Curriculum Vitae

HEATHER I. BATES
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SUMMARY

Heather Bates is a managing director with BRG in Washington, D.C. and provides consulting and analytical services to life sciences clients and their counsel regarding economic, regulatory, damages, and discovery issues. In particular, her capabilities relate to developing analyses to answer complex questions based on a detailed understanding of disparate but interrelated financial and healthcare data.

Ms. Bates' consulting work has focused on pharmaceutical, biotech and medical device manufacturers, pharmacies and PBMs facing compliance issues, litigation, disputes, federal and state investigations, regulatory change and other business challenges. She has significant experience in the areas of government pricing (AWP, AMP, Best Price, and ASP), off-label marketing, regulatory compliance, the False Claims Act, anti-kickback laws, state consumer protection statutes, product liability, good manufacturing practices, and contract disputes.

Ms. Bates uses structured and unstructured data to assess allegations of fraud, non-compliance with federal and state regulations and commercial contracts, antitrust activity, and other business conflicts. She develops models that incorporate manufacturer sales, profit and marketing data, medical and pharmaceutical claims data, public healthcare utilization and cost data, Medicare and Medicaid data, and third party vendor data. Her data analysis and models inform life sciences clients and their counsel of potential liability and exposure, allowing them to make data-driven decisions in the face of complex disputes and investigations. She has also been qualified as an expert witness and has provided deposition testimony.

Ms. Bates has 15 years of consulting experience in the life sciences industry. Prior to joining BRG in June 2010, Ms. Bates was with Navigant Consulting and LECG.

AREAS OF EXPERTISE

- Anti-Kickback Statute and False Claims Act investigations and litigations
- Pharmaceutical pricing and reimbursement (AWP, WAC, MAC)
- Government price calculations and reporting (AMP, Best Price, 340B)
- Off-label sales and marketing
- Product liability
- Good manufacturing practices
- Financial projections and impact analyses
- Contractual performance
- Contractual disputes
- 3rd party data analysis

- Regulatory compliance and internal controls
- Health economics
- Pharmacy benefit management processes and systems

CLIENTS

- Pharmaceutical manufacturers (brand and generic)
- Retail, long term care, and specialty pharmacies
- Medical device manufacturers
- Biotech companies
- Pharmaceutical benefit managers
- Commercial insurance companies

TESTIFYING EXPERIENCE

Medco Health Solutions, Inc. and Express Scripts, Inc. v. State of Florida Department of Management Services (State of Florida Division of Administrative Hearings, Case Nos. 15-4685, 15-4686, 15-4687, 15-4688, 15-4766, December 2015: Deposition)

Impax Laboratories, Inc. v. Turing Pharmaceuticals AG (United States District Court Southern District of New York, Case No. 1:16-CV-03241, October 2016: Deposition)

REPRESENTATIVE ENGAGEMENTS

Drug, Biotec and Device Manufacturers

- **State Consumer Protection Matters**
  Provided consulting services to counsel for multiple pharmaceutical manufacturers defending claims brought by various State Attorneys General under state consumer protection statutes involving allegations of fraudulent marketing, off label marketing, misrepresentations of drug safety, and failure to warn.

- **Pharmaceutical Off-Label Promotion Litigation**
  Developed potential exposure models and provided discovery assistance to outside counsel for multiple pharmaceutical manufacturers facing allegations of marketing of various drugs for unapproved indications to members covered by State Medicaid programs and private insurance.

- **Government Investigation Related to GMP Violations**
  Provided discovery assistance and potential exposure calculations for counsel for a global pharmaceutical manufacturer accused of GMP violations and distribution of tainted products into the stream of commerce.

- **Pharmaceutical and Medical Device FCA and AKS Investigation.**
  Provided discovery assistance, potential exposure analyses and litigation support to outside counsel for a medical device and pharmaceutical manufacturer facing multiple qui tam actions that alleged millions of dollars in government purchases and reimbursements for products and services were induced by kickbacks the manufacturer provided to healthcare providers.

- **Medical Device FCA and AKS Investigation.**
  Provided discovery assistance and developed potential exposure models for a medical device manufacturer under investigation by the DOJ for allegedly providing kickbacks to encourage purchases by healthcare providers reimbursed by State and Federal programs.

- **Multidistrict Pharmaceutical Antitrust Litigation**
  Analyzed the economic impact on payors (state Medicaid programs, commercial insurers, self-pay patients, etc.) for a pharmaceutical manufacturer accused of causing delayed market entry of certain prescription drug products.

- **Antitrust Litigation**
  Provided discovery assistance and supported testifying expert for pharmaceutical manufacturers facing allegations of delayed market entry from direct and indirect purchasers.

- **Product Liability**
  Evaluated potential exposure for a pharmaceutical manufacturer defending liability and damages claims filed by a purported class of insurance plans related to reimbursement for an allegedly defective product that was eventually pulled from the market.

- **Product Liability Modeling and Damages Estimates**
  Developed models to estimate potential number of cases and damages for counsel defending pharmaceutical manufacturers facing claims of defective and harmful products.

- **State AG AWP Litigation**
  Assisted counsel for generic pharmaceutical manufacturers accused of defrauding the State Medicaid programs by reporting falsely inflated prices (AWPs) for their products, thereby causing the State to over-pay pharmacies for drugs utilized by the Medicaid population.

- **Pharmaceutical Pricing Litigation**
  Provided consulting services to counsel for a pharmaceutical manufacturer defending allegations of racketeering, Medicare and Medicaid fraud and other allegations brought by multiple parties, including the Federal and State governments, private insurers and individuals. Allegations involved average wholesale pricing (AWP), marketing practices, and failure to provide rebates to Medicaid under federal “best price” rebate programs.

- **Congressional Pricing Inquiries**
  Provided discovery support and pricing analytics to a generic manufacturer facing inquiries from Representative Elijah Cummings and Senator Bernie Sanders regarding price inflation of its drugs.

- **Investigation of Medicaid Best Price, AMP and Rebate Calculation**
  Performed potential exposure analyses and provided support for settlement negotiations to counsel for a pharmaceutical manufacturer under investigation for “bundled sales” that allegedly lowered drug rebate payments to State Medicaid agencies and elevated 340b pricing to qualified entities.

- **AMP Litigation**
  Provided consulting services to multiple pharmaceutical companies accused of reporting inaccurate Average Manufacture Prices (AMPs) through improper reporting of off-invoice price increases and wholesaler services fees, thereby reducing the company’s Medicaid rebate payments.

- **AMP Restatement**
  Evaluated a pharmaceutical manufacturer's Medicaid rebate liability related to its AMP calculation for a number of products sold under bundled and non-bundled contracts in order to assess the need for AMP restatements and disclosure to CMS.

- **340B Public Health Services ("PHS") Pricing Litigation**
  Reviewed processes, procedures and pricing calculations for a pharmaceutical company facing multiple allegations of inaccurate 340B pricing. Provided litigation support throughout the case that ultimately resulted in a favorable decision for the manufacturer by the Supreme Court of the United States.

- **340B AIDS Healthcare Foundation Litigation**
  Provided analytical services to a global manufacturer of HIV and other prescription drugs confronting a complaint filed by the 340B-eligible AIDS Healthcare Foundation (AHF) which alleged the manufacturer did not provide the correct discounted pricing to AHF under the terms of the 340B program and 340B contracts.

- **ASP and AMP Bona Fide Service Fees Investigation**
  Assisted a leading biotech company assess HHS OIG allegations that the company mistreated non bona-fide service fees in its Average Selling Price (ASP) and Average Manufacturer Price (AMP) calculations.

Pharmacies

- **Specialty Pharmacy Compliance Review.**
  Performed a comprehensive compliance review of a specialty pharmacy on behalf of the parent company, including policy and procedure review, assessment of adherence to Federal and State law, quantification of potential overpayments by Medicare and Medicaid, identification overcharges to Medicaid and other private payors, and provided recommendations for numerous compliance and business improvements.

- **Long Term Care Pharmacy Audits.**
  Performed data analytics and potential damages assessments for counsel to a long term care pharmacy facing numerous audits and investigations by several State Attorneys General and US Attorneys around allegations of improper billing of Medicaid, Medicare and other third parties, documentation failures, lack of medical necessity for prescriptions dispensed, and improper dispensation of controlled substances.

- **Long Term Care Pharmacy FCA Qui Tam**.
  Provided expert support services and calculated potential exposure for a large long term care pharmacy facing a qui tam complaint filed under seal by the U.S. government alleging the LTC pharmacy accepted rebates and discounts from a large drug manufacturer in exchange for switching LTC patients to the manufacturer's drug, and placing patients on the therapy unnecessarily.

- **Specialty Pharmacy Federal FCA Matter.**
  Performed data analytics and provided litigation support to counsel for multiple specialty pharmacies facing a Federal qui tam complaint intervened by most states that alleged the pharmacy knowingly accepted disguised cash payments and patient referrals from a large manufacturer in exchange for recommending specific drugs.

Insurers and PBMs

- **PBM Litigation with Plan Sponsor**
  Analyzed allegations by a plan sponsor of PBM contract mismanagement and overcharges and related under-reimbursements to the PBM by the plan. Assessed potential damages to both parties based on review claims data and invoices. Prepared and expert report and provided deposition testimony.

- **PBM Qui Tam Litigation**
  Provided discovery assistance, assessed allegations, and calculated potential damages for counsel defending a PBM against accusations it submitted false claims to CMS for Part D plans and failed to administer drug benefit plans according to federal and state regulations and private contracts with plan sponsors.

- **Government Investigations**
  Provided discovery assistance, data analytics and assessment of potential exposure for PBMs responding to subpoenas, CIDs, and other investigations initiated by State AGs, AUSAs, the DOJ, and HHS OIG involving various issues from rebate contracts with manufacturers, to pharmacy benefit administration, to federal reporting of discounts under the Part D program, etc.

- **Plan Sponsor Audits**
  Analyzed data, reviewed audit findings and developed potential damages calculations for PBMs facing demands from multiple plan sponsors engaged in contract administration disputes.

- **Insurer Internal Audit**
  Assisted outside counsel conducting an internal audit for a large health insurer, including review of fraudulent activity by employees accused of accepting kick-backs from physicians and Medical Services Organizations in exchange for directing business to those providers and shifting risk away from providers under capitated contracts.

- **PBM Rebate Contract Dispute**
  Provided consulting and analytical services to counsel for a PBM engaged in arbitration with a former commercial customer over the terms and execution of a multi-million dollar prescription drug rebate contract.

- **Medical Claims Reimbursement Disputes**
  Performed potential damages calculations and supported testifying expert for insurance companies facing allegations that the Usual, Customary & Reasonable rates used to reimburse providers for out-of-network medical claims were too low and based on inaccurate average payment data.

EDUCATION

B.A. The University of Virginia (Economics)

PREVIOUS POSITIONS

LECG, 2007 – 2010

Navigant Consulting, Inc., 2001 – 2007

PROFESSIONAL MEMBERSHIPS

Healthcare Businesswomen's Association

National Council for Prescription Drug Programs

The American Health Lawyers Association