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.
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.

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. 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.

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 to offer insightful and effective analyses. We combine technical expertise, access to the latest platforms, and high-performance tools with a deep knowledge of litigation and regulatory issues. 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 delayed or suppressed generic competition. Clients facing regulatory challenges to proposed mergers have also retained Cornerstone Research staff and experts to define relevant markets and evaluate competitive effects.
Alleged Delay or Suppression of Generic Competition

In FTC v. Actavis, the U.S. Supreme Court established that pharmaceutical patent litigation settlements involving “reverse payments” must be evaluated under the rule of reason and that “large, unexplained” payments may be anticompetitive. In the antitrust disputes that our clients face, lower courts are interpreting the Actavis decision. These matters require a careful economic evaluation of:

- The value of the alleged payment, taking into account any consideration provided in exchange for the payment
- Whether there are explanations for the payment other than delay—for example, risk aversion or avoided litigation costs (including business disruption costs)
- Whether a settlement would have been possible without the alleged reverse payment
- Whether generic competition was actually delayed
- What the brand company’s actions would have been, in particular, with respect to brand-authorized generics

Case Studies

Product Hopping

Pharmaceutical manufacturers have been accused of engaging in product hopping by introducing modified versions of branded drugs nearing patent expiry while simultaneously withdrawing the older drugs to hinder generic substitution.

We assisted counsel in evaluating potential damages in a case where a branded pharmaceutical company was accused of harming competition by introducing new versions of a drug with longer remaining patent protection and withdrawing 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 in order to estimate the damages corresponding to conduct that might ultimately be found to be anticompetitive.

In re Skelaxin (Metaxalone) Antitrust Litigation

Defense counsel retained Cornerstone Research and Professor James Hughes of Bates College to address class certification issues.

The plaintiffs in this case alleged that the defendants conspired to prevent or delay entry of a generic version of the branded pharmaceutical Skelaxin. Professor Hughes submitted expert reports on both the end payor class and the indirect purchaser (retail pharmacy) class.

In the end payor case, Professor Hughes demonstrated that determining whether any end payor for a given prescription would have been injured by the plaintiffs’ allegations would require individualized inquiry because of the complexity of the contractual relationships among the parties.

In the indirect purchaser case, Professor Hughes demonstrated that determining whether any end payor for a given prescription would have been injured by the plaintiffs’ allegations would require individualized inquiry because of the complexity of the contractual relationships among the parties.

The judge denied certification for both purported classes, citing several facets of Professor Hughes’s arguments.
**Breach of Contract**

Breach of contract disputes often require detailed 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 therapeutic alternatives space
- Reasonableness of commercial efforts
Case Studies

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.

An investment firm that owned the intellectual property rights to a branded drug brought suit against its partner, a pharmaceutical company. The investor plaintiff alleged that the defendant 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 where the drug was not promoted to physicians, which irreversibly damaged the drug’s long-term value.

Plaintiff counsel retained Cornerstone Research and an affiliated valuation expert to assess the role that consistent supply and promotion play in generating drug sales and to estimate damages by valuing the drug before and after the alleged breach of contract.

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. He then compared this amount to the value the plaintiff actually received to arrive at an estimate of damages.

Biotechnology Joint Development Agreement

Cornerstone Research worked with Professor 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.

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 assistance, 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.
False Claims

Life sciences firms are often the target of False Claims Act allegations of unlawful marketing and sales practices, improper pricing, and violations of the Anti-Kickback Statute. During the investigation and litigation phases of these matters, we work with clients to identify and assess the information needed to analyze causation, injury, and damages claims.

Attorneys and corporations also call on our experts to evaluate class certification, liability, and damages issues in class actions that often follow the unsealing of qui tam complaints. We address these issues in cases involving proposed classes of patients, insurance companies, pharmacies, and wholesalers. We also assist attorneys representing parties involved in private reimbursement disputes.
Average Wholesale Price Litigation

Cornerstone Research has worked with counsel for several pharmaceutical companies on state False Claims Act cases alleging that these companies caused state Medicaid agencies to overpay for prescription drugs by posting fraudulent prices. The allegations center on the reporting of average wholesale prices (AWPs) for branded and generic drugs that were sometimes used as the basis for reimbursing pharmacies for the prescription drug acquisition costs.

States’ attorneys general claimed that state Medicaid agencies’ reimbursements to pharmacies were inflated because pharmaceutical companies posted false and inflated AWPs.

Cornerstone Research has supported experts who responded to this claim. Our work demonstrated that AWPs were widely known to exceed pharmacy acquisition costs, that information on actual pharmacy acquisition costs was available to state Medicaid officials, and that state Medicaid officials took this information into account when setting reimbursement levels. We also showed that the plaintiffs’ “but-for” pharmacy reimbursement levels would have resulted in pharmacies losing money on prescriptions filled for Medicaid beneficiaries, potentially resulting in greatly reduced access to pharmacy services for Medicaid beneficiaries in violation of federal Medicaid requirements.

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 payers (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: Professor W. David Bradford of the University of Georgia; Professor Pradeep K. Chintagunta of the University of Chicago Booth School of Business; and Ms. 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.

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 worked on a variety of matters, including those involving allegations of off-label marketing and physician kickbacks.
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.
Case Study

Alleged Theft of Trade Secrets for a Drug in Development

Cornerstone Research and Professor 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.

Research

Patent Challenges under Hatch-Waxman

The 1984 Hatch-Waxman Act was designed to encourage intense generic price competition while preserving sufficient patent exclusivity to create incentives for drug research and development.

The act also created incentives for generic drug companies to challenge patents on branded drugs. Since 1984, the number of patent challenges has grown rapidly, leading to ongoing debate as to whether this is a response to an increased number of “weak” patents filed by branded drug firms or a reflection of stronger economic incentives for generic drug firms to challenge patents regardless of their merits.

Cornerstone Research worked with Professor Henry Grabowski of Duke University to assemble a unique dataset of patent challenges for new drugs approved between 1994 and 2006. Using the dataset, Cornerstone Research and Professor Grabowski documented the behavioral changes of generic firms, such as racing to file patent challenges to achieve first-filer status, and of branded drug firms. The dataset includes detailed information on litigation outcomes for top-selling pharmaceuticals, allowing us to compare the strength of various types of drug patents and to determine the effect of patent challenges on branded drug firms’ market exclusivity periods.
Securities

In securities litigation, clients draw on our expertise in finance, accounting, economics, and biostatistics, along with our knowledge of the competitive and regulatory environments that impact life sciences firms. Attorneys and businesses often retain us when facing government investigations or private litigation to address class certification issues, evaluate loss causation, and estimate damages. Our experience includes matters related to:

- Announcements of FDA approval decisions
- Publication of clinical trial results
- Accounting treatment of expected penalties for off-label marketing
- Announcements of drug safety concerns
- Value of pharmacy benefit manager contracts in a pharmacy merger
Case Studies


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 Professor Paul Gompers of Harvard Business School.

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.

Misleading Disclosure of Clinical Trial Results

Plaintiffs filed a securities class action against a major pharmaceutical company alleging that the company made false and misleading statements regarding the results of a drug’s safety study. Specifically, the plaintiffs contended that the safety study indicated that the drug was no safer than its alternatives and that the company altered the protocols of the study to present the results in a more favorable light.

As a result of these alleged misrepresentations, the plaintiffs contended that the company’s stock and bonds traded at artificially inflated prices. The plaintiffs alleged that an article in a medical journal and subsequent public press revealed unfavorable results from the safety study.

Working with Cornerstone Research, a finance expert examined whether the allegedly corrective disclosures were associated with statistically significant changes in the company’s stock price. He found that the statistical evidence did not establish a causal link between the release of allegedly corrective disclosures and decreases in the company’s stock price. Furthermore, the expert documented that all the facts contained in the allegedly corrective information had previously been in the public domain. Finally, an analysis of the market for the company’s corporate bonds showed that they did not trade in a well-developed, efficient market.
Selected Experts

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. He has coedited the American Economic Journal: Economic Policy and the Journal of Public Economics.

Henry Grabowski
Professor Emeritus and Director,
Program in Pharmaceuticals
and Health Economics,
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 U.S. Federal Trade Commission, and the National Academy of Sciences.

Rahul Guha
Chief Executive Officer,
Cornerstone Research

Rahul Guha is a former cohead of Cornerstone Research’s antitrust and competition practice and founder of the firm’s life sciences practice. He combines knowledge of the life sciences industry with over twenty years of experience in antitrust, intellectual property, breach of contract, and class action matters. Dr. Guha has written several articles on pharmaceutical and biologic drug markets. He has testified on commercial success, irreparable harm, reasonableness of commercial efforts, and damages.

James W. Hughes
Thomas Sowell
Professor of Economics,
Bates College

James Hughes has extensive experience opining on class certification 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.

Zoya Marriott
Principal,
Cornerstone Research

Zoya 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. Dr. Marriott 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.

Sean Nicholson
Professor, College of Human Ecology,
Cornell University; Senior Advisor,
Cornerstone Research

Sean Nicholson specializes in the analysis of pharmaceutical competition, innovation, and reimbursement. He 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. His research has been published in the New England Journal of Medicine, the Journal of Health Economics, and other publications.
Resources

Trends in Paragraph IV Challenges
The Economics of Irreparable Harm in Pharmaceutical Patent Litigation
The Economics of Commercial Success in Pharmaceutical Patent Litigation
Economic Approaches to Remedies in Trade Secret Cases
Regulatory and Cost Barriers to Biosimilars Development
Evaluating Reverse Payment Settlements after Actavis
An Alternative Activation of Actavis
Interpreting Stock Reactions to Reverse-Payment Settlements
Does Generic Entry Always Increase Consumer Welfare?
Generic Drug Price Surges Don’t Always Point to Collusion
Emerging Competition Issues in Biologics
Hatch-Waxman: Generic Competition Intensifies

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