumer protection laws
- Unfair competition laws

Interactions with SEC

Securities Exchange Commission

- Publicly traded companies have an obligation to disclose material information to investors
- FDA typically does not scrutinize communications that are truly investor-focused (SEC filings, investor communications)
- In 2004, FDA/SEC cooperative procedure to permit FDA referral of potentially false and misleading statements regarding matters with FDA's jurisdiction to the SEC (e.g., progress of FDA's premarket review)
  - Procedure for FDA employees to refer suspected misstatements to SEC
  - Training of FDA and SEC staff
  - Sharing of non public records between agencies

"Accuracy of reporting in your dealing with the FDA is critical to getting investors the information they need. FDA dealings and approvals are the lifeblood of your business and so are important to investment decisions. . . . So much turns on those interactions and not being straight with investors will have significant consequences."

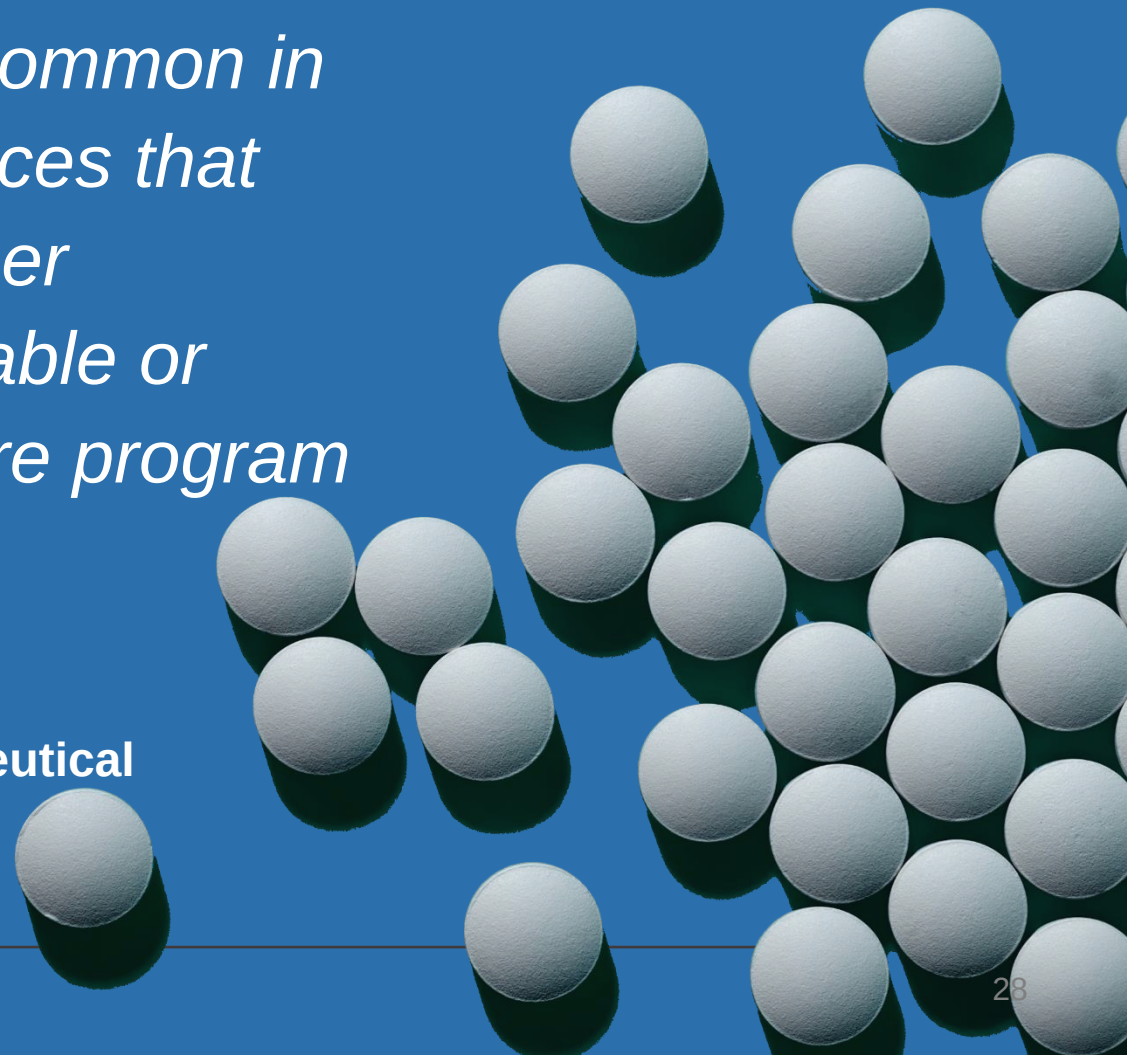
SEC Alleged Misrepresentations

False Claims Act, Qui tam Actions, and Anti-Kickback Statute

Healthcare is Different

“ [T]he anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.”

— HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (May 2003)



Federal Anti-Kickback Statute (AKS)

Basic Prohibition:

- Unlawful to knowingly and willfully (intent)
- pay (or offer) or accept
- remuneration (anything of value)
- to induce another to:
  - refer Medicare/Medicaid program patients or other federal health care program patients or business
  - purchase or order covered items or services
  - arrange for others to make such referrals/purchases/orders
  - recommend that others make such referrals/purchases/orders

HCPs, Hospitals, Pharmacies, PBMs, Patients, Other Referral Sources

Service fees, discounts, free product, meals, travel, gifts, etc.

Purchases, recommendation of products, referrals, etc.

Manufacturer, Distributor, DME provider/supplier, etc.

Federal Anti-Kickback Statute (AKS)

- ***42 U.S.C. § 1320a-7b(b)***
- Federal **criminal** statute
- All U.S. HCP interactions must comply with the AKS
- The AKS affects virtually every interaction with a U.S. healthcare professional, implicating all areas of the business
- Examples:
  - Free product, discounts, meals, grants, consultants, advisory board members, clinical investigators – any interaction in which an HCP receives remuneration, including consulting fees, a meal, a cup of coffee, or any other item of value, must be fashioned thoughtfully to comply with the AKS

One Purpose Test

- The AKS can be implicated if even “one purpose” of the payment/item of value was to encourage the use, purchase, etc. of covered drugs or devices

- Intent can be evidenced by emails, statements, tracking metrics like ROI analyses

Exceptions and Safe Harbors

- **5** exceptions and **28** regulatory safe harbors
- Failure to meet an exception/safe harbor does not mean that the arrangement per se violates the AKS
- Commonly used safe harbors
    - Discounts (rebates)
    - Personal Services
    - Group Purchasing Arrangements
    - Warranties

AKS Penalties

Criminal
10 years imprisonment, $100,000 fine per violation, and/or mandatory exclusion

Civil
$100,000 CMP per violation, up to treble damages, and/or permissive exclusion

Collateral
False Claims Act liability

Civil False Claims Act (FCA)

- 31 U.S.C. §§ 3729-3733
- Makes it illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent
  - Includes *qui tam* (whistleblower) provision
- Violations of AKS, as well as FDCA, might serve as basis for FCA claims
- A civil penalty of not more than $10,000 per claim [as adjusted]
  - *Plus, treble damages (*up to three times the federal health care programs' loss)
- There is also a criminal False Claims Act (18 U.S.C. § 287)

Vast majority of cases come from *qui tam* actions

FCA: Whistleblowers

- Over **90%** of healthcare fraud cases are started by a whistleblower
    - **85%** are current or former employees (40% are managers/executives)
- Whistleblower typically recovers **15-30%** of total recovery
- Examples:
    - Novartis sales representative: **$109,000,000**
    - GSK whistleblowers: **$300,000,000**
    - J&J whistleblowers: **$168,000,000**
- Complicity is not a bar to recovery
- A "race to the courthouse" ("*Scorpions in a bottle*")

State Laws Regulating HCP Interactions

In addition to federal laws, a number of individual states impose compliance requirements and regulate HCP interactions (*irrespective of whether or not product is reimbursed*)

- **Gift Bans**: Prohibit the provision of certain payments or transfers of value to HCPs, such as meals (e.g., VT)
- **Compliance Programs**: Impose compliance program requirements on manufacturers (e.g., CA, CT, NV)
- **Aggregate Spend**: Require tracking and reports on interactions with HCPs (e.g., MA)
- **Registration/Licensing**: Licensing/registration requirements (e.g., DC, NV, Chicago)

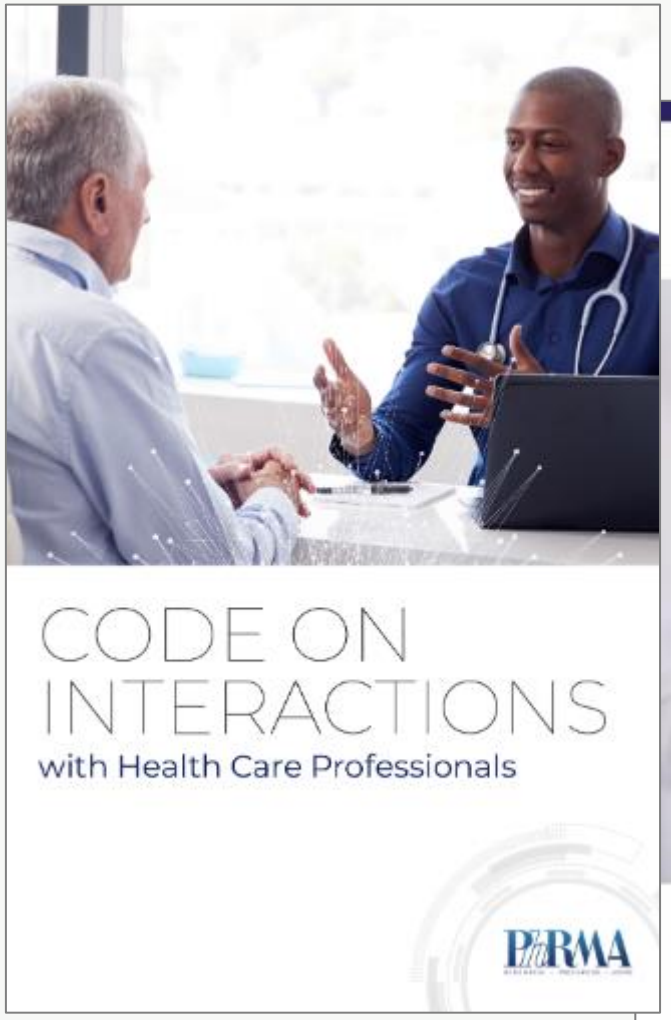
Industry Codes of Conduct

PhRMA
RESEARCH • PROGRESS • HOPE

AdvaMed
Advanced Medical Technology Association

Industry Codes of Conduct

- Sets forth guardrails for common interactions with HCPs
- Compliance is voluntary, except in a handful of states



Significance of Code Compliance

- Remuneration paid to customers that is not protected by an exception or safe harbor raises potential risks
- Codes provide guardrails for many activities that are not protected
- Enforcement authorities view the PhRMA Code as setting a baseline for ethical interactions with HCPs
- Code compliance can be evidence of proper intent
  - Conversely, non-compliance could be used as evidence of improper intent

Meals	Providing items of value	Prohibition on entertainment and recreation	Consulting and speaking arrangements	Conducting speaker programs	Supporting third party conferences and CME events

Sunshine Act

Physician Payments Sunshine Act

"Sunshine Act" enacted as part of Affordable Care Act of 2009

Intended to promote transparency related to financial relationships between drug/device manufacturers and physicians and teaching hospitals

Annual reporting

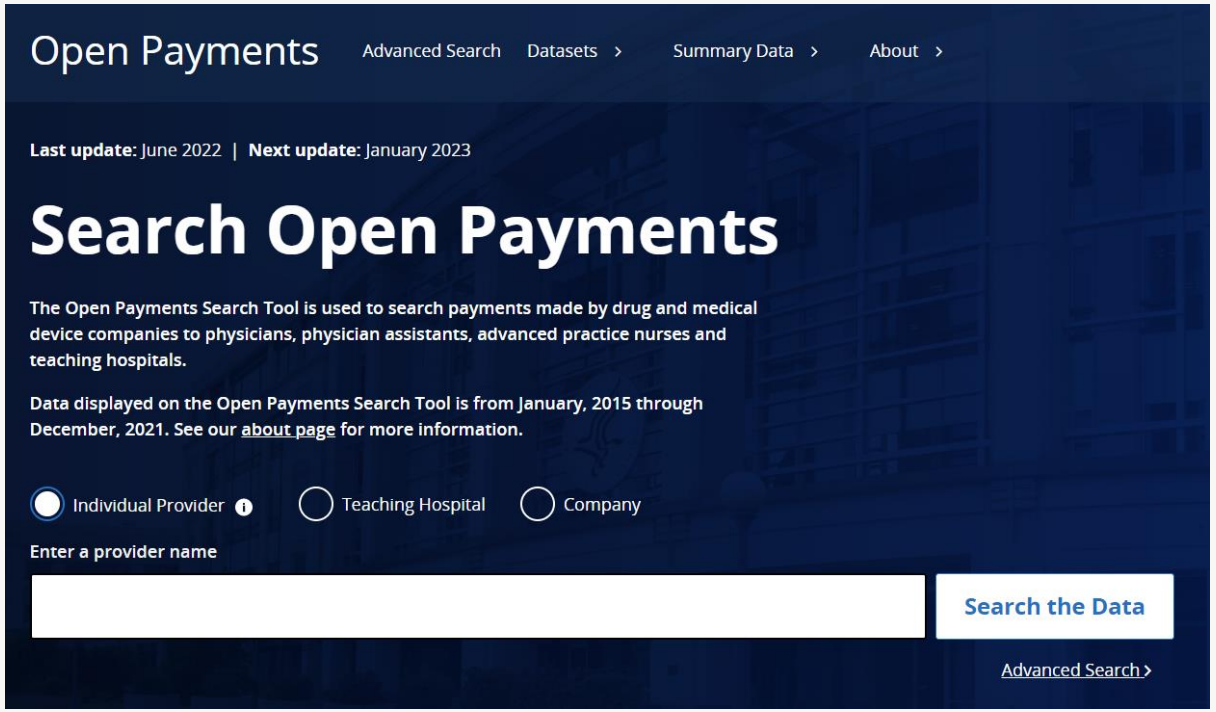
Who reports?	What's reported?	Nature of payments
Manufacturers of drugs, devices, biologics and medical supplies reimbursed by Medicare, Medicaid, or the Children's Health Insurance Program (CHIP)	• Cash and cash equivalents • Stock and stock options • Loans • In-kind items • Etc.	• Consulting fees • Speaker fees • Honoraria • Gifts, food, beverage, entertainment • Travel and lodging • Research payments • Royalties/licensing fees • Grants • Etc.

Physician Payments Sunshine Act

Posted to CMS website and searchable by company or physician/teaching hospital

Reporting and publication of data is a gold mine for:

- Industry critics
- Media
- Competitors
- Plaintiffs' attorneys
- DOJ
- HHS OIG
- Employers
- Payers



https://openpaymentsdata.cms.gov/

Privacy

Privacy

- HIPAA: Health Insurance Portability & Accountability Act of 1996
    - Provides a framework for establishment of a nationwide protection of patient confidentiality, security of electronic communications, and standards and requirements for electronic transmission of health information
    - Privacy Rule: protects individual's healthcare data (PHI) and gives patients more control over their health information
    - Security Rule: requirements for the storage and accessibility of PHI
- Pharmaceutical companies are typically not "covered entities" under HIPAA
    - Business Associate (BA) agreements may subject you to many HIPAA requirements
- Exception for adverse event reporting obligations

Privacy

State Privacy Laws

- Do apply to pharmaceutical companies – including patient information and other personal information
  - Covers information collected from your websites
- Generally prohibit the transfer or sharing of patient information without the patient's consent
- Some states have notification requirements (e.g., CA, TN, WA)
- Some states have information security requirements (e.g., CA, NV, MA)

Questions?

Other Agencies and Considerations

OCTOBER 11, 2022

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- Focuses on regulatory strategies and initiatives for the labeling, advertising and promotion of FDA-regulated products
- Serves as a legal and/or regulatory member on promotional and medical/scientific review committees
- Over 20 years of experience in FDA law at major law firms, in government, and in-house

PRESENTED TO:

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