Curriculum Vitae

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Claire V. MacKoul is an Associate Director in BRG's Health Analytics Practice, based out of BRG's Boston office. She provides consulting services to life sciences companies with a specific focus on new product development, drug pricing and reimbursement, and product liability. Ms. MacKoul has experience in advising pharmaceutical and healthcare companies as well as providing expert support through a variety of quantitative and qualitative analyses for litigation matters and investigations.

Ms. MacKoul has led the day-to-day operations of BRG teams providing complex sales and claims analyses, potential exposure analyses, electronic data collection and discovery services, and expert opinions on industry standards and damages. She specializes in applying industry knowledge and litigation experience to efficiently and effectively analyze documents and data and present findings in easily digestible, informative work product.

Ms. MacKoul has consulted both pharmaceutical manufacturers and PBMs on a variety of drug pricing and reimbursement matters, particularly related to generic pharmaceuticals. Most recently, she has conducted exposure modeling and litigation support for clients involved in the generic drug pricing antitrust litigation and the MAC pricing litigation.

Ms. MacKoul has also been extensively involved in consulting for pharmaceutical manufacturers and PBMs involved in the ongoing opioid litigation—both advising companies on potential exposure and assisting with expert opinions on industry standards and damages analyses.

In both litigation and business advisory roles, Ms. MacKoul has assessed the development, regulatory approval, and commercialization of new pharmaceutical products as well as performed product sales forecasts and valuation analyses.

Through her work with pharmaceutical companies and PBMs, Ms. MacKoul has significant experience with the pharmaceutical supply chain as well as the various types of business data used by these companies, including pharmaceutical sales and chargebacks, third-party market data, and regulatory databases. Ms. MacKoul and her team manage and analyze these data in a variety of softwares, e.g., SQL, Tableau, Microsoft Excel, SAS, and Stata. Her quantitative experience includes market share analyses, product market models, damages analyses, statistical sampling and extrapolation, time series regression modeling, and survey methodologies.

Ms. MacKoul has provided consulting services with BRG for over seven years, and she holds a BA in Economics and International Affairs from the George Washington University.

REPRESENTATIVE ENGAGEMENTS

- **Pharmaceutical Manufacturer Controlled Substance Act Litigation**
  BRG was retained by Counsel for an opioid pharmaceutical manufacturer facing multiple federal and state lawsuits as well as government investigations related to the ongoing opioid litigation. Claims included violation of the Controlled Substance Act, product liability, false advertising, and public nuisance. During the initial stages of litigation and investigation, BRG has provided litigation support throughout the discovery process as well as performed analytics to inform defense strategy. In expert discovery and trial stages for these matters, BRG has developed complex pharmacy claims analyses, potential exposure analyses, and expert opinions on industry standards and damages. BRG's support and analytics have been critical to refuting Plaintiffs' theories of liability in each case.

- **Pharmacy Benefit Manager Generic MAC Pricing Litigation**
  BRG was hired by Counsel for a PBM involved in early stages of litigation related to the PBM's MAC pricing used to reimburse independent pharmacies for generic products. During initial discovery phases, BRG coordinated with client stakeholders to identify, extract, and prepare client data and documents relevant to requests for production and interrogatories, including pharmaceutical claims data, MAC lists, and contracts. This process required forward-thinking pertaining to the information relevant for subsequent exposure modeling and expert testimony. BRG also assisted with several expert declarations describing PBM reimbursement to Plaintiff independent pharmacies.

- **Pharmaceutical Manufacturer Generic Pricing Antitrust Litigation**
  BRG was asked by Counsel for a generic pharmaceutical manufacturer to analyze potential routes of settlement with various Plaintiff groups in the generic pricing antitrust litigation. BRG analyzed the potential impact of the alleged price increase throughout the supply chain – including sales to direct purchasers, downstream sales from wholesaler to indirect purchasers, reimbursement by payers, and patient cost sharing. BRG prepared easily digestible, clear settlement analyses, which evaluated various scenarios. Counsel and Client leveraged these analyses for settlement discussions with Plaintiffs.

- **Pharmaceutical Manufacturer False Claims Act and Anti-Kickback Statue**
  BRG was retained by defense Counsel for a pharmaceutical manufacturer executive facing a criminal indictment related to the company's speaker program, which was alleged to be a sham program used for funneling kickbacks in exchange for prescriptions. BRG conducted numerous analyses assessing the relationship between HCP involvement in the speaker program and prescribing patterns. The team leveraged the company's internal data, prescription dispensing data collected through the product's Risk Evaluation and Mitigation Strategy (REMS) program, third-party prescriber-level data, and several publicly available resources reflecting individual prescriber data (including Medicare Part D utilization and Open Payments data). BRG's analyses were used to inform defense strategy, and our analytical visualizations were used as demonstratives at trial.

- **Pharmaceutical Manufacturer Government Pricing Forecast**
  BRG was retained by Counsel to model the potential financial impact of a change in a pharmaceutical manufacturer's procedures for Best Price government pricing calculations. BRG built a dynamic five-year, four-product model to assess impact on Medicaid and 340B utilization under a variety of potential scenarios. BRG presented model results to several groups of key stakeholders at the manufacturer, and the model was used by the manufacturer's internal finance department as a tool for decision-making.

- **Pharmaceutical Manufacturer Government Pricing Review**
  BRG was retained by Counsel to review a pharmaceutical manufacturer's transactions and government pricing in context with their policies and procedures. BRG designed and implemented a review of the company's processing and recording of direct and indirect sales, returns, rebates, and administrative fee transactions as well as the company's calculation of government prices required under certain government programs. BRG's assessment included examination of the company's policies and procedures as well as analytical tests of the company's transaction process and government pricing calculations. BRG presented its findings and suggested changes to policies, procedures, and process designs in a final advisory report, which subsequently informed the company's government pricing calculation process the following year.

- **Biopharmaceutical Development Company Acquisition Valuation**
  BRG was retained to advise a biopharmaceutical development company on its potential acquisition of a company with several products in development that relied on patents for a specific peptide. The target company's lead product was entering Phase III clinical trials for the treatment of a type of metastatic breast cancer. BRG collaborated with the biopharmaceutical company's board and market research firm to develop a market forecast for the lead product and perform a DCF valuation analysis to inform potential offers. The lead product's Orphan Drug Designation provided seven years of market exclusivity, which was a crucial component of BRG's product valuation. Due diligence also uncovered limitations on the product's patent portfolio, which impacted assumptions of generic competition after expiration of market exclusivity.

- **Pharmaceutical Development Company Product Market Forecast**
  BRG was retained by a pharmaceutical development company to forecast the market for its pipeline fixed-dose combination product with an application under review by FDA. BRG evaluated existing market research and conducted market analysis of the intended indication, post-operative pain treatment combined with an antiemetic to prevent nausea and vomiting. BRG prepared a net sales forecast and DCF analysis for the company to use on an ongoing basis, along with detailed support for analysis assumptions and inputs.

- **Pharmaceutical Manufacturer Licensing and Development Dispute**
  BRG was retained by a pharmaceutical manufacturer that had licensed the US rights for its pharmaceutical product for certain oncology indications. The company's US partner failed to reach licensing milestones for the lead orphan drug oncology indication, triggering a clause in the licensing agreement allowing the company to take back the US rights to the lead indication. BRG's market model forecasting team collaborated with

valuation experts to calculate the NPV of the lead indication at the time the clause was triggered. This analysis included the review of multiple revenue projections for the indication, modeled at various points throughout the indication's development, as well as independent research and analysis of the indication's potential market. BRG assessed each assumption underlying the indication's revenue projections, including development costs, likelihood of approval, and expected orphan drug exclusivity, and these revenue projections served as the basis for the DCF valuation analysis.

- **Pharmacy Benefit Manager Contract Dispute**
  BRG was retained by Counsel representing a pharmacy benefit manager (PBM) in a dispute between the company and one of its health plan clients. The claimant alleged the PBM improperly continued the use of inflated AWP for the health plan's pharmacy reimbursements after publishers of AWP agreed in a litigation settlement to decrease AWP by 5% for certain NDCs. BRG prepared expert opinions on the PBM's response to changes in industry benchmark pricing and the administration of the contractual pricing terms. To do so, BRG reviewed the parties' contract in comparison to other benchmarks and analyzed the PBM's claims data and reports to determine the company's performance under the contract. BRG's work on this matter ultimately influenced the parties reaching a settlement agreement.

- **Pharmacy Benefit Manager Intellectual Property Dispute**
  BRG was retained by counsel representing a pharmacy benefit manager (PBM) in an arbitration between the PBM and a healthcare solutions company in the Middle East. The PBM alleged the healthcare solutions company used the PBM's intellectual property outside of the parties' joint venture to create a competing product. BRG performed onsite interviews with employees of the healthcare solutions company as well as reviewed the product's functionality and supporting source code. With this information as well as analysis of documentation and correspondence produced through discovery, BRG provided several expert reports for consideration by the arbitrator.

- **Specialty Pharmacy Prior Authorization Review**
  BRG was retained by Counsel for a specialty pharmacy to perform an independent assessment of the company's prior authorization process for rheumatoid arthritis and osteoporosis drugs. BRG designed and implemented a statistically representative random sample of new prescriptions for these drugs. With this sample, BRG reviewed medical records, prior authorization documentation (both verbal and written), and patient file notes to determine whether the specialty pharmacy had properly represented each patient in performing the patient's prior authorization. This included assessing whether the patient had certain diagnoses and complied with step therapy prerequisites. BRG extrapolated the results of the sample review to estimate the error rate among the population of prior authorizations and prepared a report detailing the methodology of the sample and results.

EDUCATION

B.A. Economics and International Affairs
The George Washington University, 2014
Summa cum laude, Phi Beta Kappa

PUBLICATIONS

Cantor, R., H. Bates, and C. MacKoul. (2021). Risk Attenuation and Amplification in the U.S. Opioid Crisis. *Risk Analysis*, 1-16.

MacKoul, C., Irwin, B., and Buthusiem, E. Quarterly M&A Report. *Berkeley Research Group*. Q1 2021.

Meer, S., C. MacKoul, and R. Cantor. (2017). Payment Card Data Breach Class Actions: Who Foots the Bill? *American Bar Association Commercial & Business Litigation*.

MacKoul, C. and D. Boada. (2015). The History Underlying the Use of Price-Cost Tests. *The Price Point*, 15(2), 8-10.