

HEALTH CARE HIGHLIGHTS

Recent cases and expanded capabilities
in our Health Care Practice

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Analysis of Medicare reimbursement policies is cited extensively in court decision

In 2007, a federal court jury found that a drug Hoffman-La Roche intended to sell in the United States infringed certain patents held by Amgen. Following the jury verdict, the judge scheduled a four-day hearing to determine whether Amgen should be granted a permanent injunction preventing Roche from selling its drug in the United States. Counsel for Amgen retained Bates White to provide an economic opinion on the four factors described in the U.S. Supreme Court's recent opinion in *eBay Inc. v. MercExchange, L.L.C.* relevant to the Court's determination of whether to grant the permanent injunction:

1. Harms Amgen would suffer if Roche were permitted to sell its drug in the United States
2. Whether monetary damages would be adequate to compensate Amgen for those harms
3. How the burdens an injunction would impose on Roche would compare with Amgen's harms if Roche were not enjoined
4. Whether the public interest would be disserved if the injunction were entered by the Court

Since the drugs at issue are primarily covered by Medicare Part B, the Bates White team, led by Partner **Douglas Bernheim**, performed a detailed analysis of the economic incentives created by Medicare's Average Selling Price (ASP) reimbursement system for entrant and incumbent drug manufacturers. The team developed innovative game theory models of competition under the ASP reimbursement system to predict pricing strategies that Roche and Amgen likely would employ should Roche be permitted to enter the U.S. market. The predictions were shown to be consistent with the parties' business planning documents and ultimately helped the court understand the consequences of the strategies. In conjunction with this analysis, Bates White developed a historical data set of pricing information from the Centers for Medicare and Medicaid Services (CMS) to analyze the pricing decisions of previous entrants and incumbents in a variety of therapeutic segments under the ASP system.

On the basis of these analyses, Dr. Bernheim concluded that, unlike typical competition described in economics textbooks, under Medicare's reimbursement policies, Roche's entry would likely result in *higher* prices and *increased* Medicare expenditures. Dr. Bernheim also testified that Roche's entry would cause substantial recurring harm to Amgen that would not be adequately compensated by monetary damages and that Amgen's harms would outweigh any burden on Roche stemming from the permanent injunction.

After a lengthy review, the judge issued a [court order](#) that agreed with Dr. Bernheim's conclusions and cited his testimony extensively. Our client obtained a favorable outcome with the court issuing a permanent injunction against Roche. The case is *Amgen, Inc., v. F. Hoffman-La Roche*.

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Experienced AWP team provides key support for pharmaceutical manufacturers

Since 2004, Bates White has been providing consulting and expert services on behalf of certain pharmaceutical manufacturers in lawsuits involving published Average Wholesale Prices (AWPs) and Wholesale Acquisition Costs (WACs). These matters span a variety of jurisdictions and include lawsuits brought by a class of private payors, attorneys general in numerous states, and other government agencies. Plaintiffs in these matters allege that pharmaceutical manufacturers illegally inflated providers' profits by creating "spreads" between published AWPs/WACs and the prices that were charged to wholesalers, pharmacies, and physicians.

A joint defense group of pharmaceutical manufacturers initially retained Bates White in a multidistrict class action litigation in federal district court in Massachusetts. During the class certification phase, Bates White Partner **Eric Gaier** testified that the alleged conduct would not have had common impact on the putative class members. The Judge denied certification to the self-administered drug class, which represented most of the commerce at issue. After the class certification phase, Dr. Gaier and the Bates White team analyzed the merits of plaintiffs' allegation with respect to the remaining commerce associated with physician-administered drugs. Ultimately, Dr. Gaier testified at the bench trial that the plaintiffs were not injured as a result of the defendants' alleged conduct. Dr. Gaier's testimony included conclusions based on an exhaustive review of evidence pertaining to market participants' understanding of the meaning of AWP, an evaluation of the competitive dynamics between providers and payors, and an analysis of the effect of the Medicare Prescription Drug Improvement and Modernization Act of 2003 on Medicare expenditures. The judge found liability and damages for two of the defendants and dismissed two others.

Building on our work in the class action matter, Bates White has become a leading provider of consulting and expert services on behalf of certain pharmaceutical manufacturers in numerous lawsuits brought by state attorneys general. Dr. Gaier has provided deposition or trial testimony in lawsuits brought by attorneys general in Alabama and Massachusetts. In addition, the Bates White team has provided support for a number of external experts, including academics at top universities, who have been retained in other AWP-related matters.

Bates White's clients rely on our expertise in all phases of litigation—from discovery support to trial testimony. In particular, with nearly five years of experience on AWP-related matters, Bates White has developed a deep knowledge of health-care markets; pharmaceutical distribution and pricing; and Medicare, Medicaid, and third-party payor policies. Furthermore, our team has developed a mastery of a variety of relevant databases and has built an infrastructure to quickly and efficiently respond to requests for attorney support and analyses. These databases include information from numerous pharmaceutical manufacturers, wholesalers, pharmacies, Medicaid agencies, Medicare, third-party payors, and publishers such as First DataBank.

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Ongoing work assists clients with merger and single-firm conduct issues

Bates White is supporting a number of antitrust matters in the health care industry. We have assembled teams of consultants and testifying experts to conduct economic analysis for mergers and lawsuits that include allegations of anticompetitive behavior. Our projects include the following:

- Performed market definition and competitive effects analyses on behalf of the DOJ in a recent merger investigation in the health care sector. Analysis of competitive effects included an econometric study to predict the likely shares incoming entrants would obtain in the market. Subsequent events have borne out this prediction.
- Working with an outside expert to analyze claims of bundling, tying, and tortious interference. Evaluating the nature of competition in the markets for inpatient and outpatient surgical services and analyzing the impact of exclusive contracting arrangements.
- Providing a client in the hospital industry with antitrust and industry expertise to assist it and the DOJ in investigating alleged anticompetitive conduct by competing firms. Investigations involve complex issues of horizontal and vertical market foreclosure.
- Providing antitrust and industry expertise to investigate anticompetitive conduct by competing firms on behalf of a medical imaging center.

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Academic affiliates broaden pharmaceutical economics and health policy expertise

In our ongoing efforts to meet client needs for litigation support services and expert witness testimony, we recently expanded our network of academic affiliates to include two well-known health care academics, Professors David Bradford and David Dranove. Both are experienced testifying experts with deep expertise in a range of specialties related to the health care industry.

W. David Bradford, Ph.D.

[David Bradford](#) is the Busbee Chair in Public Policy in the Department of Public Administration and Policy at the University of Georgia. He is the former Director and founder of the Center for Health Economic and Policy Studies at the Medical University of South Carolina, and he was a visiting faculty member at Yale Medical School. Dr. Bradford specializes in health economic policy, the impact of advertising on pharmaceutical markets,

and behavioral and neural economics. He has served as a consultant to health insurance companies and medical care centers, and he has provided testimony in private litigation.

David Dranove, Ph.D.

[David Dranove](#) is a Professor of Health Industry Management and Professor of Management and Strategy at Northwestern University's Kellogg School of Management. He is also the Director of Kellogg's Center for Health Industry Market Economics. Dr. Dranove specializes in medical and pharmaceutical economics, industrial organization, business strategy, and cost-benefit analysis. He has served as an expert economist for various state antitrust agencies and private law firms, and he has authored expert reports and given deposition testimony in several health care antitrust cases.

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ESMT partnership is well positioned to provide transatlantic health care solutions

In 2006, Bates White and ESMT Competition Analysis (based in Berlin, Germany) formed an exclusive partnership to provide antitrust services in the United States and Europe. Over the past two years, our firms have worked together to provide joint consulting services on a number of antitrust matters under the purview of U.S. and EU regulatory authorities.

Our capabilities in the health care industry also span the Atlantic. In particular, we leverage the experience of ESMT President **Hendrik Röller**, who was the first Chief Competition Economist of the European Commission from 2003 to 2006. During his tenure, Dr. Röller was involved in all phase-two merger cases and many first-phase merger cases in front of the EC. He experienced, first hand, the agency's response to the high merger activity in the pharmaceutical sector during 2004-2006, and he worked alongside agency officials in developing enforcement policies associated with competition for brand-name and generic pharmaceuticals. This past spring, Dr. Röller prepared a [presentation](#) on the EC's pharmaceutical sector inquiry that addressed the extent to which this inquiry will set the ground for an economic approach that integrates antitrust concerns with innovation incentives.

In addition to Dr. Röller's experience, ESMT Competition Analysis Managing Director **Rainer Nitsche** conducted an impact and market study on the pharmaceutical industry for EC's Directorate General Enterprise. In the study, he investigated falling marketing authorization applications, whether there is a worldwide crisis in innovation in the pharmaceutical sector, the reasons behind this crisis, and the tools available to kick-start innovation. The project also involved forecasting future authorization applications, analyzing the drivers of innovation, and developing recommendations for regulatory and governmental bodies on pharmaceutical and biotechnology companies.

Bates White's partnership with ESMT Competition Analysis enables us to combine our complementary experience and expertise to offer tailored solutions for complex antitrust and health care matters in the United States and Europe.



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Bates White's Health Care Practice

Clients depend on Bates White for expert testimony, consulting and litigation support, as well as class certification, liability and damages analysis, and other economic analyses in connection with a full range of health care issues. Our approach involves meticulous data analysis and statistical modeling, and our clients gain a significant advantage from our ability to explain complex methodologies and present our conclusions in plain language. Our cross-functional teams combine health care industry knowledge with expertise in other areas, such as antitrust, mergers and acquisitions, product liability, and intellectual property. Our team of academicians, economists, and experts possesses comprehensive knowledge of institutions across the health-care industry.

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