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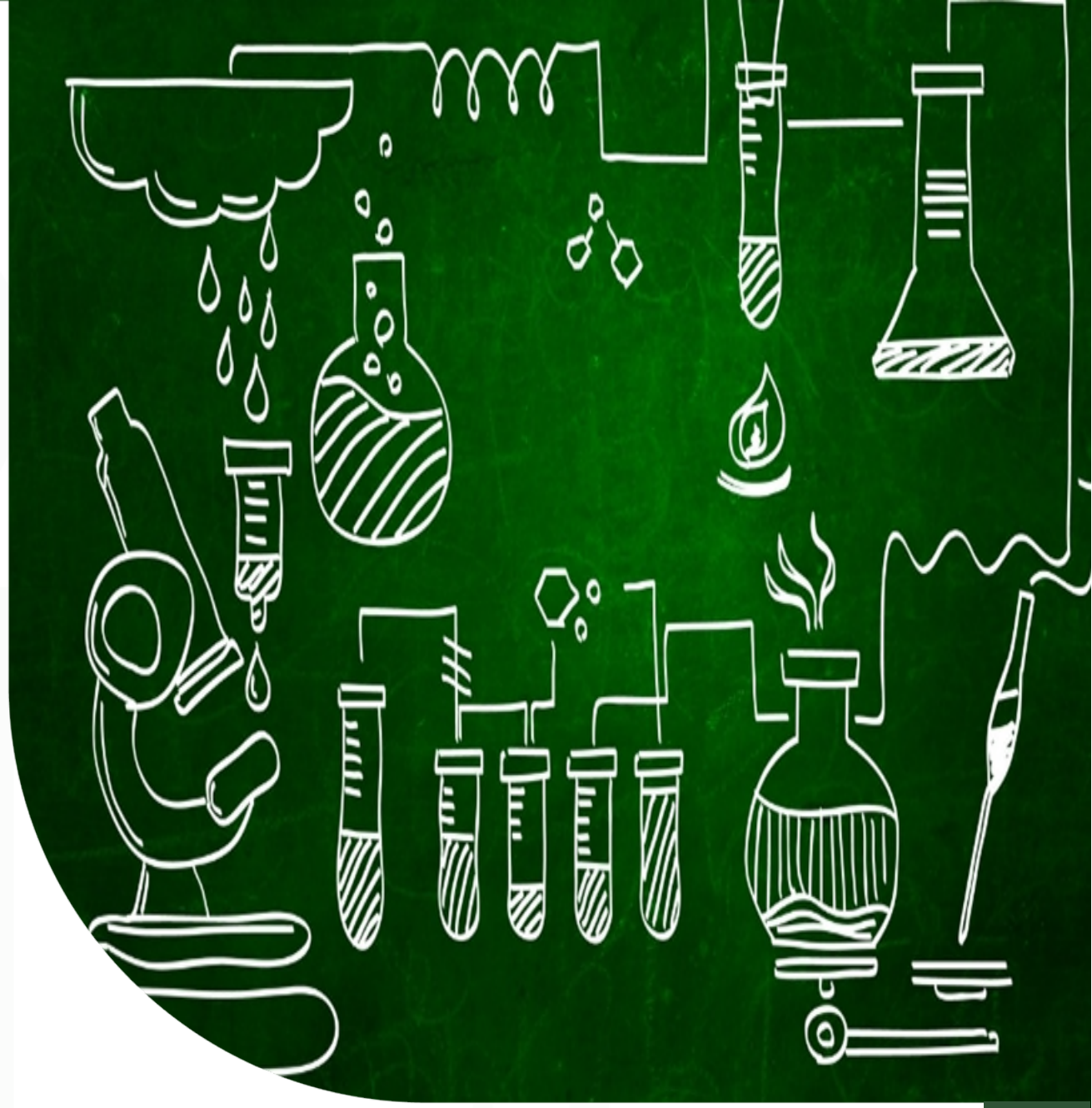
Pharma & Medtech Symposium

Legal and Compliance Considerations for DTC Advertising, Consumer Interactions, and Patient Advocacy

June 2, 2026



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Highlights from Recent Enforcement & Related Healthcare Compliance Developments

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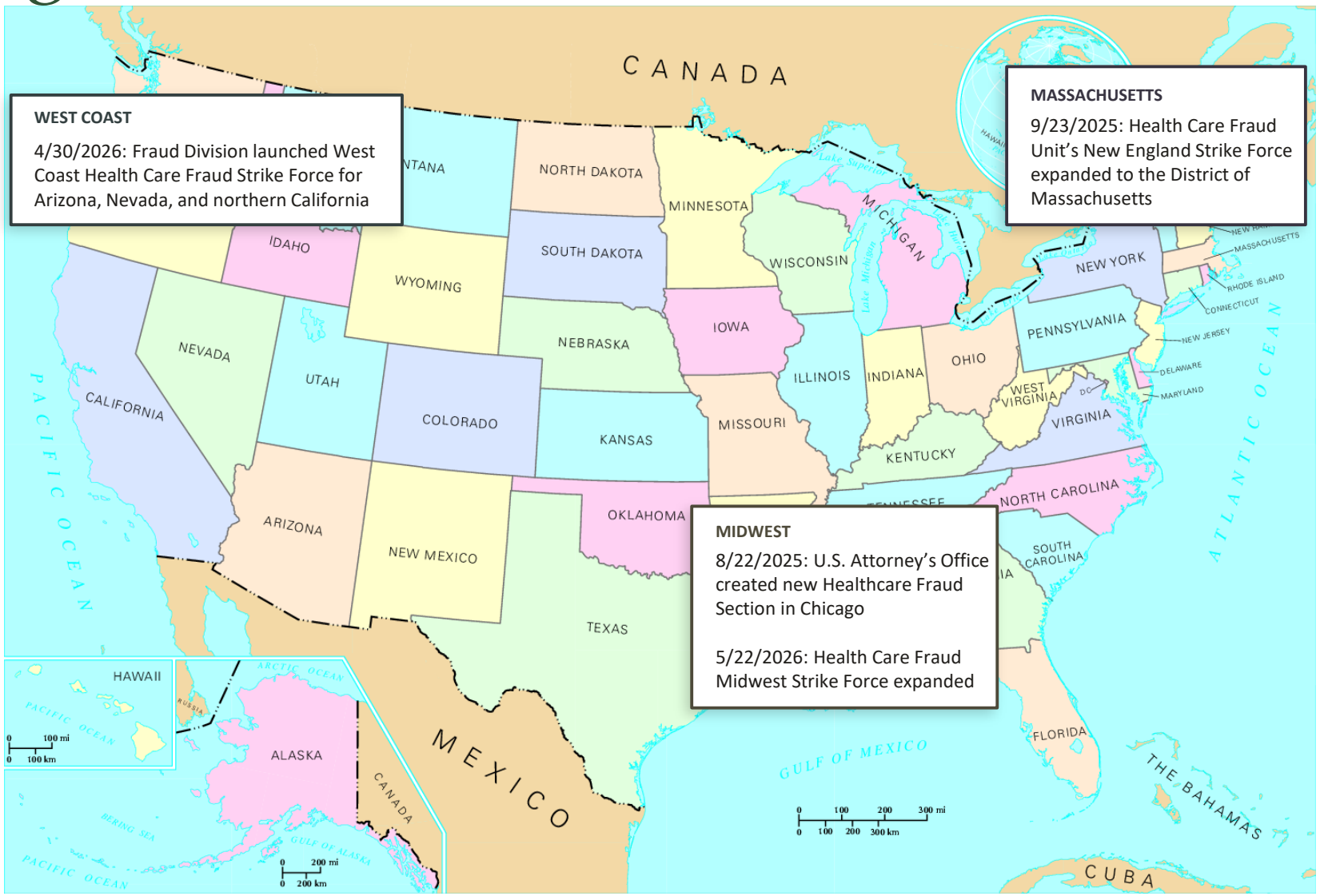
Highlights of DOJ Policies, Priorities & Programs

"Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime" Memorandum (5/12/2025)	• DOJ prioritizing investigations and prosecutions in high-impact areas including waste, fraud and abuse and including health care fraud
Updated Corporate Whistleblower Awards Pilot Program (5/12/2025)	•Under the pilot program, whistleblowers providing Criminal Division with "original and truthful information about corporate misconduct that results in a successful forfeiture may be eligible for an award" •The information must relate to one of the subject matter areas, including, for example, certain health care fraud schemes
Health Care Fraud Data Fusion Center (6/30/2025)	•Created by DOJ, HHS-OIG, FBI and other agencies "to bring together experts from the Department's Criminal Division, Fraud Section, Health Care Fraud Unit Data Analytics Team; HHS-OIG; FBI; and other agencies to leverage cloud computing, artificial intelligence, and advanced analytics to identify emerging health care fraud schemes"
DOJ-HHS False Claims Act Working Group (7/2/2025)	•Jointly led by HHS General Counsel, Chief Counsel to HHS-OIG, and the Deputy Assistant Attorney General of the Commercial Litigation Branch •Examples of priority enforcement areas: Drug, device or biologics pricing (including arrangements for discounts, rebates, service fees, and formulary placement and price reporting); Kickbacks (related to drugs, medical devices, durable medical equipment, and other products paid for by federal healthcare programs); Manipulation of Electronic Health Records systems
First-Ever Uniform Corporate Enforcement and Self-Disclosure Policy for Criminal Matters (3/10/2026)	•Applies Department-wide (except for antitrust cases), includes flow-chart and emphasizes companies that voluntarily self-disclose and meet other requirements will receive declination (not just presumption of declination) •Aligned with and replaced Criminal Division's Corporate Enforcement and Voluntary Self-Disclosure Policy (last updated in 2025) •Supersedes all component-specific or U.S. Attorney's Office-specific corporate enforcement policies currently in effect
Memorandum on the Creation of the National Fraud Enforcement Division (4/7/2026)	• Assumes operational control of the Health Care Fraud Unit
Civil Division's FOCUS initiative for data miners filing *qui tam* complaints (4/30/2026)	•Fraud Oversight through Careful Use of Statistics ("FOCUS") initiative prioritizes "working with data miners that demonstrate an insightful application of sophisticated technological capabilities to regulatory frameworks to help identify potential fraud that would otherwise go undetected"

DOJ's Regional Health Care Fraud Initiatives



DOJ: Record FCA recoveries in FY 2025

PRESS RELEASE

False Claims Act Settlements and Judgments Exceed $6.8B in Fiscal Year 2025

- Reflects highest annual total in the history of the FCA; over $5.7 billion was healthcare-related
- Record-breaking whistleblower filings
  - 1,297 new FCA *qui tam* cases in FY25, a 32% increase from the prior record of 980 cases in FY24
- DOJ reiterated its commitment to incentivize self-disclosure of misconduct, cooperation with investigations and effective remedial measures
- FY25 ended September 30, 2025

Photo credit: The Associated Press (2/19/2026)

Federal Causation Standards for Kickbacks and Related Developments

REGENERON®

- 2/18/2025: Joining the Sixth and Eighth Circuits, in United States v. Regeneron Pharmaceuticals, the First Circuit Court of Appeals adopted a more stringent "but for" causation standard in most False Claims Act cases premised on violations of the Anti-Kickback Statute, i.e., "to demonstrate falsity under the 2010 amendment [to the Anti-Kickback Statute], the government must show that an illicit kickback was the but-for cause of a submitted claim."

- 8/4/2025: U.S. District Court in Massachusetts granted prosecutors' request to pursue a theory of false certification (that Regeneron misrepresented compliance with the Anti-Kickback Statute on federal agency forms)

Medtronic

- 11/14/2025: On motion for reconsideration, U.S. District Court in Massachusetts again denied summary judgment to Medtronic on the basis that the whistleblower provided evidence sufficient to survive summary judgment under the newly adopted but-for causation standard

These developments suggest a potential change in legal strategy in False Claims Act cases premised on violations of the Anti-Kickback Statute

Compliance Developments in the News

- OIG issued numerous advisory opinions (some favorable and unfavorable), including related to access, assistance with travel and lodging and associated expenses, financial contributions to a foundation, discounts and rebates, and consulting services
- OIG's new fraud and abuse FAQ #17 (added 4/23/2026), "Can fair market value arrangements violate the Federal anti-kickback statute?" reiterates that an arrangement may violate the statute even where it involves remuneration consistent with fair market value
- OIG updated its Corporate Integrity Agreement ("CIA") template including related to the Compliance Officer, independent Board compliance expert, documentation, use of generative artificial intelligence ("AI") in connection with compliance program, etc.
- FTC's 2026-2030 strategic plan includes numerous strategic goals such as protecting Americans from unfair or deceptive acts or practices in the marketplace; strategies include other enforcement leads such as online "surfs" and direct referrals from government and private sector partners

Recent Enforcement Examples (Speaker Programs)

Pfizer Inc. (1/2025)

- Biohaven Pharmaceutical Holding Company Ltd., now a Pfizer subsidiary, allegedly caused submission of false claims by paying kickbacks to HCPs; agreement to pay $59.7 million
- Allegations involved inappropriate speaker honoraria, meals at high-end restaurants, repeat HCP attendees at programs, and attendance by spouses, family members, friends, etc.

Gilead Sciences, Inc. (4/2025)

- Company agreed to pay $202 million
- Allegations involved kickbacks in form of honoraria payments, meals and travel expenses to speakers (many of whom also attended programs on exactly the same topic); speaker programs often held at high-end restaurants; repeat attendees

Takeda Pharmaceuticals, U.S.A. Inc. (5/2026)

- Company agreed to pay $13.6 million
- Allegations involved improper speaker honoraria and meals at high-end restaurants, multiple attendees on same topic received meals and drinks from Takeda
- According to Settlement Agreement, "Takeda received credit under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112."

Recent Enforcement Examples

Nader Pourhassan, former CEO of CytoDyn (1/2026)

- After 12/2024 conviction, sentenced to 30 months in prison for misleading investors about company's development of new drug, then selling personal stock in company at artificially inflated prices
- At sentencing, was ordered to pay more than $5.3 million in restitution and to forfeit more than $4.4 million
- Separately, FDA sent warning letter to CytoDyn in 2022 for CytoDyn CEO's video interview that allegedly represented in a promotional context that the investigational drug leronlimab was safe and effective

ExThera Medical Corporation (3/2026)

- Former Chief Regulatory Officer pleaded guilty in connection with failing to file adverse event reports with intent to defraud and mislead the FDA in connection with blood filtration device used on cancer patients
- ExThera entered into 3-year DPA in connection with criminal information charging failure to file adverse events with intent to defraud or mislead the FDA; ExThera agreed to pay $750,000 criminal penalty and consent to entry of a forfeiture order of $5,694,750
- First resolution of corporate defendant by New England Strike Force since expansion to Massachusetts

Purdue Pharma LP (4/2026)

- After 11/2020 guilty plea involving three-count felony information charging it with one count of a dual-object conspiracy to defraud the United States and to violate the Food, Drug, and Cosmetic Act, and two counts of conspiracy to violate the Federal Anti-Kickback Statute, Purdue sentenced and ordered to pay criminal penalties of over $5 billion (including criminal fine and criminal forfeiture)

Recent Enforcement Examples

Felipe Ruiz and Jose Aguirre (4/2026)

- Ruiz, a podiatrist, purchased skin grafts from Aguirre, a pharmaceutical sales representative who sold the skin grafts to Ruiz and his practice, and permitted Aguirre to apply skin grafts and perform other medical procedures on patients suffering from severe wounds
- Ruiz and Aguirre allegedly submitted fraudulent claims to Medicare, Medicaid and Medi-Cal falsely representing Ruiz and other physicians had performed the procedures
- Ruiz and Aguirre were sentenced to 63 months in prison for conspiracy to commit healthcare fraud; forfeiture of 9 properties and personal forfeiture money judgments also ordered ($2.6 million against Aguirre and $12.1 million against Ruiz)

Recent Enforcement Examples

SpineFrontier (5/2026)

- CFO Aditya Humad pleaded guilty in connection with kickback scheme to bribe surgeons to use company products in exchange for sham consulting fees; sentencing scheduled for 8/2026
- Humad previously agreed to pay civil settlement of $150,000 and additional contingent payments based on annual income
- Humad was charged in 9/2021 along with SpineFrontier and Dr. Kingsley R. Chin, SpineFrontier's Founder, President and CEO
- In 5/2025, Chin pleaded guilty to making false statements to CMS Open Payments Program and was sentenced in 8/2025 to 1 year supervised release with first six months served in home confinement; $9,500 fine; $40,000 in personal civil settlement and $855,000 his wholly-owned company agreed to pay as part of the same settlement
- 8/2020: Guilty pleas for related criminal prosecutions of surgeon and medical device distributor (sentencing scheduled 9/2026)

DOJ Scrutiny of Third-Party Arrangements

"The department is committed to protecting the integrity of federal health care programs and the medical care received by their beneficiaries. A primary focus of this effort is the pursuit of kickback schemes that can allow third parties, such as pharmaceutical manufactures [*sic*], to insert themselves into the doctor-patient relationship and potentially undermine the objectivity of treatment decisions by physicians and patients."

"We are always on the lookout for financial kickbacks that can improperly influence medical decisions, undermine patient care and cause waste to federal healthcare programs. As medical practices evolve, our office is committed to ferreting out improper financial kickbacks of any permutation."

"Prescription decisions should be based on accurate data regarding a patient's medical needs, untainted by corrupt schemes and illegal kickbacks."

"Not all kickbacks come in the form of cash going into a doctor's or a patient's pocket."

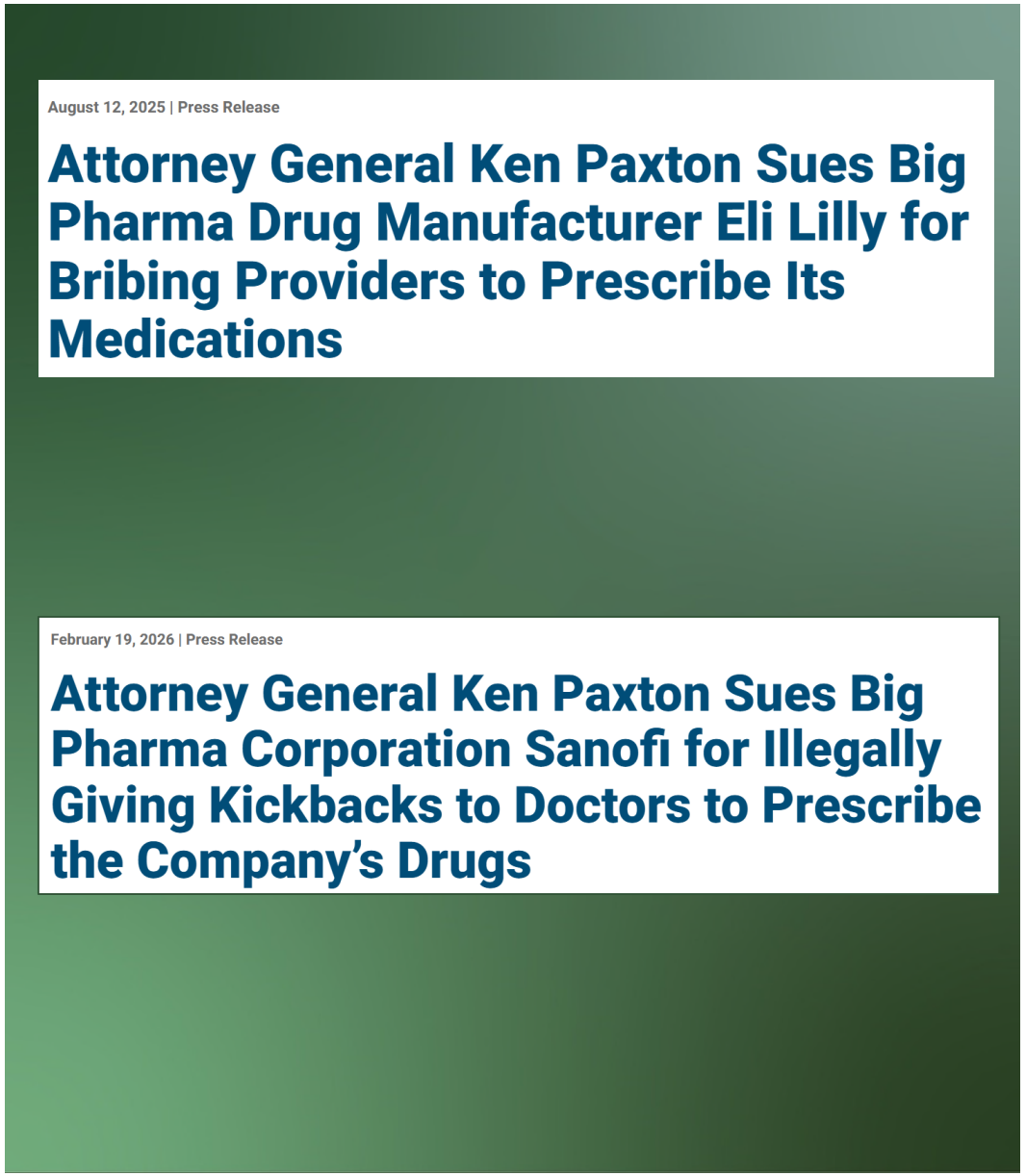
Areas of recent attention and enforcement: (1) manufacturer-sponsored testing arrangements and (2) Electronic Health Record (EHR) vendor/payment arrangements

Enforcement Examples (Patient Support)

Texas AG Lawsuits

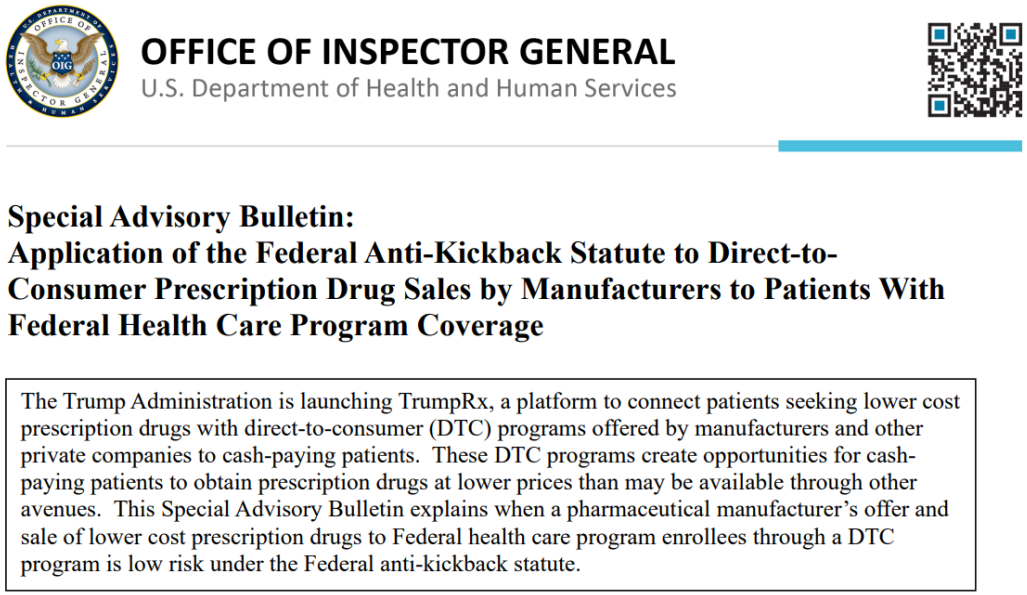
Eli Lilly and Sanofi-Aventis

- In August 2025, Texas Attorney General Ken Paxton announced lawsuit against Eli Lilly “for bribing and illegally inducing medical providers to prescribe its most profitable drugs, including the high-demand GLP-1 medications Mounjaro and Zepbound that are used for weight loss and diabetes treatment” in violation of the Texas Health Care Program Fraud Prevention Act
- In February 2026, Paxton announced similar lawsuit against Sanofi “for providing illegal kickbacks to providers to incentivize them to prescribe Sanofi’s drugs over alternatives”
- Allegations in both cases, which also involve corporate relators/whistleblower entities, focus on each company’s **free nurse services and reimbursement support services programs**
- Eli Lilly allegedly “touts” aspects of its nurse program in product brochures and highlighted reimbursement support services in sales pitches
- Sanofi allegedly “actively promotes” its free nurse program, including in product brochures and websites. The availability of its reimbursement support services was alleged as a “key part” of Sanofi’s marketing and promotional strategies



OIG Special Advisory Bulletin: DTC Sales (1/2026)

- Patients may elect to purchase prescription drugs through manufacturers' direct-to-consumer ("DTC") programs, including through TrumpRx (President Trump announced expansion of TrumpRx.gov in 5/2026)
- *"...there is a low risk that a manufacturer would violate the Federal anti-kickback statute provided that: (1) the prescription drug is not billed to a Federal health care program, (2) the sale of the prescription drug is not conditioned on the current or future order or purchase of any other item or service that is or could become billable to a Federal health care program, and (3) the arrangement aligns with the other characteristics listed [in the Bulletin]."*
- What doesn't the Bulletin cover? For example:
  - The Bulletin states that it "addresses only the DTC sales transaction between the manufacturer and the cash-paying patient" and that it "does not address the cash application of the Federal anti-kickback statute to any arrangements that the manufacturer may have with physicians, pharmacies, pharmacy benefit managers, telemedicine vendors, marketers, or other individuals or entities" and "It also does not address any arrangements that those individuals or entities may have among themselves or with Federal health care program enrollees."
  - Footnote states, "This Bulletin does not address the civil monetary penalty provision prohibiting inducements to beneficiaries because the provision does not apply to arrangements between pharmaceutical manufacturers and beneficiaries."
- OIG separately issued request for public comment

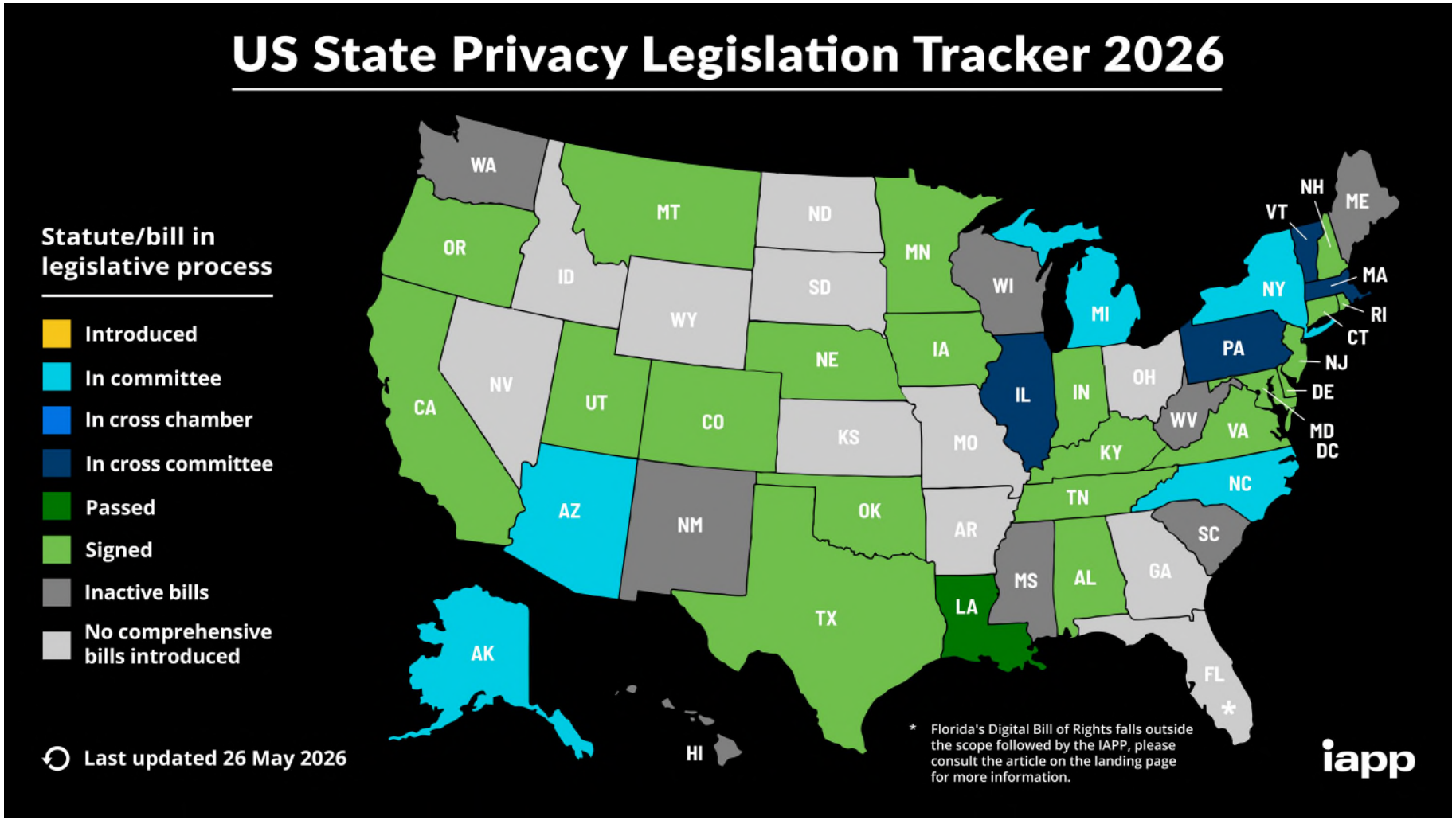


OFFICE OF INSPECTOR GENERAL
U.S. Department of Health and Human Services

Special Advisory Bulletin:
Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients With Federal Health Care Program Coverage

The Trump Administration is launching TrumpRx, a platform to connect patients seeking lower cost prescription drugs with direct-to-consumer (DTC) programs offered by manufacturers and other private companies to cash-paying patients. These DTC programs create opportunities for cash-paying patients to obtain prescription drugs at lower prices than may be available through other avenues. This Special Advisory Bulletin explains when a pharmaceutical manufacturer's offer and sale of lower cost prescription drugs to Federal health care program enrollees through a DTC program is low risk under the Federal anti-kickback statute.

Privacy Developments



DOJ Enforcement Example

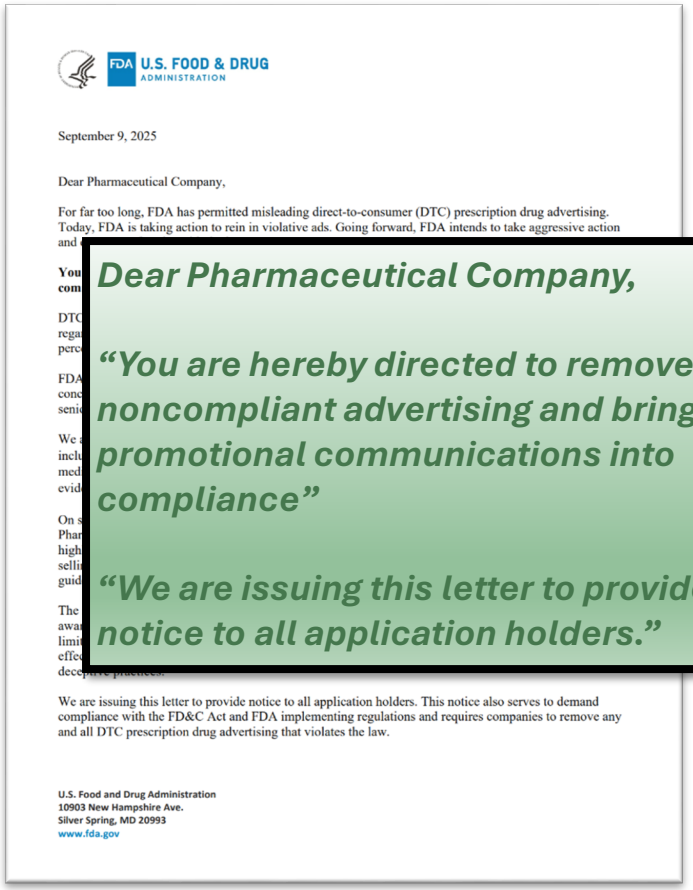
Cybersecurity (7/2025)

- Illumina agreed to pay $9.8 million to resolve False Claims Act allegations relating to cybersecurity vulnerabilities
- Allegations from first-of-its-kind False Claims Act suit:
    - Illumina sold genomic sequencing systems with software containing cybersecurity vulnerabilities to federal government agencies without having an adequate security program and sufficient quality systems to identify and address those vulnerabilities
    - Illumina knowingly failed to:
        - Incorporate product cybersecurity into software design, development, installation, and on-market monitoring
        - Properly support and resource the personnel, systems, and processes responsible for product security
        - Adequately correct design features that introduced cybersecurity vulnerabilities
    - Illumina also allegedly falsely represented that the software on its genomic sequencing systems adhered to cybersecurity standards, including those of the International Organization for Standardization (ISO) and the National Institute of Standards and Technology (NIST)

FDA September 2025 Crackdown

FDA Press Release Issued September 9, 2025

- FDA sent "thousands of letters warning pharmaceutical companies to remove misleading ads" and issued "approximately 100 cease-and-desist letters to companies with deceptive ads."
- "In addition to enforcing existing law, the FDA is initiating rulemaking to close the 'adequate provision' loophole created in 1997, which drug companies have used to conceal critical safety risks in broadcast and digital ads, fueling inappropriate drug use and eroding public trust."
- "An increasing reliance on digital and social media channels, including undisclosed paid influencer promotion, has blurred the lines among editorial content, user-generated media and pharmaceutical advertising, making it increasingly difficult for patients to distinguish between evidence-based information and promotional material."
  - "The FDA will no longer tolerate such deceptive practices. Going forward, the agency will aggressively deploy its available enforcement tools. The FDA is already implementing AI and other tech-enabled tools to proactively surveil and review drug ads."



Dear Pharmaceutical Company,

"You are hereby directed to remove any noncompliant advertising and bring all promotional communications into compliance"

"We are issuing this letter to provide notice to all application holders."

2026 FDA (OPDP) Enforcement Actions (as of 5/28/2026)

Warning Letter

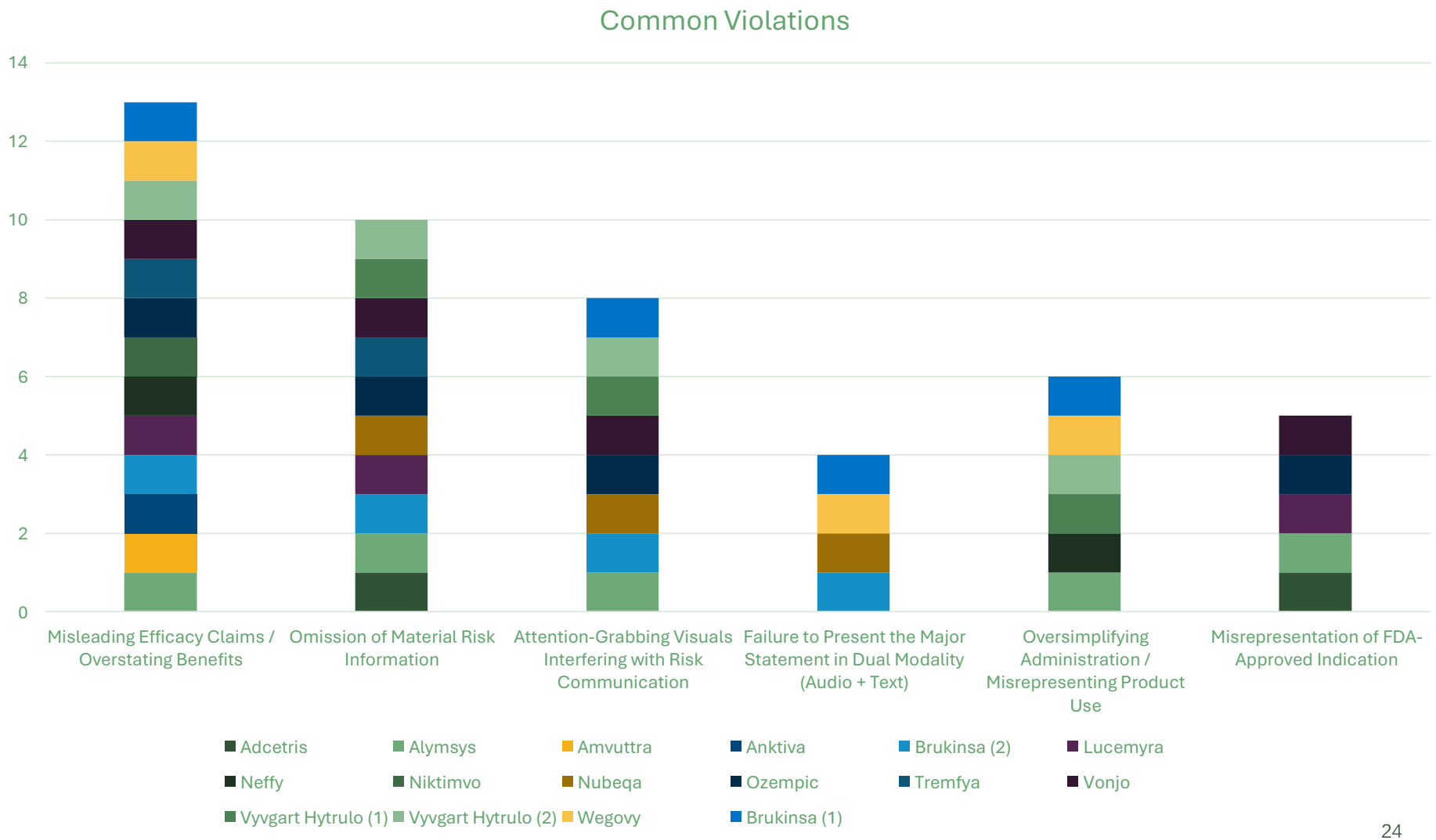
- One (1) letter

Untitled Letters

- Sixteen (16) letters

FDA's Main Focus

- DTC advertising
- Evidence-based benefit claims
- Risk disclosure and fair balance



Questions?

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Thank You!

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Best Practices for Policies/SOPs Addressing Patient-Related Interactions and Engagements

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The Evolving Patient-Centric Landscape

Provider to Patient	→	Shift from traditional provider-focused model to patient-centricity
Regulatory Emphasis	→	Agencies increasingly emphasizing patient voice (e.g., FDA patient-focused drug development)
Digital Channels	→	Rise of digital health, social media, and direct-to-patient channels
Patient Advocacy	→	Growing patient advocacy movements and community engagement
Key Stakeholders	→	Industry recognizing patients as collaborators, not just product end users

The Value of Patient Interactions & Engagement

→ Improved Health Outcomes

Education, access, and adherence through meaningful engagement

→ Enhanced R&D and Clinical Trials

Improvements in trial design, recruitment, and retention

→ Improved Patient Education & Support

Empowers patients through education and support services to improve understanding and access to treatment

Additional Value

- Increased understanding of patient needs
- Builds trust and transparency between industry and patient communities
- Supports development of patient-relevant therapies and endpoints
- Informs product development, labeling, and post-market surveillance
- Enhances disease education and product communications

Why Compliance Matters

- Patient interactions create unique compliance risks distinct from HCP interactions
- Patients are generally more vulnerable populations with less medical sophistication
- Regulatory framework is complex and multi-layered (FDA, OIG, FTC, state laws, HIPAA/other privacy laws)
- Reputational risk is significant — public perception of industry exploiting patients
- Enforcement trends show increased scrutiny of patient-facing activities (e.g., patient support activities)
- Policies and SOPs provide guardrails to enable interaction and engagement while managing risk

Key Insight: Compliance can enable innovation and mitigate risk.

Key Insight: Compliance can enable innovation and mitigate risk.

Examples of Patient Interactions & Engagement

- Patient Community & Advocacy Engagement
- Patient Education Programs
- Product Communications
- Patient Consultant & Speaker Arrangements
- Clinical Trials & Recruitment
- Social Media & Digital Engagement
- Patient Support Programs/Financial Assistance

Key Compliance Laws and Regulations

Interactions and engagements with patient can implicate various laws and regulations:

- Anti-Kickback (and False Claims Act)
- Beneficiary Inducements (CMP Law)
- FDA Regulations – Clinical trials, Product Labeling/Communications, AE/Product Complaint Reporting
- Privacy – HIPAA, state privacy laws, GDPRs
- FTC & Consumer Protection (Unfair or deceptive trade practices)
- Corporate practice of medicine laws

Industry Codes/Guidance may also apply – PhRMA, BIO, Advamed, EFPIA, etc.

Key Compliance Issues at a Glance

Anti-Kickback / Patient Inducement

- Items of value, meals, travel to patients
- Service arrangements and compensation
- Patient support/financial assistance/free drugs

FDA Regulatory

- Clinical trials
  - IRB oversight and informed consent
  - Clinical trial recruitment requirements/restrictions
  - Subject protections/no undue influence
  - Clinical trial integrity
- Product/Disease Communications
  - Promotional vs. non-promotional communications/unbranded
  - Direct-to-Patient and DTC
  - On-label v. off-label
  - Fair balance and safety disclosures
  - Pre-approval communications
  - Social media/Influencer considerations
- Adverse event reporting

FTC & Consumer Protection

- Endorsement/testimonial guidelines and disclosures (FTC Endorsement Guides)
- Substantiation of health claims
- State consumer protection
- Social medial/influencer considerations

Privacy & Patient Information

- HIPAA, state privacy laws, GDPRs
- Notices/consents/authorizations; data security; de-identification
- Collection and use of patient data; Data minimization

No Corporate Practice of Medicine

- No medical or treatment advice
- No interference in doctor-patient relationship
- Appropriate disclaimers
- Direct patients to HCPs

Other Issues

Industry Codes/Guidelines
Use of Artificial Intelligence
Telemedicine
OUS considerations (e.g. DTC, Social Media)

Hypothetical #1: Patient Advisory Board

Your company wants to establish a patient advisory board for a rare disease treatment. Plans include compensating patients for participating, covering travel and expenses.

Questions to Consider:

- What policies/SOPs should be in place to govern this arrangement?
- How do you determine FMV for patient consultants?
- What are the risks if trial participants included?
- What privacy considerations arise?
- How should venue selection be addressed?

Hypothetical #1: Considerations

Policy & SOP Framework

- Policy covering patient engagements
- SOP for patient consultants/advisory boards covering selection criteria, needs assessment, engagement terms, documentation, requirements
  - Written agreements with defined scope of work/services and duration
  - FMV assessment process using independent benchmarking for patient consultant compensation
- Policy/SOP for review of advisory board content
- Other ancillary policies addressing
  - Modest meals
  - Venue selection guidelines
  - Travel & Expense
- Data Privacy Compliance Policy (see Privacy Considerations)

Anti-Kickback & Inducement Safeguards/Clinical Trial Integrity

- Screen for conflicts: identify (exclude?) current clinical trial participants; assess AKS risk and trial integrity
- Compensation must reflect FMV for time/expertise — not tied to product use
- Meals/Travel/expense reimbursement follows company T&E policy; no guests, no entertainment or recreational add-ons
- Document legitimate business need and participant selection criteria

Privacy Considerations

- Determine what patient health information will be collected or disclosed
- Provide notices and obtain appropriate consents/authorizations before collecting patient information
- Limit data collection to what is necessary for the advisory board's purpose
- Implement data security measures for any patient information gathered/obtained

Training & Oversight/Monitoring

- Train company personnel facilitating the advisory board on compliance boundaries
- Review of all advisory board content and materials
- Review advisory board report
- Consider monitoring advisory board

Hypothetical #2: Company Attendance at a Patient Event

Your company is sending a team of employees to attend and participate in a patient advocacy organization's annual walkathon and conference. The event includes a health fair, educational sessions, and networking opportunities with patients and caregivers. The company is a sponsor of the event and plans to have a booth, distribute disease education materials and branded items, and have sales representatives, medical affairs personnel, and patient advocacy team members in attendance.

Questions to Consider:

- What policies/SOPs should govern employee conduct and communications at the event?
- What materials can be distributed, and what review/approval is required?
- How should interactions between company personnel and patients be managed?
- What are the risks around product communications at a patient-focused event?
- How do you address AE reporting obligations from patient interactions at the event?
- What training should personnel receive in advance?

Hypothetical #2: Considerations

Policy & SOP Framework

- Patient Interactions Policy
- Patient Event/Conference Attendance Guidelines covering permissible activities, communications, and personnel conduct aligned with patient interactions policy
- Other applicable policies/SOPs
  - Privacy Policy
  - Communications Policy/ies
  - Social Media Policy/guidelines
  - Items of Value Policy
  - SOP for review/approval of materials
  - AE reporting SOP
  - Responding to patient inquiries
- Require pre-event compliance training for all attending personnel — tailored to role (sales vs. medical affairs vs. patient advocacy)

Communications & Promotional Compliance

- All product-related materials must be MLR-approved and consistent with FDA requirements (fair balance, on-label)
- If disease education, materials should be clearly unbranded and separated from any promotional content or activity
- Personnel must be trained permissible communications regarding product, clinical trials, etc.
- Branded giveaway items must comply with company policy and applicable industry codes

Patient Interaction Guardrails

- Personnel must not provide medical advice — direct patients to their HCPs
- Establish guidelines for responding to unsolicited questions about products and/or clinical trials (including off-label inquiries)
- Document any patient interactions involving product complaints or potential adverse events
- Ensure interactions do not create an impression of inducement (e.g., excessive giveaways tied to product use)
- Consider rules around “friending” on social media

Adverse Event Reporting & Privacy

- Train all personnel to recognize and report potential AEs heard during patient interactions
- Establish clear process for real-time AE escalation (designated point person, reporting form/app)
- If collecting patient information at the booth, provide privacy notices and obtain consent
  - Limit data collection to what is necessary; ensure secure handling per applicable laws

Sponsorship & Transparency (if applicable)

- Ensure sponsorship terms do not create undue influence over event content or messaging
- Disclose company sponsorship/affiliation clearly at booth and in materials; funding at FMV in exchange for sponsorship benefits

Hypothetical #3: Patient Ambassador Program

Your company wants to launch a patient ambassador program. Patients living with the disease will be engaged to share their stories and treatment journeys at live events, on social media, and in company-produced content. Ambassadors will receive compensation for their participation as a patient ambassador and the company will provide training, talking points/slides, and logistical support.

Discussion Questions

- What policies/SOPs should govern the structure and operation of the ambassador program?
- What FDA and FTC requirements may apply?
- How do you handle AE reporting from ambassador interactions?
- What notices or disclosures are required?
- What guardrails should address ambassador product communications?
- How do you balance authenticity with compliance oversight?

Hypothetical #3: Considerations

Policy & SOP Framework

- Policy governing patient engagements
- SOP covering identification and selection criteria, needs assessment, onboarding, engagement terms, permissible activities, and governance
  - Written agreements defining scope, compensation (at FMV), duration, deliverables, and compliance obligations
- Policy on Interactions with Patients (1-1 communications?)
- Policy on promotional communications to patients
- Cross-functional review committee SOP (compliance, legal, medical, marketing) for program oversight and materials review
- Social Media Policy
- AE Reporting SOP
- Ambassador program guidelines (supplemental)

Communications & Promotional Compliance

- Ambassador product communications will be attributable to the company — treat as promotional/FDA-regulated
- All product-related statements must be consistent with approved labeling; truthful, accurate, non-misleading, and fair balance
- MLR review process for stories, talking points, scripts, or suggested social media content
- Clear guidance/training on what ambassadors can and cannot say about products; guidelines distinguishing permissible personal experience from specific efficacy claims or comparisons

Disclosures/Permissions/Social Media

- Disclosure regarding use of product; compensation
- Patient ambassador consent to use of name, likeness, etc.; media consent
- Requirements/restrictions on social media activity
- Train ambassadors on social media communications (treat like employees?)
- Company right to review, request modification, or require removal of non-compliant content

Adverse Event Reporting

- Train ambassadors to recognize and report potential AEs
- Monitor ambassador social media and public engagements for AE information

Anti-Kickback & Inducement Safeguards

- Compensation must reflect FMV for services rendered — not a premium for patient status or endorsement
- Consider conditions of participation
- Document legitimate business need for each ambassador engagement
- Travel and expense reimbursement must follow company policy and be reasonable and necessary

Training & Oversight

- Comprehensive compliance training before ambassadors begin — FDA/FTC rules, AE reporting, privacy, social media
- Regular program audits — review content, monitor compliance, assess effectiveness
- Process for addressing non-compliance, including suspension or termination from the program

Hypothetical #4: Patient Support Program

Your company operates a patient support program for a specialty biologic. The program includes nurse educators who provide injection training and disease management support, a patient helpline, check-in calls, and financial assistance including copay support and free drug programs. The program is managed by a third-party vendor on behalf of the company.

Discussion Questions

- What are the AKS and beneficiary inducement risks?
- What are FDA regulatory considerations?
- How is the purpose/objective of the patient support program? How should that be communicated?
- What policies/SOP and other documents should govern?
- How are government healthcare program beneficiaries handled?
- What role should compliance play in program design and oversight?
- What training and monitoring should be in place for the PSP?

Hypothetical #4: Considerations

PSP Risk

- Patient support programs are a significant area of OIG/enforcement scrutiny
- Free drug/financial assistance for government program beneficiaries raises heightened AKS risk
  - Medicare/Medicaid Rules (e.g., Best Price, Part D rules)
- FDA – product communication risks
- Evaluate applicability of AKS and consider OIG advisory opinions
- Privacy laws implicated if patient information is collected, maintained, shared, or used without required consent/authorization

PSP Considerations - Generally

- Program design to facilitate access and education; no inducement
- No interference in doctor-patient relationship
- Promotional communication management
- Eligibility requirements/restrictions on participation in programs (on-label, government beneficiaries?)
- Copay, PAP, Quick Start, Bridge, and other assistance programs
- Nurse educators— on-label and balanced product communication; no medical advice
- Privacy issues, data management and classification, security
- No solicitation of adverse events
- Training

Policies & SOP Framework

- Policies, SOPs, and business rules for all patient support program elements
  - Patient Support Program/Patient Services Policy
  - SOPs/Business rules covering components, eligibility, services, governance for all programs
    - Specific rules for Medicare, Medicaid, and government program beneficiaries
  - Escalation/Exceptions SOP
- Process for disclosure and sharing of patient/health/other information
  - Obtain appropriate patient consents/authorizations for collection and use of health information
  - Address Vendor data handling - privacy laws, and company data security standards
  - Consider firewalls/restrictions on sharing of data between patient support personnel and commercial/sales teams
  - Address management of marketing, texting, or other consents
- Promotional Communications Policy
- Materials review policy/SOP (MLR) requiring review of all PSP materials
  - Review of all nurse educator content
  - Review of all case manager scripts
- AE Reporting Policy & SOPs – establish clear AE reporting workflows
- Responding to Patient Inquires SOP
- Vendor section and oversight policy/process

Types of Patient Interactions & Engagement

Interaction Type	Activities	Key Considerations
Patient Community & Advocacy Engagement	• Funding of PAO activities/programs • Participation in PAO events and community health initiatives • Patient advisory boards and focus groups • Disease awareness campaigns • Product information sharing • Clinical trial recruitment • Service arrangements	• Independence of advocacy organizations • Transparency of funding • Avoiding undue influence on advocacy messaging • Fair market value for any services • Communication rules
Patient Education Programs	• Disease awareness/education (unbranded) • Treatment and therapy education	• Promotional rules • Accuracy of medical information • Appropriate disclosures • Avoiding practice of medicine/no medical advice
Product Communications	• Direct-to-patient communications • Direct-to-consumer (DTC) advertising • Patient labeling and medication guides • Safety/Risk communications • Patient-facing websites and apps	• FDA promotional regulations • Fair balance requirements • Substantiation of claims • FTC truth-in-advertising standards • No medical advice
Patient Consultant/ Speaker Arrangements	• Patient speakers and testimonials • Patient consultants for advisory roles • Patient ambassador programs	• Fair market value compensation • Legitimate business need • Written agreements • Training requirements • Avoiding inducement / no requirement to endorse specific products
Clinical Trials & Recruitment	• Clinical trial recruitment and outreach • Informed consent processes • Patient stipends and reimbursement • Post-trial access • EAP/compassionate use	• IRB oversight requirements • Informed consent • Avoiding undue inducement to participate • Protecting vulnerable populations • ClinicalTrials.gov transparency • Diversity and inclusion in recruitment
Social Media & Digital Engagement	• Company-sponsored social media • Patient influencer relationships • Online patient communities/forums • User-generated content & testimonials • AE reporting obligations from social media	• Adverse event reporting from social media • Managing off-label discussions • Endorsement disclosures (FTC) • Platform-specific requirements • Community guidelines

Building An Effective Framework

Cross-Functional Governance

Compliance, legal, medical, regulatory, commercial, patient advocacy

Tiered Policies/Supplemental Materials

Overarching policy → activity-specific SOPs → work instructions/business rules → guidelines/guardrails

Flexible Guardrails

Innovation-friendly while maintaining compliance

→

Risk Assessments

Conduct for each type of patient interaction

Approval Workflows

Review process/SOPs and defined roles

Periodic Review

At least annually or upon regulatory changes

Best Practices - General

- Engage cross-functional stakeholders early
- Benchmark against industry standards
- Use plain language
- Include practical examples and decision trees
- Build in training requirements tied to rollout
- Conduct training
- Establish metrics and monitoring mechanisms
- Create feedback loops for continuous improvement
- Document exceptions and approval processes
- Maintain version control and accessibility

Best Practices – Instill Guiding Principles

- Be transparent and ethical in all interactions with patients, caregivers, and patient organizations
- Confirm all communications about product or a relevant disease state are truthful, accurate, balanced, and non-misleading
- Review all external communication materials used with patients, caregivers, and patient organizations prior to their use or dissemination
- Tie all engagements to a legitimate business need designed to support patients and the healthcare community, and to improve outcomes consistent with the patients' best interests
- Always be respectful of Patient privacy and handling of patient data
- Respect the independence of patients, caregivers, and patient organizations and do not impose requirements intended to, or otherwise that could be seen as, compromising their independence
- Never interfere with the HCP-Patient relationship
- Do not provide medical advice
- Always encourage Patients to speak to their HCP
- Do not directly or indirectly encourage a patient, caregiver, or patient organization to purchase, refer, sell, arrange for the purchase or sale, or recommend any company product or service
- Do not use interactions to exert improper influence or coercion on activities or choice of therapy

Best Practices – Example Compliance Materials

- **Policies to address interactions/engagements with patients/patient organization**
  - Interactions & Engagements with Patients and Patient Organizations Policy
  - External Communications/Communicating with Patients Policy
    - Promotional Communications
    - Clinical Trial Communications
    - Other
  - Clinical Trials Policy
  - Expanded access Policy
  - Data Privacy Compliance Policy
  - Social Media Policy
  - Service arrangements
  - Patient Support Programs Policy
- **SOPs**
  - Responding to patient Inquiries
  - Patient engagement process (including business needs assessment, etc.)
  - PAP SOP
  - Adverse Event reporting
  - Review of funding requests (grants, sponsorships, donations)
- **Guidelines/Guardrails to address specific activities**
  - Conference/event interactions
  - Social media engagement
  - Patient transitions from clinical trials/EAP to patient support
- **Business Rules**
  - Patient ambassador programs
  - Patient support programs (PAP, Quick Start, Bridge, Copay, other)
- **Forms**
  - Business needs assessment
  - Funding requests
  - Adverse Event reporting
- **Training programs - General**
  - Interactions/Engagements with Patients
  - Privacy
  - Social Media
  - AE Reporting
- **Training programs – Specific**
  - Patient Advocacy
  - Patient Support Services
  - Pre-Conference/Event
  - Patient ambassador/speaker

Key Takeaways

Frameworks Matter

Patient engagement is essential but requires thoughtful compliance frameworks

Tailor Your Policies and SOPs (and other compliance materials)

One-size-fits-all policies are insufficient — tailor to specific interaction types

Overlapping Obligations

Privacy, AKS, FDA, and FTC create overlapping compliance requirements

Remember

- Cross-functional collaboration is critical
- Policies must evolve with the regulatory landscape
- When in doubt, default to transparency and patient protection

Thank You!

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Porzio's Pharma & Medtech Symposium

Break

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Legal and Compliance Risks in Patient-Facing Activities

Understanding key challenges and regulatory requirements

Marty Healy
Principal

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Introduction and Scope

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Agenda and Session Overview

Session Objective

Focus on legal and compliance risks in patient-facing activities within pharma and the life sciences sector more broadly.

Enforcement Landscape

Patient-facing activities face heightened scrutiny from multiple regulators compared to traditional HCP promotion.

High-Risk Areas

Key risks include patient support programs, direct-to-consumer marketing, privacy and data security, and AI use.

Actionable Takeaways

Practical risk mitigation strategies to consider across patient-facing activity areas.

The Shifting Enforcement Landscape

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Expanding Scope of Patient-Facing Activity

Expanded Patient Support Programs

Current patient-facing activities include copay assistance, free drug programs, and nurse educator hotlines that directly support patients.

DTC Advertising

Continued scrutiny of DTC advertising, especially social media, health “influencers”, short form video ads, and tracking technologies

Digital and Telemedicine Platforms

Digital tools such as apps, websites, chatbots, and telemedicine platforms provide new channels for engaging patients and for direct to patient sales.

Patient Ambassadors and Patient Advocacy Groups

Increasing collaboration with individuals and groups especially in rare disease and disease state education.

Postmarketing Studies

FDA has balanced faster approvals with greater postmarketing clinical study obligations; companies required to collect and analyze patient data during these Phase IV studies

Familiar Legal Risks, All New Again

Anti-Kickback Statute (AKS) and False Claims Act (FCA) Risks

Government enforcement geared towards preventing compromised clinical decision-making and abuse of taxpayer-funded healthcare programs.

Advertising and Promotion Risks

FDA/FTC enforcement to ensure advertising and promotion is balanced, truthful, and non-misleading.

Improper promotion can also create potential legal exposure under consumer protection and products liability laws

Privacy and Cybersecurity Risks

A patchwork of state and federal laws Intended to protect sensitive patient data from improper exposure or use.

Why Enforcement Looks Different Now

Multi-Agency Coordination and Focus

Federal agencies and state attorneys general now coordinate closely to enforce healthcare regulations more effectively.

Increased False Claims Recoveries

Record recoveries of $6.8 billion in 2025 highlight intensified government focus on combating healthcare fraud.

Advanced Analytics & AI Use

New data analytics and AI tools allow earlier and more accurate detection of fraudulent prescribing and billing patterns.

Faster, Earlier Investigations

Investigations begin sooner and move faster, often involving multiple regulators before internal compliance teams are alerted.

Why Timing and Scale Matter

Impact of Large Data Sets

Extensive data from large programs is retrospectively analyzed to identify potential risks and enforcement concerns.

Role of Whistleblower Programs

Expanded whistleblower awards encourage reporting of misconduct by employees, vendors, and partners.

Compliance Program Expectations

Regulators demand mature compliance programs that proactively identify and mitigate risks with continuous monitoring.

Importance of Internal Detection

Failure to detect internal issues can lead to criticism, emphasizing the need for thorough documentation and oversight.

Patient Support Program Risks

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Expanding Scope of Patient Support Programs

Helping patients access needed treatment with a very broad range of assistance and support programs, including:

- Disease Education: Providing information to patients about their disease, either before or after prescribing decision

- Insurance Navigation: Helping ensure needed treatments are covered or approved for coverage by applicable insurance

- Financial Assistance: Helping uninsured or underinsured patients afford their medicines

- Adherence: Reminders and other support (i.e. transportation) to help patients adhere to their course of treatment

Even the most well-intentioned activities can create AKS, FCA and other risks

Anti-Kickback and FCA Framework

OIG Compliance Program Guidance Factors:

- Does the arrangement or practice have the potential to interfere with, or skew, **clinical decision making**?
- Does the arrangement or practice have the potential to **increase costs** to Federal health care programs or beneficiaries?
- Does the arrangement or practice have the potential to increase the risk of **overutilization** or inappropriate utilization?
- Does the arrangement or practice raise **patient safety** or quality of care concerns?
- Does the arrangement or practice raise concerns related to **steering** patients or providers to a particular item or service?

Bear in mind the growing adoption of the "one purpose" test

Examples of Scrutinized Activities

- **Copay Assistance and Foundation Funding**
  - 2024 Teva settlement
  - *Coalition* Litigations
- **Free Product Programs, "Bridge" Programs and "Seeding"**
  - Initiating long-term therapy that will eventually be billed to federal programs
- **Travel and Lodging Support**
  - Trying to eliminate non-clinical barriers to access, i.e. the need to travel to and stay near a specialized center to get advanced therapies
- **Newer Support Categories**
  - Patient testing/screening programs
    - QOL Medical and its CEO agreed to pay $47 million to resolve allegations that free breath testing services were offered to induce claims for the drug Sucraid
  - Fertility preservation support
    - *Vertex* litigation (DDC, March 2025, appeal pending)

Practical Guardrails for PSPs

Document the Rationale

When changing or expanding program offerings, document the “why” in real time; ensure program offerings continue to operate consistent with their original intended purposes.

Compliance and Monitoring

Maintain written SOPs and compliance protocols **and** active and/or passive monitoring as appropriate to the risk level of the activity.

Safeguard Clinical Independence

Avoid “marketing” of patient support services; consider what kinds of interventions or engagements are appropriate before/at the time of prescribing versus after prescribing decision has been made

Remember: whistleblowers remain a key source of information to the government in AKS/FCA cases, but with newer data and analytics, we will see more proactive enforcement

Digital and Social Media Advertising Risks

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Digital and Social Media Promotion

FDA NEWS RELEASE

FDA Launches Crackdown on Deceptive Drug Advertising

For Immediate Release: September 09, 2025

"Pharmaceutical ads hooked this country on prescription drugs," **Health and Human Services Secretary Robert F. Kennedy, Jr. said.** "We will shut down that pipeline of deception and require drug companies to disclose all critical safety facts in their advertising. Only radical transparency will break the cycle of overmedicalization that drives America's chronic disease epidemic."

Digital and Social Media Promotion

- FDA's September 2025 Letter to Industry raised several concerns with DTC advertising, especially via digital and social media:
  - "[C]an distort the patient-clinician relationship and create increased demand for medications regardless of clinical appropriateness."
  - "Violative ads can … fundamental alter patients' risk-benefit perception" about a drug, especially where "patients are not seeing a fair balance of the information regarding a drug product."
  - Companies' "increasing reliance on digital and social media channels, including undisclosed influencer promotion, has blurred the lines among editorial content, user-generated media, and pharmaceutical advertising," such that viewers do not always know they are looking at an ad.

Digital and Social Media Promotion

FTC issued Endorsement Guides in 2023, with a special focus on social media and influencers, including in the pharmaceutical promotion space

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

ıould be read in conjunction with the Health Products Compliance Guide (2022)

- FTC's goal is to ensure pharma companies' promotional communications are truthful, non-misleading, and supported by science
  - The relationship between the spokesperson and the seller of the product must be "clearly and conspicuously" disclosed in the advertisement
  - If the spokesperson says or implies they take or use the product, they must be a bona fide user
  - If the spokesperson is held out as an expert, they need to have that expertise

Digital and Social Media Promotion

- **FTC concerns about "pixel tracking"**
  - Patient-facing healthcare websites may have the ability to collect and track, and then sell or transmit sensitive patient information to third parties for use serving them targeted advertising
  - February 2023 GoodRX FTC Settlement. Not a pharmaceutical company but creates risks for pharma companies working with third-party platforms/vendors

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The Federal Trade Commission has taken enforcement action for the first time under its Health Breach Notification Rule against the telehealth and prescription drug discount provider GoodRx Holdings Inc., for failing to notify consumers and others of its unauthorized disclosures of consumers' personal health information to Facebook, Google, and other companies.

In a first-of-its-kind proposed order, filed by the Department of Justice on behalf of the FTC, GoodRx will be prohibited from sharing user health data with applicable third parties for advertising purposes, and has agreed to pay a $1.5 million civil penalty for violating the rule. The proposed order must be approved by the federal court to go into effect.

Digital and Social Media Promotion

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

- **FTC's Healthcare Task Force announced in March 2026**
  - Goal is coordinated and comprehensive enforcement across mergers and competition, investigations, and consumer protection actions
  - Task Force will also share information with DOJ and HHS
  - Companies may see more proactive multi-agency efforts and broader remedies

> As a first step, the Bureaus of Competition, Consumer Protection, and Economics, Office of Policy Planning and Office of Technology will form a Healthcare Task Force. Through the Task Force, the agency's teams will share knowledge, resources, third-party sources, market intelligence, case leads, and relationships with other agencies and stakeholders.

Beyond Regulatory Risks

- Product liability risks associated with widespread DTC marketing that does not disclose safety risks adequately or overstates efficacy – and erodes the learned intermediary protections
- Independent FCA liability based on misstatements/failures with respect to patient data usage and data protection – possibility of non-AKS related "false claims" as predicates for FCA liability
- State consumer protection and consumer fraud laws may create a patchwork that is challenging to negotiate in the context of a national/global social media based promotional campaigns
- Third party risks – consider how best to vet the many websites, platforms, vendors the company may work with to interact with HCPs and patients and/or to promote the product. Not every risk is obvious at first.

AI in Healthcare: New Risks

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Examples of Patient-Facing AI

Chatbots

Many kinds of patient portals use integrated chatbots to gather information, answer questions, and/or serve up appropriate content.

Personalized “Coaching”

Can leverage AI to interpret data from wearables or other sources to coach patients managing chronic conditions.

Virtual Health Assistants

Can help track and share with providers information about treatment results, side effects or symptoms

Patient Education

Can summarize medical information or instructions to help patients understand their diagnosis and treatment.

Sources of Legal Risk in Patient-Facing AI

Inaccurate or Misleading Information

If AI-generated content is inaccurate or misleading, depending on the nature of the content, there are myriad legal risks ranging from FDA advertising and promotion risks to FCA issues to consumer protection to products liability.

Eroding or Undermining Doctor-Patient Relationship

Infringing the “learned intermediary” places companies at heightened risk if AI delivers bad medical advice or interferes with clinical decision-making.

Privacy, Privacy, Privacy

Many state and federal laws address health data use and data protection failures by companies – including those caused by their affiliates/vendors.

Cross-Cutting Risks

AI is a newer technology but all the areas of legal risk implicated by patient-facing activities remain the same.

States Seek to Create a Legal Framework

- Utah's Artificial Intelligence Policy Act (March 2024): disclosure obligations on entities using generative AI in high-risk interactions involving health data or personalized health recommendations
- Colorado's AI Act (May 2024): governance requirements around algorithmic discrimination and documentation for high-risk AI use cases
- California's Attorney General advises (Jan 2025) consumer protection laws, including the UCL, apply to healthcare entities that develop, sell, or use AI systems in patient-facing contexts
- California AB 489, effective January 1, 2026, prohibits developers and deployers of AI systems from using terms or design elements that mislead users about the nature of AI-generated interactions

GLP-1 Enforcement: A Case Study

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GLP-1s Illustrate Converging Risks

Regulatory Enforcement Actions

Multiple agencies targeted misleading marketing, telehealth prescribing, and compounding pharmacy practices simultaneously.

Consumer Protection Measures

State attorneys general used consumer protection laws to close clinics selling unapproved or research-grade GLP-1 products.

Compounded Risk Exposure

Advertising, distribution, pricing, privacy, and product liability risks intersect creating high exposure for companies.

Key Lessons from GLP-1 Enforcement

Regulatory Scrutiny and Risk

High commercial opportunity in GLP-1 products attracts strict regulatory scrutiny and inherent high risk.

Transparency and Compliance

Claims need substantiation, pricing must be transparent, and data practices should comply with privacy laws.

Multi-Regulator Evaluation

Multiple regulators may evaluate the same conduct from different legal perspectives simultaneously.

Enhanced Review as Baseline

Enhanced medical, legal, and regulatory review is now a baseline expectation, not optional.

Key Takeaways

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Date	Action / Event	Key Details
Mar 20, 2025	**EO 14243 — Eliminating Information Silos**	Directs agencies to grant full access to unclassified records for fraud detection; rescinds data-sharing barriers within 30 days; access to state-program & third-party databases
Sep 9, 2025	**Presidential Memo + FDA DTC Ad Crackdown**	HHS/FDA enforce FDCA ad provisions; thousands of warning letters + ~100 cease-and-desist; AI tools deployed for ad surveillance
Jan 8, 2026	**DOJ National Fraud Enforcement Division Announced**	Broad mandate covering fraud against federal programs & citizens; FBI deploys forensic accountants & data analytics
Jan 12, 2026	**Record FCA Recoveries (FY 2025)**	$6.8B total (highest ever); $5.7B from healthcare; record 1,297 qui tam lawsuits
Feb 27, 2026	**CMS "CRUSH" RFI**	Request for Information on new regulatory tools to detect/prevent healthcare fraud
Mar 6, 2026	**EO on Cybercrime and Fraud**	Targets healthcare fraud by transnational criminal organizations; prioritizes cyber-enabled fraud prosecutions
Mar 16, 2026	**EO 14395 — Task Force to Eliminate Fraud**	Chaired by VP Vance; ~12 agencies; mandate: eligibility verification, pre-payment controls, inter-agency data sharing; 30/60-day compliance deadlines; AG to promote qui tam enforcement
Mar 20, 2026	**FTC Healthcare Task Force**	Dedicated task force for "coordinated, integrated" healthcare enforcement
Mar 30, 2026	**FinCEN Advisory + Whistleblower Program**	Advisory on TCO exploitation of Medicare/Medicaid; proposed whistleblower payment rule; 20% increase in healthcare SARs YoY
Apr 7, 2026	**NFED Formally Established**	Stand-alone DOJ division; consolidates HC Fraud Unit, Tax Section, Market Fraud; creates National Fraud Detection Center (proactive, multi-agency analytics); 8,000 active cases
Apr 17, 2026	**NFED First-Week Results**	$340M in enforcement actions in first operational week
Apr 30, 2026	**West Coast Strike Force**	DOJ strike force for AZ, NV, northern CA healthcare fraud; additional $91M MN Medicaid deferral
May 13, 2026	**Nationwide Enforcement Day**	$1.4B home health/hospice funding suspended; $1.3B CA Medicaid deferrals; new Medicare hospice enrollment halt; MFCU audits in all 50 states
May 21, 2026	**Strike Force Expansion**	15 additional prosecutors for Medicaid fraud; 15 defendants charged in MN ($90M+ fraud)

Risk Mitigation Priorities

Patient Support Program Design

Design patient support programs following Anti-Kickback safe principles to mitigate compliance risks effectively.

High-Risk Marketing Categories

Treat direct-to-consumer and telehealth marketing as heightened-risk areas requiring strict oversight and controls.

Careful Management of DTC Digital Platforms

Embed privacy-by-design principles into all digital health platforms to protect patient data and ensure regulatory compliance.

Proactive AI Governance and Reviews

Establish proactive AI governance with thorough medical, legal, and regulatory reviews.

Big Data

Big data is available to the government for cross-agency collaboration on investigation and enforcement. Companies **must** use their own data in a similar sophisticated way to identify risks, develop mitigations, and monitor for compliance.

Thank You!

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Promotional Review Panel Discussion: DTC Advertising & Social Media

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Networking Coffee & Lunch

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