Fall 2026

TWENTY-SEVENTH ANNUAL
PHARMACEUTICAL AND MEDICAL DEVICE
ETHICS AND COMPLIANCE CONGRESS

THE DEBRIEF

OCT 13 - 16, 2026

WASHINGTON D.C.



SPECIAL EDITION

INSIGHTS FROM

THE PREMIER

LIFE SCIENCES

COMPLIANCE CONGRESS

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Congress BINGO

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WELCOME

It is a privilege to present *The Debrief* for the 27th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress ("Congress"). This is my fourth year covering the Congress, and I have been part of this event as a presenter or attendee for at least the past 15 years. It is always a thrill to be in Washington DC for this event.

Last year, the government shutdown kept most agency speakers away. This year, OIG, the DOJ Civil Division, and the DOJ Criminal Division all returned to the main stage. For compliance professionals who count on those annual updates, it was good to have them back.

The Congress also tried something new. For the first time, it opened on Tuesday afternoon with five half-day Focused Sessions on hot topics. That afternoon came before the full program of plenary sessions began. The format allowed deeper discussion of issues in areas such as investigations, medical and commercial interactions, government pricing, privacy, and AI. The agenda also included 52 mini summits on topics from first product launches and rare disease to sponsorships and relationships with specialty pharmacies.

This year, data came up in nearly every session. Enforcement is shifting toward data miners and analytics, and the government can often see patterns in a company's data before the company does. Panelists urged compliance teams to know their own data first. The AI conversation also matured. Attendees moved past which tools to use and focused on governance, measurable value, and the role of human judgment.

The Debrief highlights each of the Congress' plenary sessions and select mini summits. It's written to be actionable, so you won't just read about topics. You'll find practical ideas to implement at your company and, ultimately, strengthen your compliance program.

As do each of the Congress presenters, I, too, provide my disclaimer. The following pages are my interpretation of what I heard at the sessions and from the speakers and are in no way intended as my advice. Others who attended the Congress may have different takeaways. That is to be expected, since everyone's compliance program and circumstances are different.

Strategic Versatility's commitment is to equip life sciences organizations with the tools and knowledge they need to build and evolve their compliance programs. Educating on important topics like this is a meaningful step in that mission. Whether you're refining your existing program or embarking on a new compliance journey, I am pleased to share these insights with you.

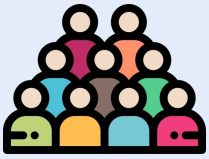
Amy P.

Amy Pawloski,
President, Strategic Versatility

BY THE NUMBERS

The 27th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress was held at the Washington Hilton. The Congress brought together Compliance and Legal professionals, regulators, prominent thought leaders, and vendors to discuss Compliance topics in the life sciences industry. The Congress is produced by Global Health Care, LLC (GHC). Here's who attended in 2026.

Overview



708

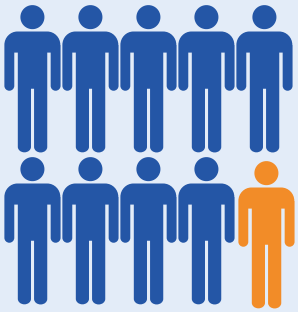
Total Attendees



163

Pharmaceutical and Medical Device Companies Represented

Company Attendees



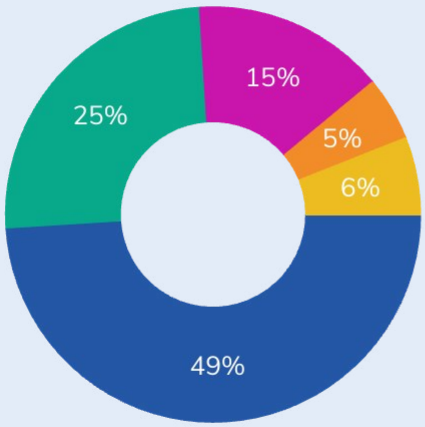
90% Pharma/Biopharma/Biotech

10% Medical Device

48%

Director-and-Above Industry Registrants

Attendees by Org Type



- Pharma/Biopharma/Biotech
- Consultant/Industry Partner
- Law Firm
- Medical Device
- Other

THEN VS. NOW

A year can change a lot in life sciences compliance. Some topics carried over from last year's Congress, some took a new direction, and others appeared for the first time. This side-by-side look shows how the conversation shifted from 2025 to 2026.

	2025 — 26th Congress | Oct 22–24, Grand Hyatt Washington	2026 — 27th Congress | Oct 13–16, Washington Hilton
Government Speakers	A government shutdown meant no keynotes from OIG, US Attorney's Offices, or FDA. DOJ's Acting Criminal Division head still joined a fireside chat.	Government keynotes returned. OIG, DOJ Criminal, and DOJ Civil all took the stage, and the agenda also included CMS and FDA. Ms. Riordan noted her last update to this group was in October 2024.
Criminal vs. Civil	The Investigations panel expected a civil focus, with fewer criminal cases unless there is extreme wrongdoing.	DOJ reported four corporate criminal health care fraud matters so far, tying last year's record. It expects to exceed that record before year end.
Data	DOJ described a new data fusion center to strengthen fraud detection.	The National Fraud Detection Center now drives cases. DOJ Civil described its FOCUS initiative for data miners who file qui tams.
Self-Disclosure	Examples cited: Liberty Mutual (FCPA), Troy Health, and Kimberly-Clark.	A department-wide Corporate Enforcement Policy. Civil multipliers of 1.1 (Dompé) and 1.5 (Traditions Health). DOJ Criminal's advice: lay down a marker, then investigate.
Market Access	The New Patient-Centered Business Models panel focused on telehealth, digital tools, and keeping sales and marketing out of patient support. Pfizer for All was one example.	The Market Access panel turned to PBMs, GPOs, health systems, and specialty pharmacies. The Veloxis allegations of sham data arrangements and sham patient adherence services were a key example.
Risk Areas	Speaker programs, sampling, and "mission creep" in field reimbursement roles.	Wound care and skin substitutes came up across sessions. OIG noted an uptick in settlements and criminal resolutions involving skin substitutes.
AI	The conversation moved from "what if" to real use cases: speaker program monitoring, communications review, policy chatbots.	The focus turned to human in the loop and proportionality. DOJ asks whether compliance has the same data and tools as the business. It warned about compliance teams working with "the equivalent of spreadsheets."
Trade Associations	MFN pricing proposals, tariffs, and FDA changes, including the pause on new applications.	MFN pricing and tariffs remained a focus. Newer items included FDA user fee reauthorization and direct patient sales programs.

MEDICAL & COMMERCIAL INTERACTIONS

For the first time, the Congress opened with an afternoon of focused sessions on October 13, ahead of the full Congress program and plenary sessions. The format provided time for deeper discussion of specific topics. I was fortunate enough to attend the sessions on medical and commercial interactions, as this is a hot topic with a number of my clients.

Medical and commercial teams operate within the same company, yet their responsibilities require different controls. The discussions at these focused afternoon sessions explored how to maintain those distinctions as companies pursue more coordinated strategies and introduce specialized field roles. Speakers described a movement away from the extreme separation that followed earlier enforcement actions, while emphasizing the continuing need to protect independent medical decisions.

> A medical title does not itself establish that an activity is nonpromotional.

The rationale for independence remained central. In the legal discussion, one speaker distinguished risks associated with communications from those associated with remuneration, such as research arrangements and other transfers of value. Medical personnel may undertake activities subject to different controls from those governing commercial colleagues. The assessment therefore depends on what they do, why they do it, and the surrounding circumstances.

Align on Strategy, Examine the Decisions Beneath It

Speakers discussed alignment on broader strategy, with medical and commercial retaining responsibility for their respective tactics and budgets. One panelist illustrated this through preparation for a label expansion. Both functions understood anticipated data readouts, conference activity, and the expected approval timeline. Medical independently established criteria for additional KOLs and planned its activities; commercial separately developed targeting, segmentation, and its approach to the market. Access to unpublished data was restricted, with documented reasons for commercial personnel who needed access.

The strategy vs. tactics boundary and distinction is sometimes still a grey area. Who participates in a planning conversation, the level of detail shared, and the influence of budget decisions can affect independence and should be considered. Speakers distinguished discussions between functional leaders from those involving individual field personnel. They also emphasized what happens when medical rejects commercial input. A documented decision has limited value if each refusal triggers escalation until an exception is granted.

Customer experience provided a practical reason for coordination. One panelist described allowing personnel to see that another function had visited an HCP without providing access to the substance of an individual medical discussion. Higher level medical insights could be shared through a separate process. The example distinguished awareness of company activity from access to information generated through scientific exchange.



AI Notetaker Example

A strategy meeting may separate medical and commercial participants for particular segments, yet an automated note taker could capture the entire meeting and circulate a combined summary to everyone.

- One panelist used this example to show how a new tool can undermine information controls without anyone intending to cross a boundary

MEDICAL & COMMERCIAL INTERACTIONS (CONT'D)

Expanding Field Roles Require Ongoing Governance

The field roles discussion traced how more complex therapies and treatment pathways have expanded the expertise companies deploy. Reimbursement requirements, specialty pharmacy coordination, diagnostics, and institutional decision making can involve stakeholders well beyond the individual prescriber. Examples drawn from job postings included strategic account managers, patient access liaisons, thought leader liaisons, and medical roles serving population level decision makers. These positions introduced questions about office support, patient information, overlapping responsibilities, and coordination with existing teams.



Panelists described beginning with the business need and intended responsibilities before a job description is published. Subsequent steps included aligning affected functions, assessing how existing policies apply, establishing practical business rules, and reviewing compensation. Leadership agreement was particularly important where different people held different views of what a role was supposed to accomplish. One participant noted that questions raised during these discussions can even help define the role itself.

Inside the Room

A patient access liaison (PAL) job description shared on the big screen in the room led to an engaging audience discussion and questions about reimbursement assistance, office support, and influence on prescribing.

Participants described company approaches that made support available after a prescription, limited sales involvement to identifying the resource, and required hub enrollment and privacy consent before patient contact. They also discussed where in an organization some of these newer roles sit.

Audience members also discussed challenging whether assistance could replace work ordinarily performed by practice staff (especially in light of the recent Texas ruling).

That work continues after hiring. One panelist described nurse educators whose responsibilities expanded from educating practices to educating patients about product use. The change introduced additional consent, privacy, and data security considerations. Compensation changes also warranted continuing review, particularly where measures for noncommercial personnel could become more closely connected to prescriptions or fill rates.

Joint Interactions Need a Defined Purpose

Limited customer time was a frequent argument for joint meetings. Panelists described arrangements for institutional and C-suite customers with defined purposes and separate portions for different functions. One approach had medical personnel leave before contracting discussions; another had account managers leave before the medical presentation or questions. Speakers emphasized identifying the contribution required from each participant.

The legal discussion addressed the difficulty of extending a narrowly designed arrangement to other circumstances. An approach developed for a payer or institutional customer can become a precedent for requests involving smaller practices or individual prescribers. Maintaining the original conditions, and recognizing when those conditions have changed, creates an ongoing governance challenge.

MEDICAL & COMMERCIAL INTERACTIONS (CONT'D)

Make the Boundaries Usable

Participants described handbooks and training that explain how specific field roles can interact with one another. One panelist paired a handbook of do's and don'ts with scenarios in which different characters represented different field functions. An audience participant described a "Ways of Working" document for each field role, with a section that listed every field function and addressed permitted interactions, including who could attend conferences and participate in particular activities. These resources gave employees a way to understand how the rules applied across an expanding set of colleagues.

Monitoring perspectives differed. One panelist questioned how much a ride along reveals when employees know compliance is observing and suggested examining patterns in medical insights and CRM information over time. Another described field visits as useful opportunities to identify misunderstandings, provide immediate coaching, and understand operational pressures. The discussion presented both longitudinal review and direct observation as ways to examine how boundaries work in practice.



Let's Talk Football (...and not about the Philadelphia Eagles)

"Stay in your lane" can sound isolating, particularly when employees are also being encouraged to collaborate. One panelist described how she replaced that message with a football themed compliance training that explained how distinct field roles contribute to the same team.

Just like different positions on a football team, with limits on when each could participate and what each could do, it was the same with the various field roles. Some players could enter only at certain points in the game. The training also incorporated penalties like they have in football for offenses.

The football analogy gave employees a more concrete way to understand collaboration. Being on the same team does not mean every player belongs on the field for every play. Participation depends on the situation and the role needed at that moment. Each position has a purpose, and effective coordination requires people to understand their own responsibilities and those of their teammates.

The panelist acknowledged that she had considered whether the team metaphor might blur the distinctions she needed to reinforce. She chose it as a way to explain those distinctions through specific roles and rules. Good news, too ... she reported an enthusiastic response from employees about the training.

SMALL & EMERGING LIFE SCIENCES COMPANIES

This optional lunch session on the first plenary day of the Congress was worthwhile for understanding challenges faced by smaller companies. Building a compliance program at a small or emerging company calls for different choices than at big pharma. Jeffrey Kawalek, MBA, Chief Compliance Officer at Zambon, and Greg Demske, JD, Partner at Goodwin Procter and former Chief Counsel at HHS OIG, led the session. When Mr. Kawalek asked for a show of hands, many attendees in the room said they run compliance programs of one or fewer than five people.

Mr. Demske called leadership messages that invite questions and encourage speaking up a "low cost, high return" measure. Leaders signal their values through how they communicate and run the company. Compliance officers can work with the CEO on ways to deliver that message, including in meetings that aren't about compliance.

Other simple steps include:

- A short policy that requires employees to report possible violations
- A seat on interview panels for senior hires, since every hire shapes culture
- A slide or two of compliance content added to existing training

What Makes Small Different

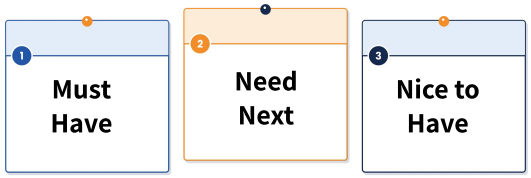
Mr. Kawalek said small companies rely more on vendors, outside counsel, and manual processes. Employees wear many hats. Some hold senior titles with less experience behind them, which affects how training should be built. A single departure can leave gaps, so transition plans and document retention matter.

How Regulators See It

Mr. Demske said regulators do take size into account. OIG's General Compliance Program Guidance includes a section on smaller entities. DOJ's Evaluation of Corporate Compliance Programs also considers size and resources. Compliance still can never be zero. A contemporaneous record of the company's biggest risks, and why it set its priorities, carries weight if the government later asks.

Three Buckets

Mr. Kawalek sorts program needs into must haves, things the company needs but can wait on, and nice to haves. When the budget falls short, he lays out the cost and lets the Compliance Committee and/or Board decide whether to accept the risk.



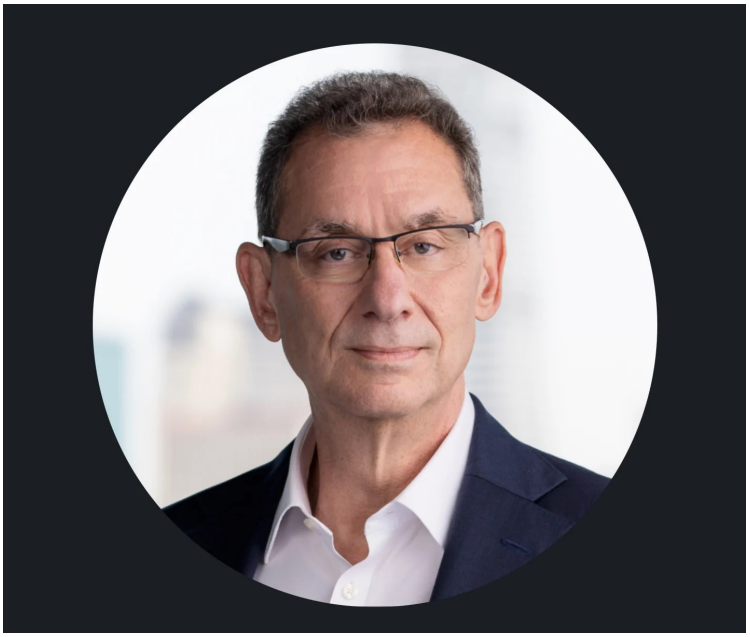
Speed and Relationships

Mr. Kawalek described a press release that went out at his company within hours. At a large company, it would take about a month. Mr. Demske said leaders need to accept that a short delay is worth it to avoid risk. He also urged compliance to build relationships with leaders early, before a product is commercial. Mr. Kawalek added that consultants' policies and risk assessments still need careful review and customization.

Finding Issues Without a Busy Hotline

Hotlines get fewer calls when anonymity is hard to keep. Mr. Kawalek found that formal compliance exit interviews have surfaced many of the issues he handles. Compliance questions can also be built into HR's exit interviews.

VIRTUAL C-SUITE KEYNOTE



"I've learned trust is built in drops and lost in buckets."

- Albert Bourla,

Pfizer Chairman & CEO

The 27th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress plenary sessions opened with a virtual message from the top of one of the industry's largest companies. Albert Bourla, DVM, PhD, Chairman and Chief Executive Officer of Pfizer, welcomed attendees by video.

Leadership Sets the Tone

Peter Brensilver, Pfizer's Senior Vice President, Chief Global Commercial Compliance and Risk Counsel, introduced the video. Compliance professionals shape culture, design risk solutions, and raise hard questions that take courage. Business leaders matter even more, Mr. Brensilver said, because they set the tone and role model behavior. They also decide whether compliance gets a seat at the table and the resources to do its work. He pointed out that good leaders understand that "innovation and integrity are not conflicting. They go together, and they need one another to be successful."

Trust as a License to Operate

Dr. Bourla built his remarks around one word: trust. He called trust "our industry's license to operate." He described an industry with growing need. Cancer touches too many families, chronic disease is rising, and the population is aging. He said the industry has never been better positioned to respond, because biology and AI together are revealing new insights into disease. Innovation alone is not enough, he said. It needs a foundation of trust with patients, healthcare professionals, regulators, investors, and society. "Our challenge is to move faster responsibly."

Skills for the Next Five Years

Dr. Bourla said the skills the industry will need are "still being defined," but there are three areas that will matter:

- Fluency in data
- AI governance
- Transformational technologies

"I do not see compliance as separate from the business. It's an enabler of sustainable innovation."

- Albert Bourla, *Pfizer Chairman & CEO*

OIG UPDATE

She's back! We were excited to see Mary E. Riordan, JD, Senior Counsel to the Inspector General at the HHS Office of Inspector General, return this year to give the annual OIG keynote. This was her first Congress appearance since October 2024 because the government shutdown kept her away last year. Ms. Riordan started off her keynote by talking about recent changes at OIG and noting that the Office of Counsel has been hiring, so companies may soon work with new people in the industry guidance branch and on FCA investigations.

Kickbacks Are Still a Big Issue

Most of the matters Ms. Riordan reviewed involved kickbacks. As always, she reviewed cases from the past year.[1]

COMPANY	MATTER
Veloxis Pharmaceuticals	Kickbacks, False Claims Act, and Sunshine Act reporting
Dompé U.S.	Kickbacks through copay assistance from patient assistance foundations
Takeda Pharmaceuticals	Speaker program kickbacks
EyePoint Pharmaceuticals	Kickbacks to ambulatory surgery centers through assurance program & free samples
Aesculap Implant Systems	False claims for knee implants that failed prematurely, kickbacks to a surgeon, and distribution of devices without FDA clearance
Semler Scientific and Bard Peripheral Vascular	False claims from Medicare reimbursement representations for PAD testing

Look Beyond the Sales Force

Ms. Riordan said compliance programs have historically focused on sales representatives. In Veloxis, many of the people implicated worked in market access, the group responsible for insurance coverage and access. The Veloxis CIA deliberately uses the term "field personnel" so that monitoring and review reach beyond the sales force. She encouraged companies to identify everyone who regularly works with HCPs, institutions, or others who purchase or recommend products. That includes people who work on formulary and protocol activities.

"Dry Topic"

Ms. Riordan urged companies to make sure they report drug pricing data accurately and on time. Companies also need to pay the correct Medicaid and inflation based rebates. Errors can lead to FCA or CMP liability, and she is currently handling several whistleblower cases in this area. "It's a rather dry topic...it's not exciting, but it's really important."

Oversight Expectations Move Into CIAs

In 2026, OIG began adding leadership recommendations from its 2023 General Compliance Program Guidance to new CIAs as standard provisions. Compliance officers should have the standing to deal with other senior leaders as equals. They should report to the CEO or board and have direct access to the board. They should not report to the general counsel or CFO, and ideally compliance should be their only responsibility. Compliance committees should include operational and support leaders and meet quarterly. They should also run the risk assessment program, which is a new CIA requirement. Each member's participation should count in performance and compensation reviews.



[1]Note that each case Ms. Riordan reviewed was covered in SV Publications' The Compliance Debrief over the past year and are available on the subscriber website.

OIG UPDATE (CONTINUED)

Reminders from Mary Riordan

01 Revisit HCP Arrangements

Consultants and ad boards still need attention. OIG's 2020 Special Fraud Alert continues to be a useful resource for speaker programs. The Veloxis CIA includes speaker program provisions that may help in setting guardrails.

02 Review Patient Assistance Foundation Donations

Look at the basis for each donation and the process followed. Watch the communications and data that pass between the company and the foundation.

03 Question Specialty Pharmacy Arrangements

For data services, ask what data the company receives, what it does with that data, and what services are actually provided. The Veloxis CIA includes monitoring provisions for specialty pharmacies.

04 Watch Kickbacks and Remember Open Payments

Kickbacks remain the basis for many settlements and can arise in arrangements with many kinds of entities. Also remember that payments to HCPs can create Sunshine Act exposure as well as kickback risk.

05 Look at the Program with Fresh Eyes

Evaluate it regularly and objectively. Consider less common risks such as manufacturing quality and the tracking and reporting of AEs. Make sure any coding and billing advice given as part of sales practices is accurate.

06 Extend Guardrails to the Right Groups

Confirm that controls cover every business unit and field role that deals with customers. In Veloxis, many of the people implicated worked in market access.

07 Address AI in the Compliance Program

Recent CIAs ask companies and independent review organizations whether they used generative AI. If they did, they must certify that they checked the accuracy of the output.

08 Verify Effectiveness

Use ride alongs and review expenses, travel, meals, samples, consulting arrangements, advisory board materials, call notes, emails, and texts. The Veloxis examples included padded attendee lists on expense reports and consulting invoices that were paid despite internal texts about "massive overbilling."

DOJ CRIMINAL DIVISION UPDATE

This year, the Congress welcomed Jacob Foster, JD, Deputy Assistant Attorney General for Health Care, Public Trust & Financial Integrity in the National Fraud Enforcement Division (NFED). He has spent 10 years in the unit and pioneered its use of data analytics. Gary F. Giampetruzzi, JD, Partner and Global Chair of Life Sciences at Paul Hastings, moderated.



A Bigger Footprint

Mr. Foster said the division's recent directives, including Directive 26-12 on corporate enforcement, are a roadmap for the next generation of health care fraud cases. The Fraud Section became a division this year, and the unit gained 15 prosecutors. He also said the unit already has four corporate criminal matters this year, which ties last year's record, and he expects to pass it.



Directive 26-12

Directive 26-12, issued October 1, tells prosecutors to give great weight to factors such as 25 or more victims, $25 million or more in loss, three or more districts, and conduct lasting three or more years.

Mr. Foster called the list a practical compliance tool. It helps separate one rep's isolated failure from a systemic practice.



Data Is a Lead

The new National Fraud Detection Center pulls together data that sat in separate silos across government. That includes CMS claims, Treasury and border records, and even online reviews. Mr. Foster said data starts an inquiry, but prosecutors still have to corroborate it.

Whistleblowers now have a criminal path too. A tip that leads to forfeiture can earn up to 30% of the first $100 million.

> f you have a business side with revolutionary technology, but a compliance function that's operating based upon ... the equivalent of spreadsheets, that's something that we're going to look at.

Jacob Foster

On Compliance Keeping Pace With The Business

HUMAN-IN-THE-LOOP

By Wednesday afternoon, "human in the loop" had come up so often that both presenters and attendees were joking about it. This panel took the phrase seriously. It looked at where AI helps compliance teams, where it falls short, and what real human oversight requires. Marci Juneau, a Founding Partner at HELIO, moderated. She was joined by Rajiv Mehrotra, MS, Senior Vice President, Data Science, at HELIO; Rawan Fusisi, Director, Integrity & Compliance, at Indivior; and Jason DiPietro, Compliance Innovation & Analytics, at Lundbeck.



NEXT GEN COMPLIANCE

Years ago, one company invested heavily in a centralized system to pull all its data together. It then shut the project down. The company had no plan for what to do once the alerts started coming in. That lesson framed this Wednesday afternoon panel on how compliance can use more data without drowning in it. Robert Melillo, JD, Co-founder and Managing Director of G&M Health, moderated. He was joined by Lindsey LaMoria Gavin, Senior Director and Deputy Compliance Officer at Lundbeck; Al Park, Senior Compliance Officer, Global Monitoring, Auditing and Third-Party Risk Management at Jazz Pharmaceuticals; and Asha Natarajan, Counsel at Arnall Golden Gregory and former attorney in the DOJ Civil Fraud Section.

How do you avoid thousands of new alerts?

Start with the decision you want to improve and work backward. Start small. Outliers do not tell the full story, and one exception is not a trend. Dashboards should be easy for business partners to understand. A wall of charts can leave them lost.

How does more data change the relationship with the business?

Compliance can now spot trends before they become problems. HCP meal spend was the example given. By the time Open Payments data is compiled in March, it is too late to act. The business often has the same data but does not look at it the same way. The discussion also stressed mapping where data lives, which third parties are involved, and whether it is protected or regulated. Compliance should also stay involved as those sources change.

How does compliance avoid looking like the police?

Employees who act out of fear may get better at hiding what they do. The panel recommended being open about what compliance is trying to achieve, then following through. Look for broader patterns and ask why a rule keeps getting broken. Often the cause is a missing or broken tool, or a training gap.

If you can monitor something, should you?

If commercial teams have spend data in their own dashboards, the government may ask why compliance did not use it. Compliance still cannot look at everything. The panel described a scope grounded in the risk assessment that is revisited periodically and leads to action. From the government's view, think like an investigator handling a subpoena or civil investigative demand. If patterns suggest a kickback, consider voluntary disclosure.

Who owns what, and what skills does compliance need?

Compliance is a shared responsibility. Sales managers can handle day-to-day oversight while compliance looks at broader patterns. Compliance teams increasingly include people with marketing, consulting, audit, and law enforcement backgrounds. Compliance should also partner with IT, data governance, and analytics groups. In one example, a platform upgrade changed a drop-down chatbot to free text, and the company did not notice.

INTEGRATED RISK

A decade ago, compliance teams aimed to be best in class. Today the conversation focuses on value, and it is hard to define. This Wednesday afternoon session asked two questions. What should compliance do differently, and how should it show its worth? Michael Reyes, Director, Risk and Regulatory Consulting at PwC, moderated. He was joined by Brian Riewerts, MPA, Partner, Pharmaceutical and Life Sciences Risk and Regulatory Leader at PwC, and Jonathon L. Kellerman, Global Chief Ethics, Compliance and Privacy Officer and Global Head of Business Transformation at Bausch + Lomb.

CASE FILE 01

Data at the Center

Panelists agreed that data must be central to an integrated risk framework. One company replaced its traditional compliance model with a hub and spoke design. Data sits at the center. Policy, training, monitoring, and audit work all start from that data.

CASE FILE 02

Down to the Studs

At one company, procurement began adding AI tools to fix its piece of a troubled source to pay process. The work was stopped because the process needed to be fixed before AI was added. The company is now redesigning the full process with an enterprise view. Compliance, finance, and procurement each build in their own controls. The lesson: Putting good AI into a broken process was described as the worst thing you can do.

CASE FILE 03

Value to the Business

Real-time monitoring of transactions found that one region had spent ~$1 million on speaker programs with <= 5 attendees. Compliance raised it to the business as not only a potential compliance issue but also as low-value spend. The business had not noticed. The head of commercial later credited compliance in front of the board and executive team, and compliance helped redesign the process. Rebuilt processes have since led to fewer violations and outliers. Bottom line = show value to the business.

THE BIGGER PICTURE

Cost pressure is pushing companies toward integrated risk. A lot of companies can no longer afford separate risk assessments and audits in each function. Some are treating regulatory change management and monitoring as shared services across the enterprise. They reinvest the savings into higher-value work, which the panel called a "risk dividend." Pricing, gross to net, source to pay, and medtech inventory management were also named as areas where compliance can help the business recover revenue.

The Skill Set Ahead



- Business Ops - Understand how the business runs and how to improve its processes
- Data Analytics - Use data productively
- AI - Build a foundation in coding and in agent design and deployment

One company made AI training mandatory and tied it to bonuses. It also reimburses outside certifications [in AI] and now hires only people with at least one of the aforementioned three skills.

The panel also warned against getting stuck in "failure to launch," where AI pilots never reach production.

CCO FIRESIDE CHAT

Paul Silver, Partner at Deloitte, returned this year to moderate the closing session of the first plenary day, the CCO Roundtable, and his BlackBerry made another appearance. This year, he had three chief compliance officers joining him onstage: Terra Buckley, JD, Chief Compliance and Ethics Officer at Bristol Myers Squibb, Christine Gordon, JD, Vice President, Risk, Assurance, and Compliance and Chief Compliance Officer, Americas, at Olympus Corporation of the Americas, and Melissa T. Lozner, JD, Senior Vice President and Chief Compliance Officer at Regeneron.



Putting AI to Work

Compliance teams use tools like Claude and Copilot to produce first drafts and cut manual work. One company built an agent that drafts investigation reports from notes, which speeds up responses. Another uses AI to screen conflicts of interest. AI champions on each team and AI goals in annual objectives help drive adoption. People skills still matter, since employees and the field need someone to talk with about real situations.

Access Matters as Much as Reporting Lines

OIG guidance favors a CCO who reports to the CEO or the board. That reporting line can raise the stature of the whole function. Under a general counsel, compliance can end up competing with legal for budget and headcount. Any structure can work if the CCO has a seat at the table and direct access to the board and CEO. In some countries, equal titles for legal and compliance leaders also matter.

Avoid the Kitchen Sink

Compliance often gets new duties such as transparency, enterprise risk, or trade compliance. The core job is to prevent misconduct and detect it quickly. Accept new work only if the headcount comes with it. If you build something new, make sure you have an exit plan from the start which includes who will own it once it's done.

Connect the Enterprise

Compliance duties often sit across quality, trade, privacy, and other functions. A joint risk and compliance committee can give leaders one full view of risk. Compliance can also coordinate these areas for the board even when it doesn't own them. Few functions see as much of the company.

From Activity to Outcomes

Most boards still see activity metrics. Start by defining what each activity should achieve, then find the data to measure it. In one pilot, a company loosened a control on field product evaluations and tracked sales before and after. Fewer field questions on a topic can also count as an outcome. Never tell the board the program is perfect. Something new is always emerging.

DOJ CIVIL DIVISION UPDATE

Brenna Jenny, JD, MPH, Deputy Assistant Attorney General for the Commercial Litigation Branch of the DOJ Civil Division, spoke with Scott A. Memmott, JD, Partner at Morgan, Lewis & Bockius LLP. Ms. Jenny previously served as Principal Deputy General Counsel at HHS and Chief Legal Officer of CMS. She also spent years in private practice defending life sciences companies in False Claims Act matters.

Civil and the New Fraud Division

Ms. Jenny described a divide and conquer approach with the National Fraud Enforcement Division (NFED), which DOJ established in April. NFED has broader criminal tools. Civil will "remain laser focused on the civil False Claims Act." Speed was already a priority. Under the May 27, 2026 benefits fraud memo, DOJ reviews qui tams involving state-administered federal programs within 60 to 120 days. Any extension needs her approval.

C2A Dismissals*

The September 2026 Justice Manual revision lets DOJ seek dismissal of *any* meritless qui tam. Before, the case had to be meritless "facially." Ms. Jenny does not expect a big shift, because she said the revision largely reflects current practice. She said the dismissal count understates the activity. When DOJ explains that a case lacks merit, savvy relators' counsel often dismiss voluntarily. Pressure tactics don't work.

> "Just because you're going to make it difficult for us doesn't mean we're going to walk away."

Guidance and Self-Disclosure

The Justice Manual revision also restores limits on subregulatory guidance. Awareness of a guidance document is not an admission that its interpretation is correct. Ms. Jenny encouraged companies to raise unlawful guidance with the agency directly.

Civil-only FCA issues should be self-disclosed to the Civil Fraud Section. To show what self-disclosure is worth, Ms. Jenny pointed to two settlements from this year. Traditions Health resolved its matter at a 1.5 multiplier, and Dompé resolved at 1.1. [A multiplier is the amount paid compared with the government's losses, so a lower number means a smaller payment.] Both settlement agreements describe in detail what each company did to earn cooperation credit. Ms. Jenny said DOJ includes that detail on purpose. It gives other companies concrete evidence that self-disclosure pays off.

~1 in 5

Qui tams in which DOJ recovers money (Ms. Jenny's benchmark)

FOCUS on Data Miners

Ms. Jenny estimated that DOJ recovers money in "a little more than one in five" qui tams overall. If a data miner's cases recovered in only one in 20, she said, that would be "a materially weaker pool." Under FOCUS, DOJ will prioritize data miners whose signals reliably point to fraud.



**A C2A dismissal is shorthand for the U.S. government's dismissal of a whistleblower lawsuit under the False Claims Act, pursuant to 31 U.S.C. § 3730(c)(2)(A). It allows the Department of Justice to seek dismissal even when the whistleblower objects.*

INVESTIGATIONS, ENFORCEMENTS, AND PROSECUTIONS

Our friend, Kip Ebel, MBA, Principal, Forensic & Integrity Services at EY once again this year moderated a roundtable with three former government lawyers who explained how government data, whistleblowers, and quality failures can turn a compliance issue into an investigation.

- Jennifer L. Bragg, JD, Partner at Latham & Watkins and former Associate Chief Counsel for Enforcement at FDA
- Greg Demske, JD, Partner at Goodwin Procter and former Chief Counsel to the HHS Inspector General
- Preeya Noronha Pinto, JD, Partner at DLA Piper and former Acting General Counsel of HHS



Data Drives the Chain

Ms. Pinto called the government's use of data, including AI, a "game changer." In wound care, cases now start with provider audits and spread to distributors and manufacturers.

Mr. Demske urged companies to compare themselves with public data, including Open Payments, the way a relator would. Ms. Bragg added that many schemes still "need a story to be told" by insiders.

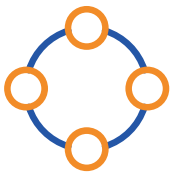
What Happened at Dompé and Vertex?



Ms. Bragg said Dompé self-disclosed and resolved civilly, but still made extensive admissions. She saw three problems:

1. Too much data sharing between the foundation and the company
2. Budget changes at undefined intervals that appeared tied to that data
3. Firewalls and guardrails that existed on paper but weren't followed

Mr. Demske discussed the D.C. Circuit's September Vertex decision. The court read the Anti-Kickback Statute broadly. It also sent OIG back to explain why the "promotes access to care" exception didn't apply. He sees that exception as a possible future path for more patient support programs.



Self-Disclosure Is Still a Hard Call

The panel didn't fully agree on how much self-disclosure buys.

- Ms. Bragg offered that disclosure is not yet a "no-brainer." Decisions often come before the facts are complete.
- Mr. Demske said FCA exposure is the real risk for life sciences companies, because DOJ has rarely charged operating companies criminally. He called Dompé's 1.1 multiplier "a positive outcome." A standard civil benefit like that would drive more disclosures.
- Ms. Pinto pushed back: "I'm seeing a little bit more criminal activity, even at the corporate side. So just stay tuned."

What to Watch Next Year

Ms. Pinto	Mr. Demske	Ms. Bragg	Mr. Ebel
In wound care, watch the discount safe harbor, the use of sales reps, ASP reporting, and bona fide service fees.	*Kickbacks "in all shapes and sizes." He also hopes for a clear civil self-disclosure benefit and more dismissals of meritless cases.*	*More FDCA settlements, especially for medical devices.*	*Your own AI tools can create risk, so include them in your risk assessment.*

INDUSTRY GROUPS

Mark C. Scallon, MHA, Principal, Risk Advisory, Life Sciences Consulting, Compliance and Ethics Market Leader at Baker Tilly, moderated the annual trade association update. He was joined by Julie Ritchie Wagner, JD, Assistant General Counsel at PhRMA, and Ida Nassar, JD, Vice President and Assistant General Counsel, Ethics and Compliance at AdvaMed. (John Delacourt of BIO was scheduled but unable to attend.)

PhRMA

- MFN pricing remains the top issue. Recent developments include agreements between individual manufacturers and the administration, the TrumpRx website featuring company direct patient programs, and the new GLOBE rule. New rebates tied to GLOBE are something to think about from a compliance perspective.
- PhRMA has worked to widen the drug pricing debate to include PBMs and insurers. Over the past year, Congress has paid more attention to their practices.
- The administration wants to bring early stage clinical trials back to the US. HHS's Operation TrialBlazer takes both an FDA and an OIG approach to supporting trials at home.
- Conflicts of interest in clinical research remain a hot topic. CMS, which spoke earlier at the Congress, plans to ramp up its Open Payments audits.
- PhRMA is running patient focus groups and surveys. An early finding is that patients want to feel integrity in their everyday experience with the industry.

AdvaMed

- AdvaMed is pressing for trade policy that strengthens supply chain resilience without raising costs or disrupting access to care.
- AdvaMed's policy teams engage FDA on approvals and CMS on reimbursement. AdvaMed sees agency changes as a chance to modernize and improve systems.
- CMS is focused on DME fraud involving fake provider and patient ID numbers. AdvaMed noted that the bad actors are not medtech companies. It is partnering with CMS to tell legitimate actors from illegitimate ones.
- More company CCOs are also becoming privacy leads. Changes such as new trade rules call on compliance to work across functions on processes, communication, and training.
- Compliance departments and agencies are both looking to use data to improve their programs. Access to patient data is also an issue in the states.



On the Radar

- The basics: Speaker programs and patient assistance still need attention.
- Price reporting: New reporting may come with GLOBE, GUARD, and other MFN efforts.
- Direct patient sales programs: These will continue to get attention, following the OIG Special Advisory Bulletin and RFI.
- PBM arrangements: New legislation addresses fees, bona fide service fees, FMV, and reporting.



Emerging Risk

Prediction markets that began with elections and sports are now moving into life sciences. Users can now bet on whether a trial meets its primary endpoints or when FDA approves a product. PhRMA has no position yet, and the market seems largely unregulated. AdvaMed noted that the issue raises a familiar question about who has access to your data and why. Compliance teams may want to review policies for employees, contractors, and vendors, along with training and codes of conduct.

MARKET ACCESS

Most compliance resources still go to sales reps and their interactions with physicians. Yet a product also needs coverage, and many of those decisions sit with PBMs, group purchasing organizations, health systems, and specialty pharmacies. This Thursday afternoon plenary session panel turned the focus to those organizational customers and the account managers who work with them. Meena Datta, JD, Partner and Global Co-leader of the Healthcare Practice at Sidley Austin, moderated. She was joined by Jill Dailey, JD, Vice President and Chief Compliance Officer, Oncology, at Menarini Stemline, and Christian Scognamillo, JD, Associate General Counsel, US Market Access and Pricing, at AbbVie.

Look Behind the Contract

Ask account teams to explain the business objective of each arrangement. Then confirm the contract matches it. Question whether the customer is the right entity for the services. "Building the relationship" is not enough of a reason.

Verify Before You Pay

Confirm that services are used and KPIs are met before payment goes out. Watch for add-ons such as sponsorships or speaker programs. Ask to sit in on periodic business reviews to listen. The business wants value for its money too.

Foundation Donations Revisited

The Dompé settlement brought an older risk back into focus. Revisit controls built years ago. Make sure business stakeholders understand the risk before early conversations with a foundation. A clear process is the best protection. It should define who is involved, who is excluded, and how the donation amount is set.

Formulary Is Not Off Limits

A whistleblower case against Roche involving its Humana contract settled after DOJ declined to intervene. It alleged that letting the plan keep rebate overpayments was a kickback. Confirm you get the formulary placement you pay for. Treat field reports of unexpected access hurdles as a red flag.

Same Rules, New Customers

PBMs, GPOs, and health systems are business customers, but meal limits and entertainment rules still apply. Ask how account managers are paid, who receives their content, and what role those people hold. Review joint visits with MSLs case by case. Set clear limits on who may discuss buy and bill arrangements.



~80%

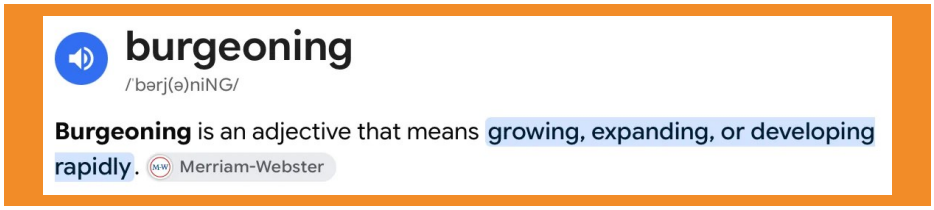
of the room said market access field staff get tailored compliance training (GOOD!)

37%

of the room said all market access meetings are recorded in a system of record. The rest record only some meetings, none, or don't know. (NOT SO GOOD!)

BURGEONING COMPLIANCE RISKS

I had to look it up.



This panel looked at how compliance teams spot compliance risks and decide when to bring them to leaders and the board. Yogesh Bahl, MBA, Partner and Practice Leader at Resolution Life Sciences and Healthcare, moderated. The panel was Brian C. Barry, JD, Vice President and Chief Compliance Officer at Vertex Pharmaceuticals; Jennifer Dubas, JD, Chief Ethics and Compliance Officer at Jazz Pharmaceuticals; Shannon Kelley, JD, Executive Vice President and Chief Legal Officer at Madrigal; and John S. Rah, JD, Counsel and Head of the Life Sciences Compliance Practice at Potter & Murdock.



WHERE SIGNALS COME FROM

Panelists described three places to look:

1. The first is patterns inside and outside the company. In one case, a helpline matter about a vendor payment had a cyber component. A major cyber story was in the news at the same time. Compliance worked with IT to brief the executive team before the next board meeting. That let the company show control over the issue instead of reacting to the headline.
2. The second is company strategy. When one CEO announced a focus on rare disease, compliance looked at the new risks in engaging with HCPs, patients, and patient advocacy groups.
3. The third is the external environment, including what DOJ and OIG are signaling. Planning years ahead helps the program avoid "fighting yesterday's war."



WHAT TO ELEVATE

There may be no formal rubric. Risks tied to strategy go to the executive committee and the board because those leaders are already discussing them. For other risks, credibility matters. Leaders should trust that compliance will bring them what they need to know, with context. If compliance treats every issue as urgent, it loses the ability to get immediate attention when something serious happens.



AI GOVERNANCE

AI governance for the company was named as another emerging risk. One company built a questionnaire and assessment for AI projects, similar to third party risk reviews, which brings legal, compliance, and IT together. Another is updating its governance model so that familiar use cases get a lighter review. It uses a principles-based policy with standards such as a human in the loop.

Higher risk uses include tools that touch personal health information in patient support programs, uses that may go beyond existing consents, and external content that still needs fact checking. AI can speed up misconduct as easily as it speeds up work. The moderator pointed to the NIST framework as a starting point. He also noted that AI logs are being subpoenaed. A panelist added that the concern is less the search itself and more what someone does with the result.

Something to Think About...

One of my favorite panelists described complacency as a growing risk. When leaders hear about large settlements, they may assume the conduct doesn't apply to them. Compliance should look at what led to the conduct, such as competitive pressure, pricing changes, or how employees are evaluated and paid. Most people are not trying to do the wrong thing. The pressure they feel is often the root cause, and senior leaders are the ones who can change it.

AI & THE EVOLVING COMPLIANCE FUNCTION

After two days of AI sessions, this afternoon plenary panel began by suggesting everyone take a deep breath. [Great advice...I know I needed it!] Neeraj Gupta, MBA, President and Chief Technology Officer at Cresen Solutions, moderated. The panel included Peter Brensilver, JD, MPH, Senior Vice President and Chief Global Commercial Compliance & Risk Counsel at Pfizer; Jennifer Dubas, JD, Chief Ethics and Compliance Officer at Jazz Pharmaceuticals; and Rebekah Latchis, JD, Vice President of Risk Intelligence & Investigations at Medtronic.

What Can Be Added to the AI Discussion?

AI can feel intimidating, and it can seem as if every other company has it figured out. Panelists said most companies are working through it at the same time. One way to make it manageable is to sort AI into two buckets. The first is AI the business is advancing, where compliance can address risks and build in controls. The second is AI for compliance. That bucket includes enterprise tools such as Claude, Gemini, and Copilot, along with larger agents for monitoring and investigations. Sorting the work this way makes it easier to set priorities.

Panelists also said the governance and risk management skills compliance teams already have apply to AI. Down the road, investigations, auditing, and monitoring data could support predictive insights. One company is focused on data readiness this year and is reviewing its processes and data before it chooses technology.

What Will Compliance Look Like in Three Years?

The mix of work will likely change before team size does. Panelists expect compliance to become more focused on systems and technology, more involved with the business early on, and more focused on accountability and critical thinking. Compliance leaders should shape that story for senior leaders. It would be a mistake, especially early, to assume AI means fewer people are needed for monitoring, risk assessment, or advice.

AI may also take over the lower risk monitoring and investigations that once trained new compliance professionals. Panelists urged teams to make room for that development even if it is less efficient. Teams may also need skills they haven't needed before, such as predictive analytics. Those skills can be built, borrowed from elsewhere in the company, or bought.

THE NEXT 90 DAYS

- ☑ Look for lower risk quick wins, such as using AI to review or write policies.
- ☑ Assess where your team sits on the maturity scale, from personal productivity tools to agents.
- ☑ Try something. One company built policy chatbots in Copilot that now run in several markets.
- ☑ Map longer term ideas and work with IT on how to build them.
- ☑ Find work that self-service tools can take off compliance's plate, so human judgment goes where it is needed.
- ☑ Take inventory of AI tools other functions are building to avoid duplicate work.

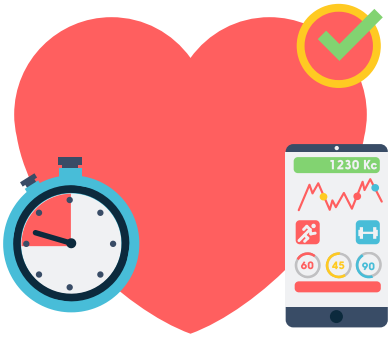
MANAGING RISK IN UNSETTLED TIMES

The Congress closed with a look at risks most compliance teams have never had to track. Forrest Deegan, JD, Principal Consultant at Spark Compliance Consulting and former Chief Ethics and Compliance Officer at Abercrombie & Fitch and Victoria's Secret, moderated. He was joined by Deborah A. Curtis, JD, Partner and Co-Chair of the White Collar Defense & Investigations Practice at Arnold & Porter and former Deputy General Counsel at the CIA. Ambassador Barbara A. Leaf, Senior International Policy Advisor at Arnold & Porter and former US Ambassador to the United Arab Emirates, completed the panel. They split the discussion into what has changed and what companies should do about it.

WHAT HAS CHANGED		SO WHAT
Sustained global turbulence. Conflicts, political shifts, and a US administration that sees America's role abroad very differently all affect business. Even companies that are not interested in geopolitics are affected by it.		Build an information flow. Name someone to track key regions and alert leaders. Sales teams and QA staff in factories can serve as eyes and ears. Every employee can play a part.
Products as national security assets. The government may ask who controls the money behind a clinical trial, where genomic data goes, and who can access company data in the cloud.		Know the answers first. Current diligence may not reach these questions. In house lawyers can separate legal requirements from prudential ones across jurisdictions.
Supply chains under pressure. COVID and the Iran war widened what governments see as strategic. Closing the Strait of Hormuz affected far more than oil.		Plan for redundancy. Know where backups exist, how long a switch takes, and whether alternates avoid the same country of origin issues. Run a tabletop on a risky supply channel and test who can make decisions.
No longer a protected industry. Life sciences' size and success have drawn the attention of nation states and bad actors. Companies can no longer count on general licenses or past treatment under outbound investment rules or the Biosecure Act.		Use free resources. US embassies and consulates can help. Country managers should meet regularly with the commercial and economic sections. Visiting leaders should ask to see the ambassador.
Resilience as deterrence. Many countries now invest in resilience to withstand pressure from rivals.		Put it in business planning. Include national security risks in the planning horizon so leaders can make proportionate decisions later. Choosing not to decide is also a decision.

AT A GLANCE

INSIGHTS FROM SELECT MINI SUMMITS



01

DATA ANALYTICS

Panelists in the Best Practices for Data Analytics session discussed how compliance teams can anticipate risk instead of reacting to flags. One panelist, a former sales representative and college hockey referee, compared analytics to officiating. Referees are rarely surprised by a fight because they watch the behaviors that lead up to it. Program design starts with the risk assessment, which pairs the external enforcement environment with company activities. Teams can then focus on their top three to five risks and ask questions that go beyond yes or no. The panel also advised adding extra time to project plans for IT work and building ties with commercial insights and analytics teams.

Outliers do not always signal risk. A top performer may stand out simply because of passion for a disease area. Panelists recommended confirming the reason behind a flag, bringing in medical or market access or sales colleagues, and documenting how each flag was closed. Conversations with reps work best when they start with questions. A pattern across a region or team may point to performance pressure and call for a conversation with sales leadership. Tracking whether observation rates drop after retraining can show that a program works in practice.



The Medical Device Annual Industry Roundtable opened with a look at recent enforcement. The panel described a shift away from waiting for whistleblowers and toward mining data. 45% of qui tams were filed by data miners in the past two years. The government can now see patterns in a company's data before the company does. Sunshine reporting, long treated as a filing exercise, now carries penalties. Quality and commercial risk are converging as QMSR takes effect and FDA replaces QSIT with a new inspection model. FCPA enforcement is narrower, but the statute of limitations outlasts any administration. China has begun lowering price caps as an enforcement tool, including for distributor conduct. Panelists urged companies to review their own data the way a relator would.

Recurring disputes over issues such as evaluation products or KOL engagement can move to standing cross-functional committees, where each function signs off on its own share of the risk. For AI-enabled devices, compliance has to cover the full product life cycle. FDA guidance allows manufacturers to get advance authorization for certain planned software updates. Reps who describe features beyond those updates can create off-label or uncleared claims exposure. One company uses a cross-functional change board to review model changes, claims, and training materials together.

Other reminders: Free software, dashboards, subscriptions, and AI tools given to hospitals can count as remuneration. Data sharing deals need fair market value, a documented need, and privacy review.

MEDICAL DEVICE

02

03

RISK ADVANTAGE

In this session on Capturing Opportunity Through Uncertainty, panelists described how compliance teams take on more work without more headcount. One company shifted routine approvals to the business, with training and monitoring, and moved compliance staff into advisory roles. Another company has business leaders justify HCP engagements at the start of the year, so later requests become a quick check. Its system also keeps employees from skipping steps. Its local compliance officers must commit at least 35% of their time, cannot come from HR or finance, and have a dotted line to global compliance.

Influence without authority came up often. Compliance has to build trust early and speak the business's language.

A "speak with compliance" campaign (instead of "speak up") at one company led to more early questions. About a third of its investigations are now self-reported.





A compliance roadmap depends on where the company is in its life cycle. This session had panelists who joined companies that had products on the market but compliance programs that hadn't kept pace. They discussed building a program from scratch usually starts with prevention elements such as policies and training. Monitoring and auditing come later.

The panel's strongest theme was people. One CCO starts each new role by interviewing teams to learn their past experience with compliance and find allies. Those allies have included heads of quality and research. One CCO partnered with finance to rebuild the company's Concur setup, which gave both teams better data.

Leadership also needs to under-stand why compliance matters beyond avoiding an investigation.

Risks should be prioritized by stage, so a clinical company doesn't need commercial policies yet. Plans will shift with new products and acquisitions, and panelists recommended telling the business up front that the plan will change.

SCALING COMPLIANCE

04

05

FUTURE OF COMPLIANCE MONITORING

The session opened with a demo of AI-enabled transaction testing. The platform automatically flagged and prioritized transactions. An AI agent then reviewed an ad board payment held at a resort and auto completed a testing checklist of about 30 questions. The agent found that the agenda had more resort activities than content. Rules-based analytics would likely miss this because the evidence sat in an unstructured document. Reviewers could edit every AI output, and an audit trail captured each step.

Panelists shared other uses. AI can bring expense monitoring close to full coverage. At another company, it cut manual review of communications by >90%. A different example talked about a review focused on T&E abuse which also uncovered channel stuffing. With AI, monitoring plans can now more readily shift coverage during the year as risk signals change.



06

RARE DISEASE

In rare disease, with products often costing >$1 million, a single patient can make a difference to a company's results.

Lots of watch areas noted during this panel:

- Reps may push for patient details.
- Often the few prescribers are the same experts the company wants as advisors.
- Government programs pay for most rare disease products.
- Patient support is high touch. One company has dietitians on call.
- One company uses a matrix for each product that sets what support patients can receive.
- When the hub is outsourced, compliance should help write its business rules and monitor on site.
- Leaders of patient organizations may be patients taking the company's drug. Formal requests and documentation help keep the relationship at arm's length.
- Incentive pay for non-sales roles should not work as a proxy for sales.
- Accelerated approvals invite off-label interest, so compliance should help set call lists.
- FDA's guidance on scientific information about unapproved uses (SIUU) applies only when data exists.
- Panelists recommended monitoring trends in medical information requests. A region with none deserves a look too.
- For new field roles, Compliance can review job descriptions, goals, and performance reviews.
- OIG advisory opinions and CIAs can be reviewed as a roadmap for patient support programs.





This Thursday lunchtime panel said the return on AI can be qualitative or quantitative. Cost savings is one way to show ROI...but so is getting more for the same money, such as wider coverage or faster answers.

- One panelist measures how quickly compliance answers the business and whether the business sees value in the function.

- One company digitized its monitoring forms and added communications monitoring. The time to update training or issue an FAQ dropped from about six months to about a month.

- Another replaced two HCP tiering forms and three review groups with one four-question form. AI checks sanctions lists and reports a confidence level. Results held up after an acquisition.

- An AI agent now does the first review of communications monitoring hits, so the team spends its time on the concerning ones.

- Reviewing every email or transaction lets a team report a very low issue rate, such as 0.01%. This is important, too, because it can shows leadership that the program works.

ROI OF AI

07

08

FIRST PRODUCT LAUNCH

In this mini summit, speakers suggested that planning for a first launch should begin while business plans are still taking shape. Incentive plans are an early opening. On his second day at a newly approved company, one panelist was invited to Shake Shack by leaders from finance, legal, and HR to weigh in on sales incentives. His input covered whether violations should disqualify employees from bonuses and whether timely training completion could be recognized.

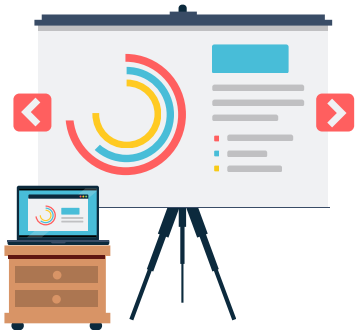
Launch training may be the best chance to set expectations before retraining gets harder. Panelists stressed role-specific practice. One recalled a sales rep who asked whether medical and commercial colleagues could "breathe the same air." That question became a lesson on handoffs.

Another panelist described a ride along where a nurse asked for meals for colleagues in other rooms. Rehearsing responses to moments like that helps reps prepare.

Early monitoring shows where to adjust. One speaker soft tests higher risk activities in the first 90 days. Another expects at least one completed monitoring feedback loop by day 180.

Other random points: Frequent exception requests can point to overly detailed policies. A monthly advisory team of sales reps and MSLs gives field concerns a separate channel. For vendors, panelists advised securing audit rights early and reviewing business rules documents.





Sponsorship and exhibit requests are getting more creative and more costly. This mini summit won the prize for best audience engagement simply by the number of audience questions. Here are some highlights.

What should a reviewer ask first?
Follow the money. Ask what the company is paying for, who receives the funds, and what benefit the company gets in return.

When does a reverse expo raise concern?
At a reverse expo, HCPs staff the tables and reps rotate among them. In one case, formulary decision makers staffed the tables at a resort meeting. The rep's request said these leaders don't see reps, which suggests the company is paying for access. Documenting an educational purpose might fix it.

Why has enforcement been limited?
When many companies fund an event, it is hard to tie any one of them to later prescriptions. A customer event with only one sponsor creates a more direct link.

What has OIG said?
In a 2022 advisory opinion, OIG rejected a plan for industry to fund an ophthalmology practice's education event for optometrists. OIG found kickback risk even with several sponsors. Panelists said some requests now come close to those facts.

What if a sponsorship tier includes more than the team can use?
Choose a lower tier or ask to reduce the fee. A $10,000 add-on for a dinner and happy hour may amount to paying for a social event.

EXTERNAL FUNDING

09

10

CAREER PATHS

This panel included seasoned chief compliance leaders. None of the panelists had a master plan for their careers. They shared their interesting stories about how they came to be in the positions they currently hold.

One was a branding consultant who complained about an 80-question compliance risk survey. Her chief compliance officer then asked her to come fix what she had complained about. Another started as a lawyer at the CIA, where a trainer suggested he sit through a full week of weapons training before teaching use of force. The third took a sales job for $35,000 and a gold Chevy Lumina. Panelists encouraged attendees to pursue what gives them energy and to think of a career as a lattice instead of a ladder.

Lateral moves can speed up a career. Moving from investigations to advising the business, or taking on global work, builds breadth and shows flexibility. Panelists suggested asking a manager early what a future role requires. They look for agility in high potentials and for people who see how their work fits the bigger picture.





11

RELATIONSHIPS WITH SPECIALTY PHARMACIES

In rare disease, the specialty pharmacy network can make or break a launch. These relationships also draw enforcement. Past cases involved rebates tied to switching, steering prescriptions to particular pharmacies, and paying for data that went unused.

Data was the biggest focus. One panelist's company has about 150 known US patients, so combining data sets could identify individuals. Another company is building an inventory of every data source, its contract limits, and who has access. That matters more as contracts increasingly bar linking or merging data.

To test whether a service is truly enhanced, compare the statement of work with the pharmacy's business rules documents. The business rules show how the work is happening in practice.

Use your audit rights. Pharmacies are pushing to narrow them, so negotiate them up front.

12

PRIVACY

There are now 23 comprehensive state privacy laws, and four were adopted in the past six months. Washington and Nevada add consumer health data laws that cover health information outside HIPAA. Panelists said companies tend to prefer one national enrollment form. It links to privacy notices that can be updated as state laws change, with added language for states such as Washington.

The website hosting the form raises its own risks. Under laws such as Washington's, simply visiting a page about a condition or drug may suggest a health condition, even before the visitor enters anything. Panelists cited the FTC's 2023 action against GoodRx ($1.5 million) and California's 2025 settlement with Healthline ($1.55 million). Both involved cookies and trackers that sent health-related information to advertisers. One panelist said most companies have turned off third-party tracking on patient-facing sites for Washington and Nevada visitors.

Regulators look first at the privacy notice, the cookie banner, and the consent tools. Panelists said these should be accurate and match actual practice. AI has also tested whether privacy programs are the right size. Weak spots in a program become harder to fix once AI is added.



CONGRESS BINGO

Phrases heard across this year's Congress sessions. Mark the ones you heard, and see how many you can line up.

B	I	N	G	O
Human in the Loop	Veloxis	The Internet Is Like a Bathroom Stall	New Field-Based Roles	Skynet
Self-Disclosure	10-80-10	Government Pricing = Challenging	Data Miners	Please Mention the FCPA
Policy Drift	1.1 Multiplier	**FREE** SPACE	Write Right	C2A Dismissal
AI Agents	Privacy by Design	Field ~~Sales~~ Personnel	Add Value to the Business	Are We Still Talking About Speaker Programs?
My Company Isn't as Far Behind as I Thought	My Company Is Way Behind	Is There Any Session That Doesn't Talk About AI?	Copilot	Skin Substitutes

CONCLUDING THOUGHTS

I know "experts" say five is the magic number for what people actually remember, so I try to keep my takeaways to that number when I present. In that same spirit, here are my five from this year's Congress.

First, I am suffering from AI fatigue. It came up in so many sessions that it earned its own square on this year's Bingo card. So I appreciated the panel that opened by suggesting we all take a deep breath. Their point was that most companies are working through AI at the same time. No one needs to have it all figured out, and a few well-chosen uses can go a long way.

Second, data, data, data. If AI was the topic everyone talked about, data was the one underneath it all. The government is using it to find cases, and others are using public sources to do the same. That puts pressure on compliance teams to have the same data and tools as the business. Without that access, it is hard to see a problem before someone else does (like those pesky data miners DOJ is courting through FOCUS).

Third, DOJ is making a stronger case for self-disclosure. It now has a department-wide Corporate Enforcement Policy, and recent settlements showed how cooperation can lower the multiplier. Whistleblowers also have more reason than ever to come forward first. Panelists agreed that deciding to disclose is still a hard call. Having the facts and documentation in order makes it easier to get that decision right.

Fourth, governance once again was a hot topic. OIG's newer CIAs make compliance committees responsible for overseeing risk assessments. Boards are asking about root causes and culture along with individual incidents. AI tools, vendors, and partners need governance too. In each case, we get the same learning. Someone has to own it and be accountable when something goes wrong.

Finally, the attendees. The Congress is one of the few places where we're all in the same room with our people (our spirit animals, really). The formal sessions are great. The time between sessions conversing over coffee or chomping on gummy bears is always a highlight. It was good to catch up with longtime colleagues and to meet people new to the field. Those connections are what bring many of us back each year.

I hope these takeaways are useful as you plan for the year ahead. Thank you to GHC for inviting me back to report on the Congress and for another outstanding job organizing it. Thank you also to PCF for sponsoring what I think is the very best conference for life sciences compliance professionals. I look forward to seeing you at next October's Congress in Washington, DC.

The Congress comes once a year. Enforcement and regulatory news moves all year long. Strategic Versatility's *The Compliance Debrief* recaps key enforcement actions, regulatory updates, and external developments that shape the industry and can help guide your compliance program. Consider subscribing to SV Publications to stay current between Congresses.

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