



## Controlled Substance Monitoring & Analytics

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# Abuse of prescription drugs has increasingly become a top priority for the U.S. Drug Enforcement Agency (DEA), the U.S. Department of Justice, and state attorneys general.

Participants across all levels of the drug distribution and dispensing supply chain face regulatory responsibilities to effectively monitor and safeguard against the diversion of controlled substances, and must be able to address government inquiries when litigation arises.

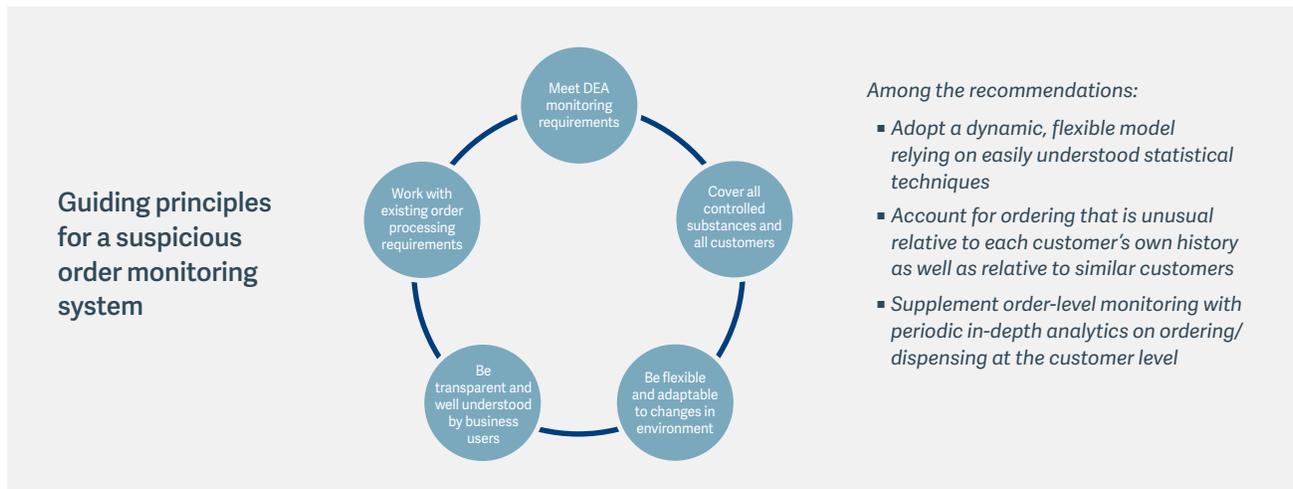
Analysis Group provides a full-service approach to meet these needs, with significant expertise in the:

- **Design and implementation of custom Suspicious Order Monitoring systems**
- **Development of data analytics and custom dashboards for effective controls against diversion**
- **Expert consulting services in regulatory investigations and litigation**

## Suspicious Order Monitoring

Analysis Group has worked with distributors and pharmacy chains to develop statistical models utilizing data regularly collected through business operations to detect high-risk pharmacies and prescribers. Recent examples of our Suspicious Order Monitoring (SOM) projects include:

- Developing robust algorithms to monitor daily controlled substance ordering (i.e., all Schedule 2 – 5 substances) for unusual size, frequency, and pattern for several clients throughout the pharmaceutical supply chain.
- Presenting our SOM framework in multiple meetings with the DEA to explain fulfillment of size, frequency, and pattern requirements.
- Creating customized automated reports, including metrics from ordering and dispensing data, to assist review teams in determining which unusual orders should be omitted and/or reported to the DEA.
- Providing on-site training to review teams and support to IT teams in implementing SOM solutions to run on company systems.



## DEA and Government Investigations

Analysis Group has assisted counsel for distributors and manufacturers in several high-profile disputes with the DEA and U.S. Attorneys' Offices around the country. The disputes have hinged on how to define "statistically unusual" dispensing or distribution, absent clear regulatory guidance.

To address allegations of ineffective controls against drug diversion and suspicious order reporting violations, we have worked with counsel for national pharmacy chains and distributors to assess dispensing and distribution data and to explain the statistical context. Our team has:

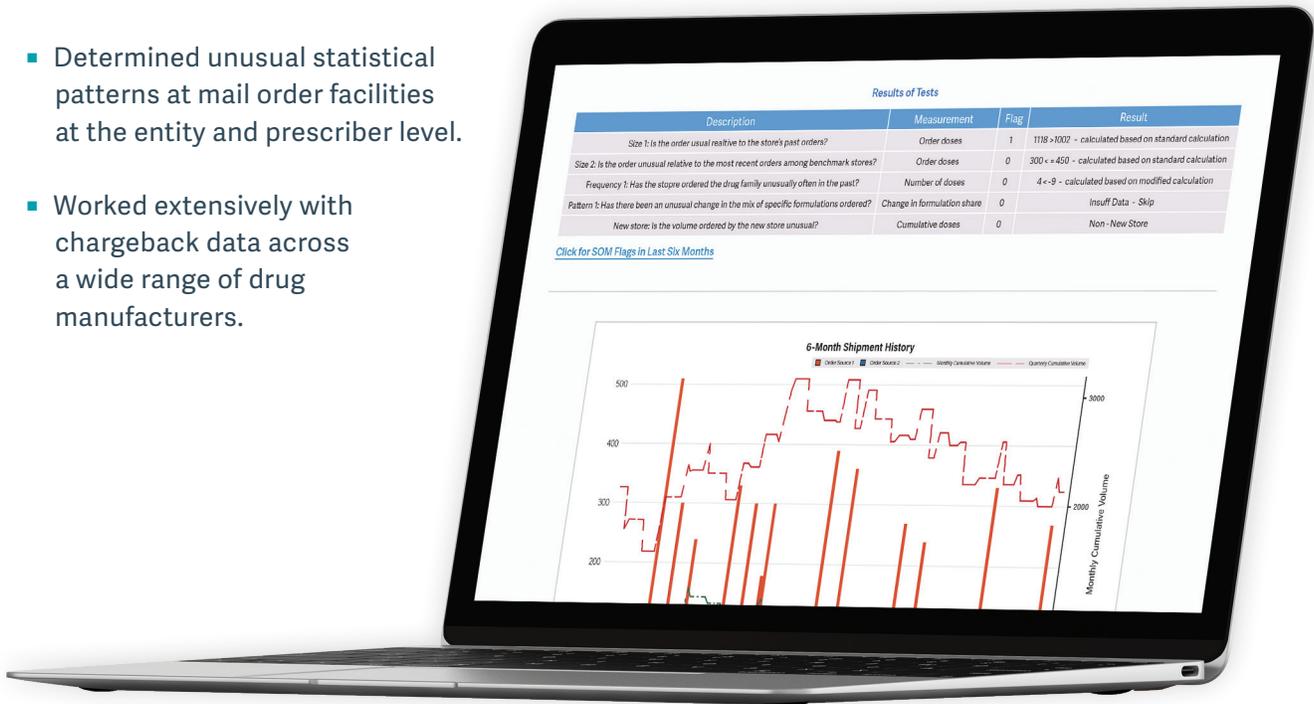
- Effectively rebutted statistical models created by the DEA and U.S. Attorneys' Offices' statisticians.
- Built models that consider a variety of alternative scenarios and potential penalty amounts.
- Provided testimony in administrative law proceedings and made presentations to the DEA and U.S. Attorneys' Offices.

## Monitoring Analytics

Analysis Group has extensive experience developing monitoring analytics to create effective controls against diversion. Our custom algorithms result not only in more cases of diversion being identified, but also in those cases being identified more quickly, thereby reducing overall liability. We have:

- Developed retrospective quarterly algorithms to identify unusual pharmacies and prescribers based on dispensing characteristics.
- Determined unusual statistical patterns at mail order facilities at the entity and prescriber level.
- Worked extensively with chargeback data across a wide range of drug manufacturers.

*A sample custom dashboard is highlighted below.*



## Further Experience with Pharmaceutical Supply Chain Regulation and Litigation

Over the past three decades, we have assisted drug manufacturers, distributors, and pharmacy chains with economic solutions to complex government investigations and litigation. Drawing on insights from numerous data sources, we have conducted quantitative investigations to assist companies, internally and externally, in negotiations and the courtroom. Selected areas of expertise include:

- False Claims Act and Anti-Kickback Statute matters
- Drug pricing litigation
- Valuation of services and fair market value
- Generic entry antitrust issues
- Breach of contract disputes
- Intellectual property disputes
- Mass tort/product liability cases
- False advertising cases

## Our Approach

- **Comprehensive:** Our expertise covers all controlled substances required to meet DEA monitoring requirements and guidance.
- **Tailored:** Our analyses are tailored to your specific business model and needs; our systems are designed to dynamically adapt to changes in customer and market data.
- **Robust:** Our algorithms apply sound statistical methods based on established principles and are calibrated to your data and customers.
- **Clear:** Our methods are simple enough to be understood by non-technical staff and we provide detailed documentation of models and analyses.
- **Collaborative:** Our team is always available to provide support depending on your unique needs and we have extensive experience in regulatory matters and presenting to the DEA on behalf of our clients.

## Our Team



**Crystal Pike, Managing Principal**

M.B.A., MIT Sloan School of Management;  
B.A., Mount Holyoke College  
617 425 8211 · crystal.pike@analysisgroup.com  
www.analysisgroup.com/cpike



**Kenneth Weinstein, Vice President**

M.B.A., MIT Sloan School of Management;  
A.B., Harvard University  
617 425 8192 · kenneth.weinstein@analysisgroup.com  
www.analysisgroup.com/kweinstein



**Pavel Darling, Vice President**

M.B.A., MIT Sloan School of Management;  
B.A., Middlebury College  
617 425 8335 · pavel.darling@analysisgroup.com  
www.analysisgroup.com/pdarling



**Nicholas Van Niel, Associate**

M.B.A., MIT Sloan School of Management;  
B.A., Colby College  
617 425 8352 · nicholas.vanniel@analysisgroup.com

### About Analysis Group

Analysis Group is one of the largest economics consulting firms, with more than 850 professionals across 14 offices in North America, Europe, and Asia. Since 1981, we have provided expertise in economics, finance, health care analytics, and strategy to top law firms, Fortune Global 500 companies, and government agencies worldwide. Our internal experts, together with our network of affiliated experts from academia, industry, and government, offer our clients exceptional breadth and depth of expertise.

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