

GERALD (JERRY) LEWANDOWSKI

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Jerry Lewandowski is a managing director at Berkeley Research Group in Washington, DC. Mr. Lewandowski provides consultation, analysis, and strategic advice to clients and their counsel regarding economic, information technology, regulatory, damages, and discovery issues. In particular, he provides expertise to address complex financial and economic questions by acquiring, assimilating and analyzing data from financial, transactional, survey, and other data systems (integrating information from internal company data and external data sources).

For almost 20 years, Mr. Lewandowski's practice is focused on clients undergoing government and internal investigations, federal and state False Claims Act and Anti-Kickback Statute matters, class action lawsuits, multi-party and multi-district litigation, and other complex issues. He provides financial and economic analyses related to fraud allegations, kickback allegations, contract disputes, pricing issues, and regulatory compliance and reporting requirements. Mr. Lewandowski has extensive expertise in healthcare and life sciences related to pricing, reimbursement, rebate and claims transactions, including how clinical documentation is interpreted and used in the payment process.

Mr. Lewandowski has significant experience analyzing the payment and rebate practices of government payors, including numerous analyses related to Medicare Part D, Medicaid and the Federal Employee Health Benefits Program. He has analyzed pharmacy claims pricing related to issues such as statutory payment rates, generic substitution impact on pricing, and comparative pricing between therapeutic substitutes for purposes of developing cost equalization calculations. He has analyzed commercial and Medicaid rebate operations from the pharmaceutical company perspective in terms of price reporting and rebate calculation and processing. With respect to Medicare Part D, he has analyzed coverage and payment issues and developed models related to claims processing and sources of payments and funding for the program. Mr. Lewandowski has also worked on many matters that involved analysis and review of pharmacy operations data including purchase, inventory, dispensing and pharmacy practice documentation.

Mr. Lewandowski's clients have included numerous Fortune 500 companies and their counsel. He has significant experience in the areas of health care and life sciences and has consulted to pharmaceutical manufacturers, medical device companies, pharmacy benefit managers (PBMs), pharmacies, managed care companies, hospital systems and other entities.

Mr. Lewandowski has provided expert testimony at arbitration and presented to State Attorneys General and Federal government officials such as officials in the Civil Division of the Department of Justice.

Life Sciences Sales and Marketing Issues

Mr. Lewandowski has been retained by a number of pharmaceutical and medical device manufacturers and their outside counsel related to government investigations and litigation related to allegations that certain sales and marketing activity violated the Federal False Claims Act and/or Anti-Kickback Statute. He has developed a framework to address far-reaching allegations that provides structure and order to the process of identifying and gathering relevant data and incorporates that data into models that address the core questions of FCA and AKS liability and damages.

These matters have included allegations of illegal promotion of products for non-FDA approved uses (i.e., “off-label” or “unlabeled” uses) based on indication, dosage or days of therapy as well as allegations of product tying or bundling, and discount or rebate shifting from one product to another. He has developed models related to both liability and damages, including financial models to quantify the sales that may be tied to the allegedly illegal promotion activity and the resulting financial impact on government payers or consumers (and in related litigation, consumers or commercial health plans).

Mr. Lewandowski’s work on these matters has involved the collection and incorporation of company sales data; pharmaceutical compendia; marketing plans, budgets, CME, publication and detailing data; retail sales survey data; and publicly available survey data into comprehensive models. He has also summarized relevant state laws and Medicaid, Medicare and managed care rules regarding coverage of off-label uses.

Mr. Lewandowski has also provided modeling of the potential economic harm to consumers and health plans in class action litigation related to these issues.

Pharmaceutical Pricing Issues

Mr. Lewandowski has extensive experience in pharmaceutical pricing matters related to Average Wholesale Price (AWP) matters; government program reimbursement; government price reporting (AMP, BP, ASP, 340B pricing, etc.); and commercial reimbursement and rebate issues. His expertise includes government pricing programs and regulations; manufacturer pricing, contracting, discounting and rebating practices; and Medicare, Medicaid, PBM and managed care coverage and reimbursement practices.

For example, Mr. Lewandowski was retained by counsel for pharmaceutical manufacturers facing litigation related to average wholesale prices (AWP) for pharmaceuticals, the manufacturers’ marketing practices, and their alleged failure to provide adequate rebates under the Medicaid Drug Rebate Program. Mr. Lewandowski has led teams that performed numerous initiatives, including electronic data discovery and the compilation and analysis of public, private and historical company data. He developed liability and damages models,

including measuring the economic impact of government and private payer allegations related to AWP on reimbursements.

Mr. Lewandowski has also worked for manufacturers in lawsuits and investigations related to the Public Health Service 340B pricing program, and various matters related to reporting of statutory prices such as Best Price (BP), Average Manufacturer Price (AMP) and Average Sales Price (ASP). He gathered and assessed historical manufacturer policies and procedures, data and documentation related to company SOPs and pricing calculations. He has performed analysis that addressed the accuracy of those calculations and also performed recalculations - quantifying the impact on prices or rebates of hypothetical changes in methodology (e.g., inclusion or exclusion of certain purchasers or costs in the calculation; reallocation of discounts and rebates for arrangements alleged to be bundled sales; treatment of administrative and other fees, etc.).

Mr. Lewandowski has also consulted to counsel and manufacturers in responding to inquiries from numerous government entities, including the House Commerce Committee, OIG and various US attorneys' offices regarding products' pricing and their impact on government, commercial and consumer payers.

Specialty Pharmacy Compliance

Mr. Lewandowski has been retained by specialty pharmacies to address both internal investigations and external allegations of fraud, violations of the False Claims Act, and violations of pharmacy practice laws. For both internal and external issues, Mr. Lewandowski and his team have performed extensive interviews, developed detailed workflow diagrams and analyzed accounting data as well as pharmacy, billing and payment data in order to determine the fact patterns related to the allegations. He performed extensive analysis of transaction level billing and payment data in order to determine the economic impact, if any, of the allegations.

For one internal investigation, Mr. Lewandowski and his team acquired a virtual copy of the specialty pharmacy's main proprietary relational database system that housed both its pharmacy operations data and its billing and collection data. He and his team converted the data and performed extensive analysis to trace and analyze the transactions relevant to the investigation.

PBM Services and Reporting, Government Health Programs

Mr. Lewandowski provided expert services and advice to a large PBM and its outside counsel related to a *qui tam* action related to a contract to provide pharmacy and pharmacy benefit services to Federal employees. Mr. Lewandowski coordinated the acquisition, organization, and production of over two terabytes of highly relational mainframe pharmacy operations data and managed the analysis of that data. Mr. Lewandowski designed analyses regarding the PBM's alleged failure to meet various performance standards (based on both contractual requirements and standards of pharmacy practice).

Antitrust Matters

Mr. Lewandowski led a team that was retained by counsel for a large pharmaceutical company that was the defendant in a multi-district antitrust litigation related to one of its products. Mr. Lewandowski provided counsel with consultation that included analysis of the economic impact on payers (state Medicaid programs, commercial insurers, self-pay patients, etc.) of an alleged delay in market entry of certain generic prescription drug products (Paragraph IV filers under Hatch-Waxman). Mr. Lewandowski's team performed analysis of contracts, internal company data, pharmaceutical industry market data, and data produced through discovery in the litigation to assess economic damages, if any, in the matter. Mr. Lewandowski assisted in preparing an expert report regarding damages as well as exposure analyses that were used in connection with a settlement with virtually all plaintiffs in the matter.

Mr. Lewandowski was also engaged by defense counsel for a large pharmaceutical company to create damages calculations and participate in settlement negotiations related to products in several therapeutic classes. The matters similarly related to state attorneys general (AG) and classes of private plaintiffs alleging that they paid inflated prices for brand name pharmaceutical products because the brand manufacturer had conspired to keep generic competition off the market through illegal patent activity. Mr. Lewandowski developed damages models that valued the impact of the alleged delay and participated with counsel in settlement negotiations with state AG representatives. As part of the negotiations, Mr. Lewandowski and his team evaluated and critiqued the plaintiffs' approach to valuing the alleged delay.

Medicare Advantage Sales and Marketing

Mr. Lewandowski led a team that worked with Counsel for a large Medicare Advantage organization that was accused of violating the Anti-Kickback Statute through allegedly improper arrangements and payments to individuals in its delegated sales force channel. He led a forensic initiative to determine whether there was any evidence of the alleged kickback activity including documenting sales agent relationships in the delegated sales channel, analyzing payments to the agents and managing general agents, and assessing the changes in agent hierarchies and structure over time.

Managed Care - Physician Billing and Payment Issues

Mr. Lewandowski led a large team that provided healthcare billing and claims payment expertise, as well as electronic healthcare data discovery assistance, to a joint defense group of managed care entities who were defending themselves in a class action litigation brought by physicians who claimed that the managed care entities routinely and unfairly denied, delayed and diminished payment for services rendered to their members.

Mr. Lewandowski provided consultation and analysis to the managed care entities' outside legal counsel on numerous issues, including financial exposure modeling, tutorials regarding physician coding and billing, tutorials regarding managed care electronic payment systems and the adjudication process, electronic discovery and data extraction, consolidation and analysis of electronic billing and payment data, coordination of medical record discovery, analysis of electronic data to isolate counterclaim issues and develop

sampling and modeling methodologies for expert analysis, extensive analysis and outline development for depositions, and other analyses.

Clinical Laboratory Billing Issues – Upcoding, Code Jamming, Unbundling

Mr. Lewandowski worked for counsel for SmithKline Beecham Clinical Labs (SBCL) on a class action dispute with insurers, as well as classes of other payers (e.g., self-pay patients) regarding the laboratory's billing practices. Specifically, Mr. Lewandowski collected and analyzed electronic data related to the clinical laboratory's general ledger, billing, and payment database archives. Mr. Lewandowski reviewed the systems documentation and interviewed IT personnel and business personnel to design the data extract process. He then successfully led the data extract and conversion process necessary to prepared the data for analysis. Mr. Lewandowski also performed analyses to determine financial exposure to the various plaintiff groups and prepared the client and counsel for settlement negotiations. After negotiations were complete and a settlement was achieved, Mr. Lewandowski performed patient class notification and adjudication of final settlement amounts.

Pharmacy Benefit Manager Contractual Performance and Pharmacy Operations Issues

Mr. Lewandowski was retained by a large PBM and its outside counsel in a number of matters that alleged the PBM had breached its contract with a client by overcharging for drugs through mail order and retail channels, withholding inappropriate amounts of pharmaceutical manufacturer rebates, and engaging in improper drug switching, among other allegations. Mr. Lewandowski performed extensive quantitative analysis related to the PBM's contractual relationships with its clients and pharmaceutical manufacturers (including a detailed review of its contractual guarantees and rebate payments), as well as its mail service pharmacy operations, retail pharmacy claim management offerings, therapeutic interchange programs, and claims processing systems.

Product Liability

In a number of large product liability cases brought against the largest U.S. tobacco companies (notably the state AG matters brought on behalf of individual Medicaid programs, the Ohio Ironworkers matter, and the Blue Cross Blue Shield matter), Mr. Lewandowski led teams for a joint defense group in evaluating, critiquing, and performing damages analyses related to the health care costs associated with smoking. Mr. Lewandowski's team converted plaintiffs' electronic claims data (i.e. over a billion healthcare claims) from multiple platforms and stored on a variety of media into a usable format consistent with available computer hardware and software, and developed analyses that allowed counsel to support both affirmative and defensive positions.

PROFESSIONAL EXPERIENCE

Berkeley Research Group, LLC, Managing Director, 2010–Present

LECG, LLC, Managing Director, 2006–2010

Navigant Consulting, Inc., Managing Director (last position), 1996–2006

EDUCATION

The College of William and Mary, BBA, Accounting

ASSOCIATIONS AND BOARD

American Bar Association

American Health Lawyers Association