Health Care Litigation

Quinn Emanuel has one of the leading healthcare litigation practices in the United States. The firm has deep substantive healthcare law expertise, unparalleled investigative experience, and a willingness and ability to try these cases to a jury if necessary. These skills have been brought to bear to achieve an extraordinary record of successful outcomes for our health care clients.

Our representations in healthcare litigation matters cover virtually every context of healthcare, such as individual physicians and hospitals involved in direct provisions of services to patients, drug manufacturers marketing products to doctors and wholesalers, and diagnostic testing companies that provide services to various end-users. Our partners bring to bear their extensive knowledge of the issues unique to the healthcare industry allowing us to expertly navigate through litigation our clients face in the following representations:

- **Revenue Cycle Disputes**: Regulations, contractual obligations, payer policies, and billing can complicate our clients' ability to effectively manage revenue cycle, leading to lost revenue and diminished ability to meet the needs of their communities. Our attorneys rely on their breadth of understanding of the inputs that complicate these decisions to leverage the best outcomes for our clients in disputes concerning proper reimbursement for the services they provide. Our firm is at the cutting edge in using claims and billing data to support our clients' claims and defenses.

- **Regulatory Actions Against Federal and State Agencies**: The healthcare industry is one of the most heavily regulated in the United States. In providing lifesaving and high quality services and products to their patients, our clients must navigate complex regulatory schemes that challenge market objectives and business operations and opportunities. The regulations cover nearly all aspects of our clients' business including, marketing and labeling of pharmaceuticals, the provision of care, and billing to Medicare and Medicaid. Our partners bring to bear their industry and government experience and understanding of the regulatory framework in defending our clients in litigations brought by federal and state agencies to undermine their claims.

- **False Claim Act Cases**: Due to the heavily regulated nature of the healthcare industry, our clients often face False Act Claims asserted by relators and federal and state agencies primarily concerning billing and reimbursement rates for services our clients render. Many of our attorneys are former federal prosecutors and assistant attorneys general who draw on their experience prosecuting False Claims Act and healthcare fraud cases in defending our clients facing similar litigations.

- **STARK Law:** Much of the healthcare industry functions on the back of referrals of providers, services, and treatments. The Stark Law prohibits healthcare providers from receiving government reimbursement for services prescribed by providers if there is an improper financial relationship between providers and the entities to whom they refer their patients. Our firm has deep experience understanding the intricacies of both the relationships between providers and entities to whom they refer patients and the legal framework necessary to achieve favorable outcomes for our clients who are accused of violating this law.

- **Antitrust Cases:** The Federal Trade Commission and Department of Justice are increasingly

turning their attention to the healthcare industry to enforce antitrust laws in the United States. Our attorneys recognize the beneficial impact that consolidation and mergers and acquisitions can have on providing efficiencies and better quality care to patients and are adept at bringing these efficiencies to light in defending our clients faced with claims of anti-competitive behavior.

- **Disputes Arising out of Hospital Acquisitions**: Disputes often arise during the course of hospital acquisition that can result in expensive litigation and loss of revenue for our clients. Many of these disputes arise from issues concerning post-closing purchase price adjustments and payout formulas, many of which hinge on government reimbursement programs. Our firm is at the forefront of busted deal litigation and the attorneys in our healthcare practice draw on their knowledge and experience to achieve the best outcomes for our clients in these disputes.

In addition to cases surrounding these core subject areas, our representations cover all aspects of traditional commercial litigation including consumer class actions, ERISA claims, employment cases, personal injury and mass torts claims, criminal/white collar actions, and intellectual property suits (including Hatch-Waxman litigation, traditional patent infringement litigation, and copyright and trademark litigation). We have substantial expertise in the federal anti-kickback statute and the legal and regulatory environment governing the off-label marketing of drugs and devices. We represent industry leaders and individuals as well as small and emerging companies and organizations.

Many of our matters involve a significant overlap of criminal and civil enforcement efforts, and require strategic planning to navigate those issues effectively. More than 20 of our litigators are former federal prosecutors, many of whom prosecuted criminal healthcare fraud cases and coordinated with civil healthcare enforcement authorities while with the government. Many of our attorneys are scientists or engineers with degrees in relevant fields; more than 140 of our litigators hold degrees in physics, chemistry, pharmacology, molecular biology, biochemistry, and chemical engineering. One of our partners is also the former general counsel of a major pharmaceutical company. On the appellate level, our attorneys have argued—and won—some of the biggest health care cases in the United States. Our litigators are not only scientists, but also veteran trial attorneys. Our success in the courtroom in healthcare matters speaks for itself.

RECENT REPRESENTATIONS

WHITE COLLAR/FEDERAL GOVERNMENT REGULATORY LITIGATION

- We represented **Novartis** in a False Claims Act case brought by the U.S. Attorney's Office for the Southern District of New York alleging that the company paid kickbacks to specialty pharmacies so that they would recommend Novartis' products. We litigated aggressively against the government for two and a half years and eventually secured for the company a settlement for 10% of what the government had claimed in court filings it was entitled to in damages.

- We represented **Actelion Pharmaceuticals** in a three year Department of Justice investigation into marketing practices related to the drug Tracleer. The investigation concluded without any criminal charges being filed and with the dismissal of the related qui tam action.

- We successfully represented **Johnson & Johnson** in an eight year criminal and civil investigation into the alleged off label promotion of the drug Natrecor.

- We represented a **Southern California hospital chain** in connection with criminal and civil investigations by the United States Attorney's Office for alleged violations of the anti-kickback statute.

- We represented the chief compliance officer of a **large Southern California hospital chain** in a federal grand jury investigation in the Central District of California for alleged fraudulent billing in seeking reimbursement from Medicare based on allegedly inaccurate diagnostic codes.

- We represented a **medical device company** in connection with parallel civil and criminal actions for alleged violations of the Food Drug and Cosmetic Act and the False Claims Act for alleged off label drug promotion.

- We are represented a **compound pharmacy** in connection with parallel civil and criminal actions for alleged violations of the anti-kickback statute.

- One of our partners represented **Alvarado Hospital Medical Center, Inc.** in an eleven-month jury trial in which the Hospital, Tenet, and a former CEO of the Hospital were accused of conspiracy and violations of the federal healthcare anti-kickback statute. Following trial, the judge dismissed all criminal charges.

- One of our partners represented **Lovelace Hospital**, which at the time was owned by CIGNA Healthcare, in a DOJ civil False Claims Act investigation and settlement of Medicare Part A reimbursement issues.

- One of our partners represented the **Orange County Health Care Agency** in a DOJ civil False Claims Act investigation and settlement of Medicare and medical billing issues.

- One of our partners represented the former Chairman and CEO of a **publicly traded pharmaceutical company** in securities litigation and governmental investigations arising from public disclosures about scientific disputes with the Food and Drug Administration over a New Drug Application. These matters included scientific and expert issues relating to the efficacy of the drug, as well as sensitive media relations issues.

- One of our partners represented a **publicly traded company** in an FDA investigation into alleged false statements in connection with a new drug application submitted to the FDA.

- One of our partners served as co-lead prosecutor in the largest health care prosecution against one doctor in the United States (total fraud amount alleged was $374 million).

- One of our partners represented **hospitals, doctors, and publicly traded companies** in a wide variety of governmental investigations into alleged violations of the health care fraud and abuse laws, including the federal anti-kickback statute.

STATE REGULATORY LITIGATION

- We represented the **largest health plan in California** in a 40-day trial arising out of an enforcement proceeding, which the Department of Managed Health Care sought to require California health plans to cover Viagra and other sexual dysfunction drugs; the court rejected virtually the entirety of the Department's case and the decision was upheld on appeal in *KFHP v. Zingale*.

- We represented **major HMOs** in numerous investigations and litigation being conducted by the California Department of Managed Health Care.

- We represented an **association of health plans** in state court action challenging the regulatory authority of the State of California.

- We represented a **health plan** in state court in California in an action to enjoin Department of Managed Health Care from compelling coverage of prescription weight-loss medications. Court granted health plan summary judgment.

- We represented a **major health insurance provider** in connection with a civil law enforcement action brought by the Los Angeles City Attorney's Office alleging violations of California's Unfair Competition Law.

- We represented the former CEO of a **large California insurance company** in governmental investigations relating to compliance with various California regulatory requirements.

CONSUMER CLASS ACTION

- We are representing **Health Republic Insurance Company** and **Common Ground** in certified class actions against the United States related to the Affordable Care Act (the ACA). We were the first firm in the nation to file a lawsuit on behalf of health insurance plans against the federal government alleging that it had improperly failed to make risk corridor payments in violation of the Affordable Care Act. Through these actions, we sought to recover payments owed to a class of health plans operating in the Health Benefit Exchanges of the ACA. To date, we have recovered nearly $4 billion in final judgments for our clients. We continue to litigate pending claims on behalf of our clients. The litigation made its way to the United States Supreme Court, where eight justices adopted the *exact* legal theory we set forth in our initial *Health Republic* complaint. As a result, the entire health insurance industry was able to collect three years' worth of unpaid risk corridors amounts that they had previously been forced to write off as a total loss—approximately $12 billion. Approximately $3.7 billion of that recovery went to our class members. Quinn Emanuel's class action triggered a series of copycat cases filed by other law firm on behalf of individual plaintiffs. Nevertheless, more than 150 health insurance companies chose to opt into Quinn Emanuel's class action.

- We represented **Pfizer** in the federal Zoloft MDL birth defects litigation; summary judgment was granted on Pfizer's behalf.

- We represented a **national health insurance carrier** sued for canceling coverage of thousands of California realtors; the motion for injunction to reinstate coverage was denied.

- We represented a **major California health plan** in a putative class action related to alleged improper "coordination of benefits" with auto-med-pay policies; case was dismissed.

- We represented a **major California health plan** in a putative class action challenging the reimbursement rates paid for out-of-network medical services; summary judgment was granted on behalf of our client.

- We represented a **major California health plan** against claims by a putative class of licensed physical therapists challenging the health plan's payment practices.

- We obtained a complete victory for **IBM**, who had been named as a defendant in a series of state and federal class actions arising out the loss of nine data tapes belong to IBM's client, Health Net, Inc. Based on a California statute, known as the Confidentiality of Medical Information Act, which appears to allow certain damages without proof of injury, plaintiffs were seeking approximately $2 Billion. After the cases were consolidated in the Eastern District of California, we filed a motion to dismiss on standing grounds. During the months

that the motion was pending, we also managed to stave off discovery by demonstrating to the Judge that they had a robust motion to dismiss and that causing IBM to engage in discovery before the motion was decided would be a miscarriage of justice.

APPELLATE

- Quinn Emanuel won mandamus relief from the Sixth Circuit for **Express Scripts**, reversing a ruling that allowed about 800 plaintiffs to add new claims against pharmacy benefit managers in the opioid MDL. The unanimous panel held that Rule 16 demands a plaintiff-by-plaintiff analysis of awareness and diligence before late amendments are allowed.

- We achieved a company-saving victory for **Corcept Therapeutics** ("Corcept") where the Federal Circuit affirmed the validity of a key patent protecting Corcept's only marketed product. Corcept is an innovator pharmaceutical company that developed the drug Korlym to treat certain manifestations of a rare endocrinological condition known as Cushing's syndrome. Teva Pharmaceuticals is a generic drug manufacturer that seeks to make a generic version of Korlym. Teva brought a Post-Grant Review ("PGR") challenging the validity of Corcept's U.S. Patent No. 10,195,214 that covers methods of using Korlym. Our team previously won the PGR against Teva before the United States Patent Office. The current action is Teva's Federal Circuit appeal of the PGR decision. Our team successfully argued to the Federal Circuit that Teva had failed to show that a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention.

- We represented **Pfizer** in a unanimous victory in the U.S. Court of Appeals for the Second Circuit, which affirmed dismissal of off label marketing claims brought against Pfizer under the qui tam provision of the False Claims Act.

- We obtained a 7-2 victory in the U.S. Supreme Court for **Roche** against Stanford University in a suit involving patents related to HIV treatment that had been developed in a collaboration between Stanford and Roche's predecessor, Cetus Corporation. The Court held that Roche was a co-owner of the patents in suit and rejected Stanford's effort to void its prior contracts based on its receipt of federal funding, reasoning that the Bayh Dole Act—the statute governing federal research funding—does not give automatic ownership of patents to universities.

- We secured a 6-2 victory for **Wyeth LLC** (part of Pfizer Inc.) in the U.S. Supreme Court in *Bruesewitz v. Wyeth*, which held that the National Childhood Vaccine Injury Act preempts state-law causes of action based on theories of defective design in governmentally-approved child vaccines. The decision has significant implications for public health and the vaccine supply, as it removes design-defect claims that if permitted would have increased manufacturers' costs and depressed vaccine supply and development.

- We represented **Ortho-McNeil**, a Johnson & Johnson subsidiary, in a unanimous Seventh Circuit victory that made new law narrowing "manifest disregard of the law" as a ground for district court vacatur of arbitral awards and reversed a partial vacatur of an award that had favored Ortho in a dispute over ownership of two patent families relating to new biological drugs for the production of red blood cells.

- We obtained a victory in the Ninth Circuit for **Sequus Pharmaceuticals, Inc.** (a subsidiary of **Johnson & Johnson**) that strengthened protection of foreign arbitral awards by holding that the removal provision of the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the "New York Convention") should be construed broadly to prevent state-court end runs around foreign arbitration.

PATENT

- We represented **The Broad Institute of Harvard and MIT** in its landmark decade-long patent dispute over CRISPR-Cas9 gene-editing technology and secured a complete victory before the Patent Trial and Appeal Board, which confirmed that Broad's scientist Dr. Feng Zhang is the rightful inventor of the eukaryotic CRISPR-Cas9 invention — not the Nobel Prize-winning opposing team. Delivered on remand from the Federal Circuit under exceptionally challenging circumstances, this fourth consecutive ruling in Broad's favor cements the Institute's intellectual property rights in one of the most consequential technologies in the history of modern medicine and science.

- We represented **Natera** as plaintiff in a highly contentious patent infringement case in the Middle District of North Carolina against defendant NeoGenomics Laboratories regarding NeoGenomics' cancer diagnostic test, RaDaR. Within four months of filing suit we obtained a preliminary injunction enjoining all making, use, sale, or offers to sell RaDaR, effective immediately. This is the first time a medical diagnostic has ever been enjoined through a preliminary injunction.

- We won a jury verdict of $333.8M for our client, **Complete Genomics, Inc.** ("CGI"), in a patent case against Illumina Inc. in which the jury found that Illulmina had willfully infringed two CGI patents covering a DNA sequencing method. The jury also found one of the three patents Illumina asserted against CGI not infringed and all three Illumina patents invalid.

- We represented **PureWick Corp**. in a patent case involving External Urinary Catheters. On April 1, 2022, a jury returned a verdict finding that the defendant, Sage Products LLC, willfully infringed two PureWick patents by making and selling Sage's PrimaFit female external urine collection device, and infringed a third PureWick patent by making and selling Sage's PrimoFit male external urine collection device. The jury awarded PureWick $26.2 million in lost profits from Sage's sales of the PrimaFit and an additional $1.8 million based on a 6.5% reasonable royalty on Sage's sales of the PrimoFit.

BREACH OF CONTRACT

- The firm successfully represented **Express Scripts** in fending off a $14.8 billion breach of contract lawsuit filed against it by Anthem in March 2016. The dispute related to a 2009 contract in which Express Scripts became Anthem's exclusive pharmacy benefit manager (PBM) for 10 years. In the lawsuit, Anthem argued that Express Scripts overcharged it for PBM services and that the 2009 contract guaranteed Anthem new, competitive pricing terms every 3 years. The Court granted summary judgment in Express Scripts' favor, rejecting Anthem's interpretation of the contract and agreeing with Express Scripts. The Court held that because the contract only required good faith negotiation—and did not require that the parties reach ultimate agreement on new pricing terms—Anthem could not recover any of the $14.8 billion in damages it sought. This victory was the latest in a string of victories in cases across the country achieved by the firm on behalf of Express Scripts.

- We represent **Dr. Patrick Soon-Shiong and the Nant companies** in arbitrations and California Superior Court litigations involving disputes over development of a would-be cancer drug and exclusive licenses to antibodies and antibody materials. The matters involve claims by both sides, and collectively seek over one billion dollars.

- We represented **a major healthcare system** in a pricing dispute with a temporary medical staffing agency involving pandemic staffing services. In March 2021, we obtained a preliminary injunction against the agency, which threatened to pull its staff from the client's hospitals in the middle of the COVID-19 pandemic, severely jeopardizing patient care. The dispute involved, among other things, the Massachusetts rate cap imposed to prevent price

gouging in crisis scenarios.

- We represented **a major U.S. hospital system** in a case against an electronic health records vendor alleging that the vendor was grossly negligent in its provision of software and services, threatening patient safety and impacting the system's ability to collect its revenues. The suit also alleged that the vendor made fraudulent misrepresentations during its sales process.

- We represented **a major healthcare system** in a dispute related to its acquisition of five hospitals from another major healthcare system. We initiated a multiple-front legal action against in multiple jurisdictions, claiming that the adverse healthcare system had improperly interpreted its post-acquisition obligations, was wrongfully withholding money owed, and was improperly threatening to terminate certain services agreements.

- We successfully defended a client against claims for breach of contract and trade secret misappropriation. The plaintiff sought $160 million dollars in damages plus trebling, but the jury awarded just $1 on breach of contract and found our client did not engage in trade secret misappropriation.

- The firm represented **Express Scripts** in a breach of contract and antitrust action in the Eastern District of Missouri in connection with Express Scripts' termination of compounding pharmacies from its network. Plaintiffs sought over $120M in damages. This was only the second case that Express Scripts took to trial in the history of the company—in the first case, Quinn Emanuel obtained a jury verdict in Express Scripts' favor. In the lead-up to trial, Quinn Emanuel moved for and obtained what were effectively case-terminating sanctions for Plaintiffs' discovery violations; the Court awarded Express Scripts $360,000 in monetary sanctions, struck Plaintiffs' damages expert, and invited supplemental summary judgment briefing. Four days before the start of trial, the Court granted summary judgment in Express Scripts' favor on all of Plaintiffs' claims to be tried and held that Plaintiffs were liable on Express Scripts' counterclaims, leaving only the amount of Express Scripts' damages for the jury to decide. Following the Court's decision and during jury selection, Plaintiffs agreed to a $20M consent judgment, the full amount of damages sought by Express Scripts. This completed a string of victories that QE obtained for Express Scripts in five antitrust cases after taking over their defense from prior counsel.

- We obtained a complete victory on behalf of our client, **Express Scripts**, in a jury trial in the Eastern District of St. Louis, just weeks after the client asked us to serve as lead trial counsel. Express Scripts is a pharmacy benefit manager that, among other things, administers prescription drug benefits offered by health plans. As part of that, Express Scripts has created a nationwide network of pharmacies that provide prescription drugs to the members of those client health plans. One of those pharmacies was OmniPlus, which specializes in extremely pricey, made-to-order medications. Express Scripts terminated OmniPlus after Express Scripts discovered that OmniPlus was failing to collect, and waiving, the copayments that its contract with Express Scripts required it to collect. OmniPlus then sued Express Scripts for wrongful termination and breach of contract. The Court denied Express Scripts' motion for summary judgment (and *granted* it as to plaintiff's motion on Express Scripts' counterclaim), sending the case to trial. Within weeks, we built a case exposing OmniPlus as a sophisticated money-making machine that waived copayments so its customers would keep buying expensive creams and gels, and that repeatedly defrauded not only Express Scripts, but its health plan clients. The jury deliberated for an hour before returning a unanimous defense verdict.

- We secured a 9-figure settlement for **a pharmaceutical company** in several contract disputes arising out of drug and device development collaboration and licensing agreements, without having to file suit or request arbitration. This is a prime example of the "Quinn Emanuel Effect," where our appearance, reputation, and initial strategic initiatives result in an early

and highly favorable outcome.

- We represented **Aids Healthcare Foundation** in a contract dispute between them and a pharmaceutical company in 2014.
- We represented **Medicis Pharmaceuticals** in the defense of a breach of contract action against Impax Laboratories in the Superior Court of the State of Arizona relating to the timing of the effective date of a patent license.
- We represented **Medicis Pharmaceuticals** as plaintiff in a breach of contract action against Actavis Mid-Atlantic LLC in the Superior Court of the State of Arizona arising out of Actavis Mid-Atlantic's breach of the non-compete provisions of a pharmaceutical distribution agreement.
- We represented **Medicis Pharmaceuticals** in the defense of a confidential arbitration with a development partner relating to the partner's claim that it had met certain development milestones and thus was entitle to the exercise of certain contractual rights.
- We represented **Foresight Biotherapeutics** in the defense of a confidential arbitration with a development partner relating to the partner's claim that a joint development program had met certain milestones and that the partner was thus entitled to receive certain financial consideration under the parties' agreement.
- We represented **Pfizer, Inc.** as plaintiff in an action against Amgen Fremont, Inc. and Amgen, Inc. arising out of the Amgen defendants' breach of the terms of a Collaborative Research Agreement and License Agreement relating to the development of monoclonal antibody treatments for various diseases.
- We represented **Mallinckrodt Pharmaceuticals** in the defense of an action brought by a development partner alleging breach of a development and licensing agreement relating to new topical anti-inflammatory drug product.
- We represented **Pharmaceutical Product Development, Inc.** in an action alleging intentional breach of contract and fraud related to PPD's acquisition of Magen Biosciences, Inc. We successfully defeated a motion to dismiss by the stockholder defendants, and after fact discovery, the parties reached an agreement to settle the case on terms favorable to our client.

TRADE SECRETS/UNFAIR COMPETITION

- We successfully represented **Pfizer** in California Superior Court in Santa Clara in the retrial of an action alleging theft of trade secrets related to the design and conduct of a clinical trial.
- We represented **D.C. Medicaid HMO** in tortious interference action over hospital's balance-billing practices directed at client's Medicaid members in D.C. Superior Court; prevailed in jury trial, including compensatory and punitive damages, resulting in defendant's bankruptcy filing.
- We represented **Ansun Biopharma** in a trade secret suit concerning inhalable flu medication. It settled in 2014.

COMPLIANCE

- Quinn Emanuel was hired to monitor **Life Spine**'s compliance with a Corporate Integrity Agreement signed as part of a settlement with the U.S. Department of Health & Human Services and Office of the Inspector General to resolve claims that Life Spine violated the anti-kickback statute. Under Life Spine's Agreement with the federal government, an outside Compliance Expert must periodically audit their company, including reviewing compliance procedures, to ensure that the company is complying with federal law and managing risk. The results of each audit are submitted to the Office of the Inspector General. In addition to these ongoing audits, we also counsel the Board of Directors and high-level company executives on compliance issues.

"The team produces excellent legal work and is practical in their analyses."
Client Testimonial, ***Chambers and Partners***