CORNERSTONE RESEARCH

Economic and Financial Consulting and Expert Testimony

Life Sciences

When life sciences litigation requires complex economic and financial analysis, attorneys and businesses rely on Cornerstone Research. Our staff and experts provide strategic advice, rigorous analysis, and persuasive testimony. From initial strategy through deposition and trial, clients have used our findings in hundreds of matters involving the life sciences industry.

Cornerstone Research Life Sciences

Experienced Staff

Attorneys and companies draw on our staff's deep knowledge of the life sciences industry—its institutional structure, its competitive environment, and its regulatory framework. Combining this industry expertise with a thorough understanding of the litigation process and training in economics and financial methods yields key insights into issues such as liability, damages, and class certification.

Credible Experts

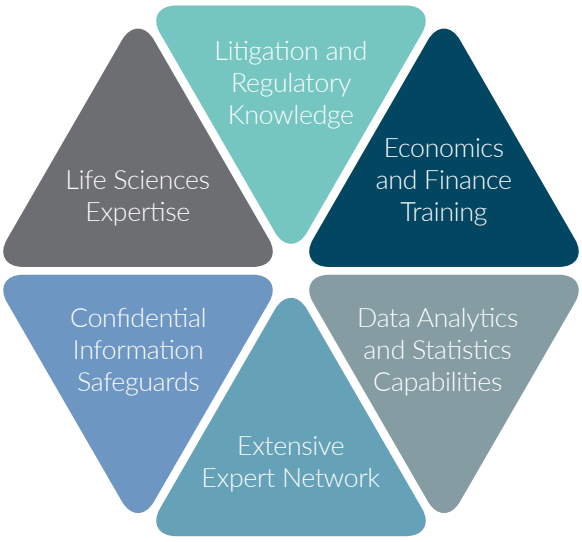
Our academic experts specialize in economics, finance, marketing, business, accounting, and statistics. Their research has been published in leading academic journals, and their findings have been presented to the U.S. Congress, the U.S. Federal Trade Commission, the U.S. Department of Justice, and other government and regulatory agencies. Our industry experts bring a wealth of in-depth experiences in different sectors of the life sciences industry.

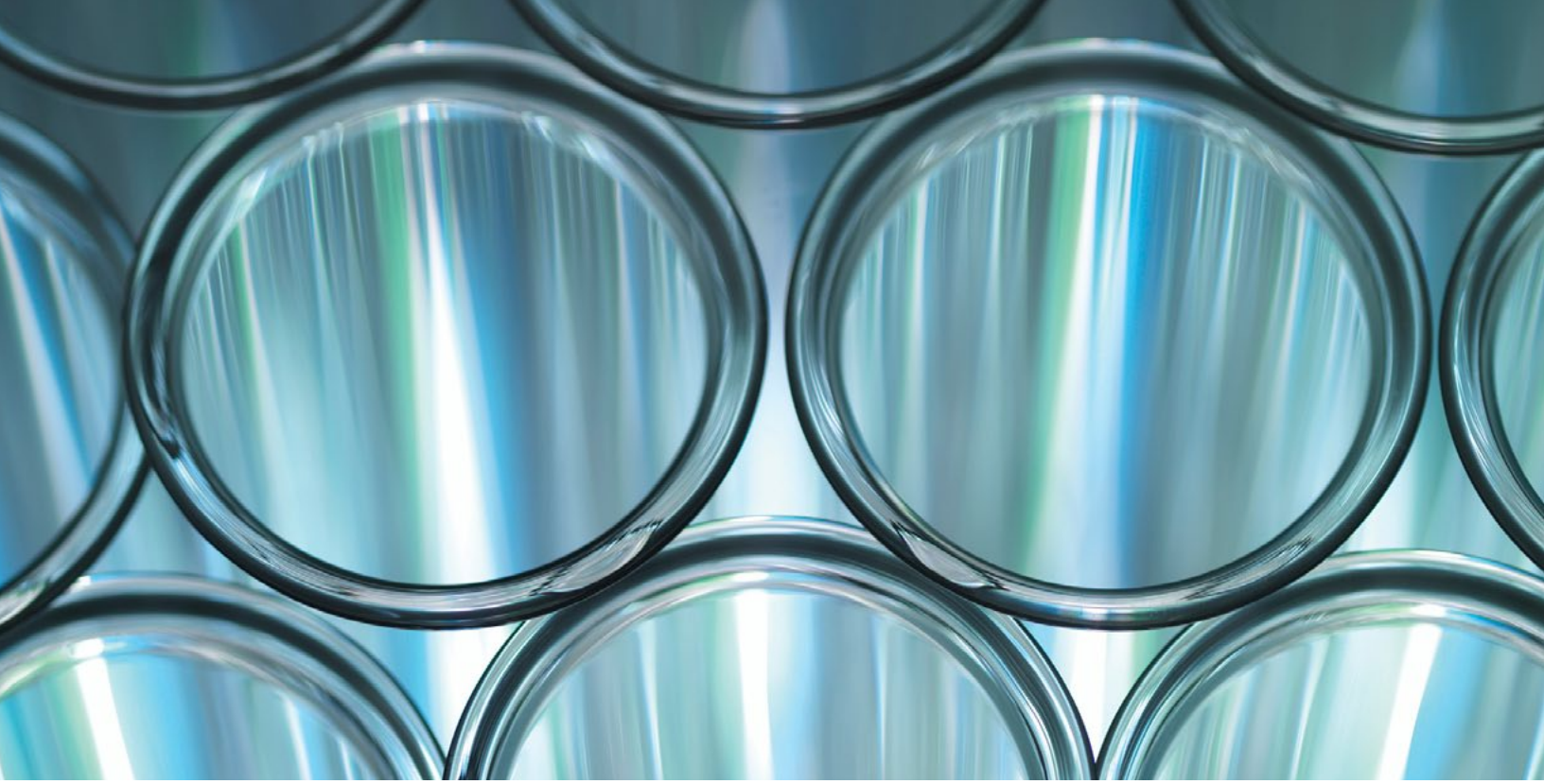
State-of-the-Art Data Analytics

Cornerstone Research's Data Science Center brings sophisticated data analytics techniques, in-house processing, and programming capabilities to deliver right-sized solutions.

We work closely with life sciences clients to determine the appropriate data sources and analyses for each matter. Our staff and experts apply advanced modeling techniques and econometric methods to address the complex issues that arise in litigation and regulatory proceedings.

We utilize large government datasets and confidential company and patient information as well as third-party data to offer insightful and effective analyses. In all our work, we safeguard the security and confidentiality of information.





Antitrust and Competition

Cornerstone Research staff and experts conduct extensive research on pharmaceutical markets and have a deep understanding of the relevant institutions and regulations.

We work with clients on a range of class certification, damages, and liability issues, including matters involving allegations of monopolization, price fixing, market allocation, and market foreclosure, among others.

Allegedly Delayed or Suppressed Competition

Cases that allege harm to competition encompass a range of purportedly anticompetitive behaviors, including allegedly collusive "reverse payment" patent settlements; market foreclosure through the filing of sham patent litigation or citizen petitions; abuse of risk evaluation and mitigation strategies (REMS) programs; product hopping; use of exclusive contracts with suppliers, distributors, or insurers; development of "patent thickets"; and use of volume or bundled rebates. In addition to such cases, antitrust theories of harm such as leveraging of bargaining power, threats to potential or nascent competition, and employment harms are gaining traction in the analyses of mergers and acquisitions in the life sciences industry.

Cornerstone Research staff and experts have substantial experience with a wide range of competition cases. Our expertise includes addressing class certification, market definition, and damages. We have also evaluated potential anticompetitive and procompetitive rationales for the challenged conduct and analyzed "but-for" world scenarios to determine whether competition has in fact been delayed or suppressed.

"Reverse Payment" Litigation

In the wake of FTC v. Actavis, we have assessed a variety of questions in our work on "reverse payment" matters:

- What constitutes a reverse payment, including evaluation of royalty payments, terms related to authorized generics, acceleration clauses, and limited volume licenses
- Valuation of alleged reverse payments and comparisons to saved litigation costs and other value received by brand companies
- Evaluation of alternative settlement analyses performed by plaintiffs
- But-for" world assessments and damages analyses

Product Hopping

We assisted counsel in evaluating potential damages in a case involving a branded pharmaceutical company that was accused of hindering generic competition. The company was alleged to have introduced new versions of a branded drug with longer remaining patent protection and withdrawn older versions of the drug.

Cornerstone Research estimated damages to three plaintiff groups—generic competitors, direct purchasers, and indirect purchasers. These plaintiffs accused the branded company of several anticompetitive acts involving its life-cycle management strategies. We analyzed various scenarios corresponding to conduct that might ultimately be found to be anticompetitive.

Class Certification

Defense counsel retained Cornerstone Research and James Hughes of Bates College to address class certification issues in delayed generic entry matters for the drugs Niaspan and Skelaxin.

In *In re Niaspan Antitrust Litigation*, Professor Hughes submitted an expert report in opposition to class certification and opined that end-payor plaintiffs (EPPs) had not provided common evidence of antitrust injury.

Professor Hughes also showed that individualized inquiry was necessary to determine whether any such injury occurred, and the extent of injury. Many groups of consumers may have been uninjured, including brand-loyal consumers; those who benefited from copayment assistance programs or received free samples; and consumers whose copayments for the brand and generic drug would have been the same.

In *In re Skelaxin (Metaxalone) Antitrust Litigation*, Professor Hughes submitted expert reports on both the EPP class and the indirect reseller purchaser (retail pharmacy) class.

For the EPP class, Professor Hughes demonstrated that, due to the complexity of the contractual relationships among the parties, determining whether any end payor would have been injured by the alleged generic delay would require individualized inquiry.

For the indirect reseller purchaser class, Professor Hughes explained how some, if not most, retail pharmacies earned higher profits selling the branded drug rather than the competing generic. Determining which pharmacies would have been injured, therefore, would also require individualized inquiry.

In both the Niaspan and Skelaxin litigations, the judge denied plaintiffs' motion to certify the classes, citing several facets of Professor Hughes's arguments.

The full case studies for each matter are available on our website.

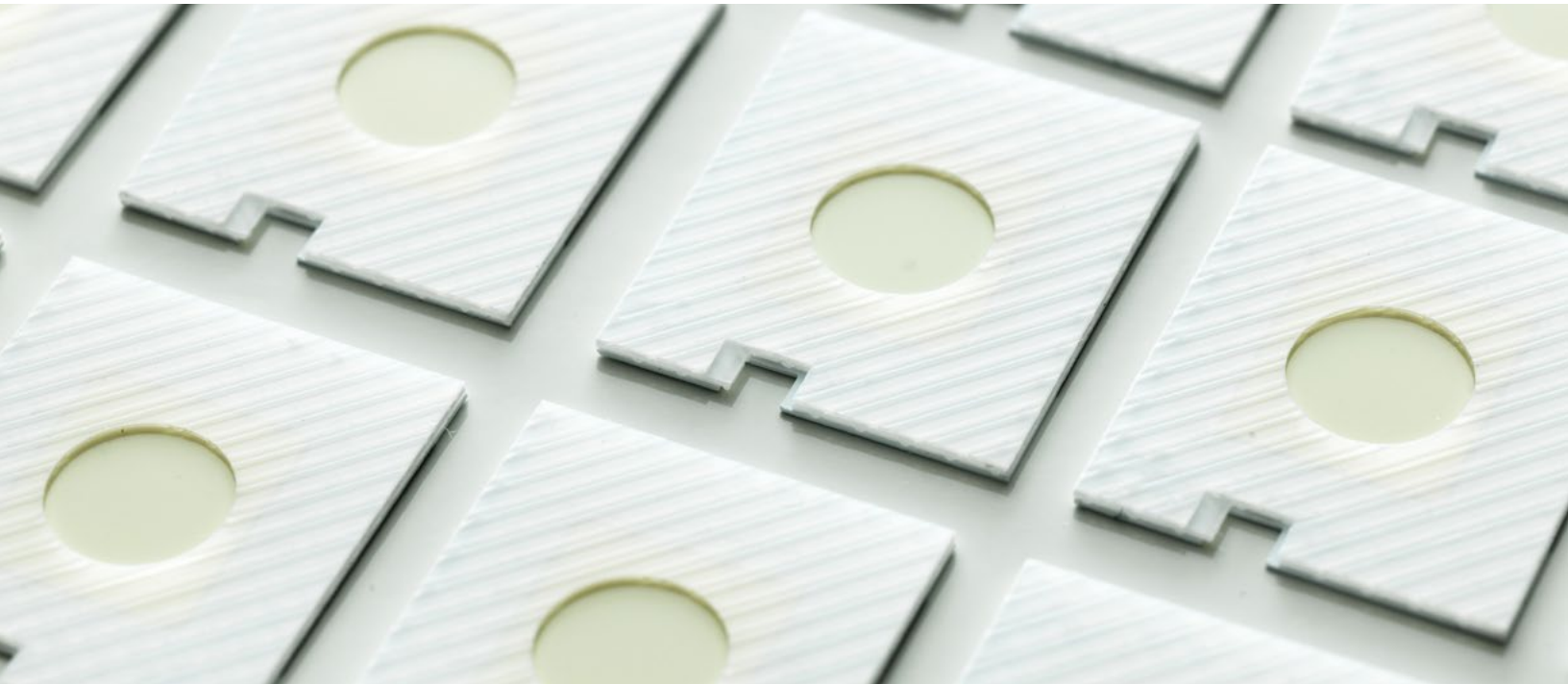
Niaspan Antitrust Litigation >

Skelaxin (Metaxalone) Antitrust Litigation >

Breach of Contract

Breach of contract disputes often require detailed liability and damages analyses. Clients call on us to construct valuation models, review financial records, and assess lost sales and avoided costs. Cornerstone Research helps clients evaluate such diverse issues as:

- Early-stage uncertainty and risk in the R&D process
- Economic implications of generic entry
- Effect of product life-cycle management techniques
- Impact of changes in the therapeutic alternatives space
- Reasonableness of commercialization efforts



ICC Arbitration Involving Commercially Reasonable Efforts to Develop and Launch a Drug

Counsel for the claimant, a specialty pharmaceutical company, retained Cornerstone Research to support pharmaceutical industry expert Brian Reisetter of RHS Inc. and economics expert Vivek Mani of Cornerstone Research in a matter before the ICC International Court of Arbitration in London.

The claimant had licensed North American rights to a drug in development from the respondent. Several years later, the respondent alleged the claimant had failed to use commercially reasonable efforts to develop and launch the drug in Canada and the United States. The claimant disputed the validity of the notice and initiated arbitration proceedings to determine whether it was in material breach of the license agreement.

Dr. Reisetter evaluated whether the development and launch decisions of the claimant were consistent with industry practices and were reasonable in light of the risks the claimant faced. Mr. Mani assessed the lost revenues estimates of the respondent's experts.

The arbitration tribunal determined that the claimant did not materially breach the license agreement, leaving the agreement in full effect. As a result, the claimant retained all North American development and commercialization rights to the product.

Joint Development Marketing Dispute

In a dispute between two pharmaceutical companies that had jointly developed a drug, Cornerstone Research worked with an expert who assessed the business incentives of the company responsible for marketing the drug. This company was alleged to have developed an inappropriate marketing plan because it had other drugs in the therapeutic space that could potentially lose sales to the new drug.

With Cornerstone Research's support, the expert established that the company had no inherent conflict in promoting the jointly developed drug. The expert also reviewed the marketing plan and concluded it was consistent with approaches found to be effective by academic researchers. An arbitration panel ruled that the company did not face any conflict and the marketing plan was consistent with the company's obligations under the development agreement.

Biotechnology Joint Development Agreement

Cornerstone Research worked with Iain Cockburn of Boston University in a breach of contract dispute between two biotechnology companies about the joint development of certain products. The analysis addressed how specific actions by the parties impacted the overall value of the collaboration.

Professor Cockburn and Cornerstone Research constructed an economic model that considered the trade-offs and challenges involved in the clinical development of biotechnology products, the implications of life-cycle management strategies, competition among therapeutic alternatives, and anticipated competition from biosimilars.

Breach of Contract for a Branded Drug

Cornerstone Research and an affiliated expert analyzed the impact on a branded drug's value when a pharmaceutical company interrupted the supply and promotion of the drug.

A plaintiff holding the intellectual property rights to a branded drug alleged that its commercialization partner, a pharmaceutical company, failed to uphold its obligations to manufacture and promote the drug. The plaintiff claimed that the defendant's failure led to supply interruptions and periods during which the drug was not promoted to physicians.

Plaintiff counsel retained Cornerstone Research and a valuation expert to assess the role that consistent supply and promotion play in generating drug sales, as well as the impact of these factors on the drug's long-term value.

Cornerstone Research and the expert analyzed the health economics literature and data on promotion and sales for drugs in the relevant therapeutic category. The expert concluded that the cessation of promotional activities and the temporary interruption in supply substantially impacted the drug's contemporaneous and future sales. Working with Cornerstone Research, the expert also calculated the economic impact of the defendant's alleged misconduct, building a discounted cash flow model to estimate what the drug's value would have been with consistent supply and promotion relative to what it actually was.

False Claims and Product Misrepresentation

Life sciences firms are often the target of class actions and False Claims Act (FCA) cases related to the marketing, sale, and pricing of their products. Attorneys and corporations call on our experts to evaluate causation, injury, and damages claims. In class actions, our experts have analyzed the appropriateness of class certification for proposed classes of patients, insurance companies, pharmacies, and wholesalers. We have consulted and supported academic and industry experts on cases involving allegations of:

- Kickbacks, in the form of speaker programs and advisory boards
- Off-label marketing
- Misrepresentation of product safety and/or efficacy
- Fraudulent list prices
- Creation of a public nuisance requiring abatement

Litigation Involving Allegations of Improper Pricing

Cornerstone Research has worked with counsel for several pharmaceutical companies on cases related to pharmaceutical pricing. Many of these cases involve the reporting of two pricing metrics—Wholesale Acquisition Cost (WAC) and Average Wholesale Price (AWP)—by drug manufacturers. WAC is a list price at which wholesalers purchase drugs from pharmaceutical manufacturers that does not include any on- or off-invoice discounts. AWP is a benchmark price typically used when setting reimbursement for prescription drugs.

There are often large differences between these pricing metrics and the net prices pharmaceutical companies receive for their drugs after accounting for all discounts and rebates. Plaintiffs and government entities have alleged that companies inflate these pricing metrics as a means to provide kickbacks either to pharmacies or pharmacy benefit managers (PBMs).

Cornerstone Research has supported experts who explained the economic and historical context of these pricing metrics and why they differ from net prices. These experts have also demonstrated that such differences were widely known among the various entities involved in the manufacture, distribution, dispensing, and reimbursement of prescription drugs.

In addition, our experts have evaluated the implications of plaintiffs' "but-for" worlds including the impact on net prices, insurance premiums, and access to pharmacy services for Medicaid beneficiaries. Finally, our experts have addressed class certification and damages on these matters.

Sampling in FCA Litigation

Clients draw on Cornerstone Research's statistical expertise to evaluate sampling analyses performed by opposing parties to prove liability and damages in False Claims Act litigation. We have analyzed sampling issues on a variety of matters, including those involving allegations of off-label marketing and physician kickbacks.

In re Actiq Sales and Marketing Practices Litigation

Counsel for Cephalon Inc., a subsidiary of Teva Pharmaceutical Industries Ltd., retained Cornerstone Research to analyze class certification and damages issues relating to the alleged off-label marketing of Actiq, a painkiller approved for the management of breakthrough cancer pain. A purported class of third-party payors (TPPs) claimed that Cephalon unjustly enriched itself by marketing Actiq for non-approved indications in order to increase prescription sales, and that they were damaged by Cephalon's actions. Cornerstone Research worked with three experts to address class certification and damages issues: W. David Bradford of the University of Georgia; Pradeep K. Chintagunta of the University of Chicago Booth School of Business; and Christine M. Hammer, CPA, senior advisor at Cornerstone Research.

A key question in this case was whether issues common to all class members predominated over issues affecting individual TPPs. TPPs each made their own coverage decisions and set their own reimbursement policies for Actiq.

Professor Bradford explained that TPPs had a number of methods by which they could and did influence and monitor the prescriptions for which they reimbursed in order to manage their costs for Actiq. He concluded that individualized inquiry would be required to establish that class members were harmed by Cephalon's alleged actions.

Professor Chintagunta showed that physician prescribing behavior is influenced by a number of different factors and that there is diversity in how physicians respond to pharmaceutical marketing; consequently, because each TPP reimbursed for prescriptions prescribed by different physicians, individualized inquiry would be required to demonstrate the impact of the alleged off-label marketing.

Ms. Hammer analyzed the plaintiffs' proposed damages model to estimate the alleged unjust enrichment.

Judge Petrese B. Tucker of the U.S. District Court for the Eastern District of Pennsylvania found that individual issues in this case predominated over common ones, and that individualized inquiry would be required to determine whether a particular prescription was unjust.

The court denied certification of the proposed class.

Intellectual Property

Our staff and experts draw on their extensive knowledge of pharmaceutical and medical device markets to estimate lost profits, reasonable royalties, and the value of innovative technologies in patent infringement and trade secret matters. Attorneys and companies also engage us in Hatch-Waxman litigation, litigation involving biosimilars, and *inter partes* reviews to assess commercial success and irreparable harm.

Alleged Theft of Trade Secrets for a Drug in Development

Cornerstone Research and Sean Nicholson of Cornell University analyzed the loss in value of a drug in development due to the advantage that the manufacturer of a competing drug obtained by allegedly stealing trade secrets.

Two pharmaceutical manufacturers were collaborating on a novel drug in the early stages of development. The plaintiff alleged that the defendant stole the plaintiff's trade secrets, annulled the collaboration, and clandestinely developed a competing drug. The plaintiff also claimed that knowledge of trade secrets gave the defendant a head start in developing its own drug.

Defense counsel retained Professor Nicholson and Cornerstone Research to analyze the loss in value of the plaintiff's drug due to the defendant's head start, and to evaluate the damages estimated by the plaintiff's expert. Professor Nicholson analyzed the various drivers of value for the plaintiff's drug, such as projected sales, marketing expenditures, research and development expenses, cost of capital, and timing of launch of competing drugs.

Professor Nicholson also calculated the alleged loss in value of the plaintiff's drug for different levels of head start obtained by the defendant (e.g., one year, two years). His analysis demonstrated that the damages estimate of the plaintiff's expert was inflated because of inappropriate assumptions about the drivers of drug value.

"Blocking" Patents in Hatch-Waxman Litigation

Defendants in Hatch-Waxman litigation have increasingly relied on "blocking" patent arguments. Cornerstone Research and affiliated experts have examined assertions of "blocking" patents by generic companies. We have also reviewed the applicability of the "blocking" patent framework offered in the *Acorda Therapeutics v. Roxane Laboratories* decision in a variety of settings.

In multiple matters, our affiliated experts have opined on the relevance of alleged "blocking" patents to the evaluation of the nexus between the claimed patented inventions and the drug's commercial success. They have also testified on the regulatory environment that governs follow-on research by third parties in the presence of alleged "blocking" patents as well as the economic mechanisms and incentives for conducting follow-on research in the presence of such patents.

Damages from Patent Infringement by a Biosimilar Drug

In matters alleging patent infringement by a biosimilar entrant, Cornerstone Research and an affiliated expert examined damages resulting from the entry of a biosimilar version of a blockbuster biologic drug.

To assess lost profits, Cornerstone Research and the expert modeled the impact of biosimilar entry on the price and volume of the reference biologic drug in the actual and "but-for" worlds. When evaluating price erosion for the biologic drug, Cornerstone Research and the expert analyzed factors affecting price negotiations between the biologic drug manufacturer and public and private third-party payors, hospitals, and physician clinics.

For one of the matters, the price erosion analysis also took into account the possibility that, in the "but-for" world, the biosimilar drug would enter the market but only for a subset of indications that the reference biologic drug was approved to treat. The lost volume analysis built upon the observed gradual acceptance of the biosimilar drug by physicians, patients, and payors, and distinguished between treatment-naïve and continuing patients to reflect differences in biosimilar acceptance.

In addition to the lost profits analysis, the expert also examined reasonable royalties under the *Georgia-Pacific* framework and assessed the value of the first-mover advantage in the context of the biosimilar manufacturer's incentives to enter into a hypothetical negotiation.

Securities

In securities litigation, clients draw on our expertise in finance, accounting, economics, and biostatistics, along with our knowledge of the complex institutional, regulatory, and market forces that shape the life sciences industry. In addition to supporting experts addressing class certification, loss causation, and damages, we have supported experts retained to educate finders of fact on such topics as:

- Clinical trial protocols and data analysis
- Drug development and the FDA approval process
- Payment flows in pharmaceutical markets
- The role of intermediaries such as drug wholesalers, pharmacies, hospitals, and PBMs
- Brand and generic drug pricing and reimbursement
- Pharmaceutical marketing and its regulation

Hsu et al. v. Puma Biotechnology Inc. et al.

In a rare securities class action trial, plaintiffs claimed that Puma Biotechnology (Puma) and its CEO made misleading statements about the results of its phase III clinical trial for a breast cancer drug. Puma and its counsel retained Cornerstone Research and Paul Gompers of Harvard University to respond to the plaintiffs' damages expert.

The plaintiffs' damages expert testified that these alleged misrepresentations were corrected when the clinical trial results were released on two separate dates and caused Puma's stock price decline. He presented claims that damages experienced by class members were $87.20 per share.

In his response, Professor Gompers testified that the plaintiffs' expert had not established loss causation and had failed to reliably quantify damages for the allegedly corrective disclosures.

The jury found in Puma's favor on three of the four alleged misrepresentations and awarded only $4.50 per share for the first corrective disclosure date, or less than 5 percent of the claimed damages per share.

Biostatistics Analysis

Cornerstone Research was retained by a pharmaceutical company that faced securities litigation after it withdrew a drug from the market because of safety concerns. Plaintiffs claimed that the clinical trial data available to the company showed that the drug was unsafe long before the company withdrew the drug. Counsel for the company retained Cornerstone Research and a biostatistician to assess these claims.

The expert reviewed the company's analysis of its clinical trial data along with the clinical trial protocols. He showed that the analysis was consistent with those protocols, including the adjudication of adverse events, the timing of data unblinding, and the meta-analysis of data across multiple trials to assess safety risks. He also concluded that the measurement of adverse events was appropriate given the hypothesized nature of the safety risks. In contrast, the conclusions of the plaintiffs' expert relied upon analyses and safety events that were not pre-specified and assumed access to data prior to its unblinding.

U.S. Securities and Exchange Commission v. Biopure Corporation et al.

The SEC brought litigation against Biopure Corporation and several current and former officers of the company involving its drug Hemopure. Counsel for Biopure retained Cornerstone Research to work with Paul Gompers of Harvard University.

The SEC alleged that Biopure misled investors by concealing negative information it had received from the FDA regarding the approval of Hemopure and that investors were damaged when Biopure's stock price declined after market participants learned that Hemopure was unlikely to be approved.

In his report, Professor Gompers opined on the lack of materiality of the alleged corrective disclosures. Using a market model, he showed that Biopure experienced large random fluctuations in its stock price during the relevant period, typical for small companies with risky revenue streams that were dependent on the success of a few research and development projects.

He also opined that the allegedly concealed information was not material to investors because (a) there were other instances in which similar disclosures had not caused a price decline, and (b) analyst reaction showed that they did not give much weight to the disclosures. Finally, Professor Gompers opined on other potential causes of the price decline, including a cash squeeze and the announcement of an SEC investigation.

Cornerstone Research Selected Experts

Laurence C. Baker

Bing Professor of Human Biology,
Senior Fellow, Stanford Institute for Economic Policy Research (SIEPR),
Stanford University

Laurence Baker specializes in the organization and economic performance of the U.S. healthcare system. His research has appeared in *American Economic Review*, *Journal of Health Economics*, and the *Journal of the American Medical Association (JAMA)*. Professor Baker has consulted and testified on a range of life sciences matters involving antitrust and intellectual property issues and has addressed class certification, liability, and damages issues.

Mark Duggan

Wayne and Jodi Cooperman Professor of Economics, Trione Director,
Stanford Institute for Economic Policy Research (SIEPR),
Stanford University

Mark Duggan is a health economist whose research includes pharmaceutical and hospital pricing, patent reform, Medicare, Medicaid, disability insurance, and the Affordable Care Act. Professor Duggan served from 2009 to 2010 as the senior economist for healthcare policy on the President's Council of Economic Advisers. His expert work has addressed pharmaceutical pricing, reimbursement, and competition.

Alice Chen

Associate Professor,
Sol Price School of Public Policy;
Senior Fellow, Leonard D. Schaeffer Center for Health Policy and Economics,
University of Southern California

Alice Chen is an expert on a range of healthcare issues including innovation and competition among pharmaceuticals, biologics, and biosimilars, and the impact of Medicare policies on provider treatment decisions and health outcomes. She has consulted for pharmaceutical companies and has addressed damages issues as a consulting expert in a life sciences matter. She has presented her work before the Federal Trade Commission and the Congressional Budget Office.

Gautam Gowrisankaran

Professor of Economics,
Columbia University

Gautam Gowrisankaran is an expert on competition economics and has particular expertise in the healthcare industry, including pharmaceutical markets. In his expert work, he has addressed damages and liability issues on matters involving pharmaceutical marketing, pharmaceutical pricing, and the 340B program, among other topics. Professor Gowrisankaran's trial testimony includes *In re: Purdue Pharma L.P. et al*.

Iain M. Cockburn

Richard C. Shipley Professor in Management, Questrom School of Business,
Boston University

Iain Cockburn addresses competition and innovation issues in the life sciences and biotechnology industries. Professor Cockburn's expert work includes matters related to pricing, the impact of marketing on prescribing, off-label promotion, Medicare and Medicaid reimbursement, competition between brand and generic products, reasonable royalties, and valuation associated with licensing and collaboration agreements.

Henry G. Grabowski

Director, Program in Pharmaceuticals and Health Economics;
Professor Emeritus,
Duke University

Henry Grabowski is a leading expert on the economics of the pharmaceutical industry. His research examines government policy actions and their effects on the pharmaceutical industry, pharmaceutical research and development costs and returns, and issues involving generic competition and intellectual property. He has served as an advisor to the Institute of Medicine, the Federal Trade Commission, and the National Academy of Sciences.

Cornerstone Research Selected Experts

Rahul Guha

Chief Executive Officer,
Cornerstone Research

Rahul Guha is the founder of Cornerstone Research's life sciences practice, and a former cohead of the firm's antitrust and competition practice. Dr. Guha combines life sciences expertise with twenty-five years of experience in antitrust, intellectual property, breach of contract, and class action matters. He has consulted on class certification, liability, and damages in multiple matters in the pharmaceutical industry, and has also served as a testifying expert.

Darius Lakdawalla

Quintiles Chair in Pharmaceutical Development and Regulatory Innovation, Director of Research, Leonard D. Schaeffer Center for Health Policy and Economics, University of Southern California

Darius Lakdawalla is an authority on pharmaceutical economics, with particular expertise in pharmaceutical industry policy, pharmaceutical marketing, and prescription drug insurance coverage and reimbursement. He has served as a consulting expert in life sciences and healthcare litigation, addressing liability and damages issues. As a testifying expert, he has analyzed pharmaceutical competition in the context of alleged collusion.

James W. Hughes

Thomas Sowell Professor of Economics Emeritus,
Bates College

James Hughes has extensive experience opining on class certification and addressing damages issues in pharmaceutical antitrust and product misrepresentation matters. Professor Hughes researches issues in antitrust economics and law and economics. His research has appeared in numerous scholarly journals, including the *International Review of Law and Economics* and the *Journal of Law and Economics*.

Matthew R. Lynde

Senior Vice President,
Cornerstone Research

Matthew Lynde heads Cornerstone Research's intellectual property practice. His work covers a range of cases, including intellectual property, antitrust and competition, securities litigation, and breach of contract. On life sciences matters, Dr. Lynde has opined on damages, commercial success, and irreparable harm. His expert testimony has been accepted in domestic and international courts, tribunals, and arbitration panels in more than one hundred instances.

Margaret K. Kyle

Chair in Intellectual Property and Markets for Technology,
MINES ParisTech

Margaret Kyle is an authority on competition and intellectual property in the pharmaceutical industry. She has examined R&D investment and competition and analyzed how incentives can promote new medical technologies and the rapid manufacture of tests and treatments. Professor Kyle consults on competition, economics, and innovation topics to European and UK policy entities. She has testified on drug marketing and pricing issues in the United States.

Zoya Marriott

Vice President,
Cornerstone Research

Zoya Marriott coleads Cornerstone Research's life sciences practice. Dr. Marriott has extensive experience in litigation matters in the life sciences industry, with an emphasis on antitrust, intellectual property, false claims, and breach of contract. She has testified as an economic expert regarding commercial success issues in Hatch-Waxman litigation. Her research includes articles on delayed generic entry and reverse payment settlements.

Cornerstone Research Selected Experts

Sean Nicholson

Professor, Department of Economics,
Professor, Brooks School of Public Policy,
Director, Sloan Program in
Health Administration,
Cornell University

Sean Nicholson specializes in the analysis of pharmaceutical competition, innovation, and reimbursement. His research has assessed pharmaceutical mergers and collaborations as well as the financing of pharmaceutical research and development. Professor Nicholson provides expert testimony on issues related to breach of contract, fraudulent pricing and promotional practices, patent infringement, theft of trade secrets, and monopolization in the pharmaceutical and healthcare industries.

Celeste C. Saravia

Vice President,
Cornerstone Research

Celeste Saravia provides expert testimony on complex competition matters and has particular expertise in the pharmaceutical industry. Dr. Saravia has been retained to address class certification, liability, and damages issues on pharmaceutical antitrust matters involving allegations of delayed generic entry, monopolization, and market foreclosure.

Erin Trish

Associate Professor, School of Pharmacy,
Co-Director, Leonard D. Schaeffer Center
for Health Policy and Economics,
University of Southern California

Erin Trish is an expert on matters at the intersection of public policy and healthcare markets. Her research has addressed such topics as insurance premiums, health plan benefits, and prescription drug spending. She has particular expertise in government health programs and regulations, including Medicaid, Medicare, and evolving price transparency mandates. She has testified in arbitration and trial on antitrust and breach of contract issues as well as before Congress on health policy proposals.

CLE Presentations

Cornerstone Research offers virtual presentations designed to provide attorneys with insights into economic and financial analyses as well as potential new areas of litigation and regulation.

Pharmaceuticals 101

The pharmaceutical industry is a frequent target of antitrust, product misrepresentation, and False Claims Act litigation. Assessing the claims in those matters requires an understanding of the institutional, regulatory, and market forces that shape the industry. This presentation focuses on small molecule drugs and covers the basics of:

- Drug development and approval
- The stakeholders involved in how drugs are marketed, prescribed, distributed, and reimbursed
- How drug manufacturers compete, including across-molecule versus within-molecule competition

Biologics 101

Over the past twenty years, spending on biologic drugs has grown enormously and accounts for more than a third of all medicine spending. This presentation explains the difference between small molecule and biologic drugs, the costs of developing biosimilars, and the current regulations governing biosimilar competition. It also provides an overview of biologic-biosimilar reimbursement and the implications for competition between innovator biologic drugs and biosimilars.

Class Certification Fundamentals

Learn the basics of class certification issues involving healthcare and pharmaceuticals, including the kinds of issues that arise and the importance of the reimbursement system in class certification assessments.

Survey Says! Use of Sampling to Access Liability and Damages

Sampling can efficiently reveal the characteristics of a larger group. Poorly conducted sampling, however, can generate false or biased conclusions. This session reviews recent guidance on the use of sampling in reimbursement cases. It will also cover methodological pitfalls with illustrations from instant surveys of attendees.

Estimating Damages in False Claims Act Litigation

Damages estimation in FCA litigation can proceed under alternative interpretations. On one hand, fraudulent claims can be interpreted as "tainted," implying damages are equal to the entire cost of the claim. Alternatively, damages can also be viewed as the net loss the government faced taking into account that there was some benefit in the provided services. This session expounds on these viewpoints, discusses the economics of estimating damages in FCA cases, and reviews recent developments.

Biologic-Biosimilar Competition

After a brief primer on the regulatory features shaping biologic-biosimilar competition in the United States, this presentation discusses emerging issues and potential litigation, including:

- The economics behind allegations in *In Re Humira (Adalimumab) Antitrust Litigation* and the motion to dismiss decision
- The "rebate trap" claims in *In Re Remicade Antitrust Litigation* and *Pfizer v. Johnson & Johnson and Janssen Biotech*, and the market and drug characteristics that are more likely to give rise to such allegations
- The FDA draft guidance addressing potentially misleading promotion of biologic drugs and the possible adverse effects of such misinformation on competition and consumption of biosimilar drugs

CLE Presentations

False Claims Act, Product Misrepresentation, and Other Reimbursement Matters

This program introduces the economic concepts and methods that underpin key components of liability and damages analyses in government and private matters involving allegations of excessive reimbursement; inappropriate pricing; and product misrepresentation for prescription drugs, medical devices, and medical services. These concepts and methods include:

- How to define the but-for world
- How to calculate the fair market value of services provided
- How to use statistical sampling

"Blocking" Patents in Pharmaceutical Patent Litigation

The "blocking" patent argument is gaining ground in Hatch-Waxman litigation between branded drugs and would-be generic competitors. This presentation explains the logic behind the argument and its potential shortcomings. Specifically, we discuss:

- The link between "blocking" patent claims and the evaluation of the nexus between claimed patented inventions and the drug's commercial success
- The regulatory environment governing follow-on research by third parties in the presence of allegedly "blocking" patents
- Economic mechanisms and incentives for conducting follow-on research in the presence of such patents

The discussion includes an overview of the "blocking" patent framework offered in the *Acorda Therapeutics v. Roxane Laboratories* decision.

To schedule a presentation, contact:

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Zoya Marriott: zmarriott@cornerstone.com

Cornerstone Research is an accredited minimum continuing legal education provider in CA and NY. We are happy to provide proof of attendance if required.

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