24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

Recent Developments in DOJ and FTC Enforcement Actions

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- This session is for informational purposes only. It is not intended to be legal advice and does not constitute an attorney-client relationship.
- Discussion reflects personal view; not attributable to our respective organizations.
- Company-specific references in slides and accompanying discussion are based on public sources—no privileged or confidential information.
- The purpose of today's discussion is to discuss recent enforcement activity and potential areas of risk—not to judge or criticize the conduct of any particular company.

Key DOJ Enforcement Trends: *An Overview*

- Recent, precipitous decline in DOJ-led corporate resolutions against pharma and device companies
- DOJ's enforcement efforts have shifted—at least temporarily—to adjacent sectors and activities
- DOJ is pursuing initiatives to encourage voluntary self-disclosure and cooperation
- DOJ has increased its presence on the compliance front

DOJ Is Highly Focused on Compliance Programs at the Policy Level

- **June 2020:** DOJ issued revised "Evaluation of Corporate Compliance Programs" guidance to assist prosecutors in assessing the effectiveness of a company's compliance program
  - Is the program well-designed, adequately resourced, empowered to function effectively and working in practice?
- **October 2021:** DOJ announced the formation of Corporate Crime Advisory Group (CCAG) and made initial revisions to its corporate criminal enforcement policies
- **September 2022:** DAG Monaco announced further revisions in a memo and speech emphasizing the need to adequately fund compliance departments and develop a compliance-oriented corporate culture
  - Directs prosecutors to examine whether the company's compensation system includes appropriate deterrence measures (*e.g.*, clawback provisions or escrowed compensation) as well as incentive measures (*e.g.*, affirmative metrics and benchmarks to reward pro-compliance behavior)
  - Directs prosecutors to evaluate how a company addresses access to data on personal devices and third-party applications
- **March 2023:** DOJ issued revised guidance for assessing the effectiveness of a corporate compliance program
  - Update performance evaluation systems to include compliance-related incentives or deterrents
  - Consider financial penalties as part of the consequences for employee misconduct
  - Implement tailored, risk-based policies on the use of personal devices and messaging applications

Avanos: *A Foreshadowing of Things to Come?*

- Avanos admitted that it falsely represented that its surgical gowns met rigorous quality standards, despite knowledge of a manufacturing issue
- Although not separately charged, Avanos also admitted to falsifying documents submitted during an FDA inspection
- Avanos received credit for its "extensive" remedial efforts and full cooperation credit
  - *No voluntary disclosure credit*
- Avanos entered into a deferred prosecution agreement (DPA) with additional compliance measures and agreed to report "any evidence or allegation" of a violation of the FDCA or U.S. obstruction or fraud laws

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Thursday, July 8, 2021

Avanos Medical Inc. to Pay $22 Million to Resolve Criminal Charge Related to the Fraudulent Misbranding of Its MicroCool Surgical Gowns

"The last thing health care workers should have to worry about is whether their personal protective equipment lives up to manufacturers' claims," said Acting U.S. Attorney Prerak Shah for the Northern District of Texas. "Misbranded PPE can pose serious risks to medical professionals and patients alike. All companies that do business in Texas, health care or otherwise, will be held accountable for the promises they make about their products."

"Medical devices, such as surgical gowns, must have truthful and accurate labeling," said Assistant Commissioner for Criminal Investigations Catherine A. Hermsen of the FDA. "Surgical gowns with false or misleading labeling can put health care practitioners and patients at risk. The FDA's Office of Criminal Investigations protects the American public by aggressively investigating allegations involving FDA-regulated products and violations of the FDCA. In this case, OCI worked with the Department of Justice to ensure a just resolution, and we applaud the exceptional work done by the team."

Avanos: *A Foreshadowing of Things to Come?*

- The Consumer Protection Branch (CPB) has created a Corporate Compliance and Policy Unit with responsibility for helping to craft compliance obligations in CPB agreements and ensuring that defendants follow compliance and reporting obligations
- CPB has promised a standardized template that will look similar to the Avanos DPA . . .
  - *Ensure strong and visible commitment to compliance by senior and mid-level leaders*
  - *Policies and procedures*
  - *Periodic risk assessments*
  - *Compliance oversight maintained by senior executive with appropriate stature, autonomy and resources*
  - *Tailored training (and training certifications)*
  - *Internal reporting and investigation processes*
  - *Disciplinary procedures*
  - *Periodic monitoring and testing to evaluate effectiveness*
  - *Remediation, including root cause analysis*
  - *M&A due diligence*
  - *Initial work plan and annual reports to DOJ (Frauds, CPB and USAO)*
  - *Failure to implement the compliance program triggers DPA breach*

Key DOJ Enforcement Trends: *Practical Takeaways*

- Incentives are arguably THE critical component of any effective compliance program
  - DOJ has made clear its belief that a program that doesn't take this into account will not be effective
- Compliance programs need to evolve to reflect changing government priorities, including with respect to increased expectations regarding the role of compliance
- Consider building a step into the investigations process to assess whether the conduct at issue is eligible for self-disclosure "credit" so that consideration is given in real time as to whether to self-disclose
- Data is key – it flows through countless channels within companies, and DOJ expects the compliance organization to leverage that data to identify compliance risks
- Upfront controls (*e.g.*, policies, training) are not sufficient – greater resources need to be devoted to back-end monitoring and auditing
- Reactive programs are no longer sufficient – DOJ expects companies to take affirmative steps to identify compliance risks (supported by good data flows)

Key FTC Enforcement Trends: *An Overview*

- Increased focus on activities that directly impact the ways in which the life sciences industry promote their products
  - Health product claims
  - Social media
- Significant uptick in enforcement actions related to the acquisition, use, and transfer of personal health information
- Evolving relationship between FTC and Main Justice's CPB

Key FTC Enforcement Trends: *Practical Takeaways*

- Update review practices and other controls to ensure they take into account the target audience and reflect updated FTC guidelines and pronouncements
- Companies are on notice that they are responsible for both understanding and monitoring how their digital platforms and online interactions with consumers may place individuals' health information at risk
  - Clearly and accurately disclose data use practices to consumers
  - Prioritize understanding how your company—and the third parties whose technology you rely on—uses and discloses consumers' health data and take appropriate steps to protect that data against misuse