

ACTHAR

On April 6, 2017, Haviland Hughes filed the first and only lawsuit in the country concerning the unconscionable prices of the prescription drug, Acthar, on behalf of private payors. The cost of the drug skyrocketed from \$40 in 2001 to over \$40,000 today! The firm represents the City of Rockford, Illinois, Acument Global Technologies, Inc. and other payors in a class action seeking justice for the monopolistic pricing behavior of prescription drug manufacturer Mallinckrodt Pharmaceuticals (formerly known as Questcor Pharmaceuticals, Inc.)("Mallinckrodt"), the only manufacturer and seller of Acthar.

Acthar is the only adrenocorticotropic hormone (ACTH) drug approved in the United States for the treatment of a rare, often fatal, condition that afflicts infants, infantile spasms ("IS"). It also treats multiple sclerosis and nephrology syndrome, among other diseases.

As the sole provider of Acthar in the United States, Mallinckrodt is a monopolist.

In 2017, the Federal Trade Commission sued Mallinckrodt for antitrust, charging the company with unlawfully wielding its monopoly power by purchasing the only competitive product to Acthar, a synthetic version known as Synacthen. Questcor paid nearly 10 times what a successful competitive bidder had agreed to pay, but then never brought Synacthen to market. The government's lawsuit contended Questcor did so only to protect its monopoly and to raise the price of Acthar to nearly \$35,000.00. Mallinckrodt settled the FTC case for \$100 million and also agreed to license Synacthen to another company.

The Haviland Hughes lawsuit contends that being a monopolist of a "specialty drug" does not permit drug companies, like Mallinckrodt, to "gouge" patients who need the medicine and payors who must pay for such drugs.

If you, your company, or your fund has paid for Acthar, we encourage you to contact Haviland Hughes right away to ensure you claim your share of any favorable recovery in the lawsuit. For more information, you can review the timeline below, review some of the pleadings in the case, or <u>view the 60 Minutes program</u> which aired on May 6, 2018 featuring the Acthar lawsuit.

The Second Amended Complaint (filed Dec. 8, 2017) is available here.

Timeline of significant events

1952: H.P. Acthar Gel ("Acthar") is developed by Armour Pharmaceutical Company in 1952. While the patent for Acthar has long since expired, there is no generic competitor. It is the only ACTH medication approved by the FDA. Although Acthar could treat 19 indications, it was primarily used to treat infantile spasms ("IS"), a life-threatening condition, but also a condition for which it was not approved – a so-called "off-label" use. Acthar was acquired by Sanofi (f/k/a Aventis) and under its stewardship was sold for **\$40** per vial.

2001: Acthar is acquired by Questcor Pharmaceuticals, Inc. ("Questcor") for **\$100,000** from Sanofi. Immediately after the acquisition, Questcor raised the price to \$1650.

2006: Questcor attempts to get the FDA to approve Acthar for the treatment of IS, not by conducting the clinical trials necessary for such approval, but by using older research conducted by others. The FDA rejects Questcor's application.

2007: Questcor embarks on what its CEO called a "new strategy." It contracts with a single specialty distributor, CuraScript SD, owned by Express Scripts, to distribute Acthar. After the contract is signed, Questcor raises the price of Acthar from **\$2,062.79** to **\$23,000**. At the same time, Questcor creates the Acthar Support and Access Program ("ASAP"), which acts as a middleman between a doctor, a patient, the patient's insurer, and CuraScript to ensure that Acthar is paid for and sent directly to the patient. Through its exclusive distribution arrangement and the ASAP program, Questcor creates a so-called "closed distribution system", which allows it to charge above-market prices for Acthar, while ensuring insurance coverage.

2013: Questcor purchases from Novartis the only other competitive product, a synthetic ACTH drug known as Synacthen Depot. While Novartis had agreed to sell Synacthen to Retrophin, Inc., the company formerly run by the infamous "pharma bro" Martin Shkreli, for \$16 million, at the last minute, Questcor swooped-in and purchased Synacthen for \$135 million. Questcor then promptly raises the price of Acthar to over **\$34,000** per vial.

2014: Mallinckrodt plc purchases Questcor for \$5.9 billion. In a call with investors prior to the transaction, Questcor's CEO concedes that Questor is essentially a one-product company because Acthar accounts for nearly 98% of its sales. Thus, Mallinckrodt paid \$5.9 billion for a product invented in 1952 and worth only \$100,000 just 13 years earlier.

In the same year, Retrophin sues Questcor claiming antitrust conduct. Mallinkrodt later agrees to settle and pay Retrophin \$15.5 million.

2017: The Federal Trade Commission sues Mallinckrodt on similar grounds as the Retrophin lawsuit. Mallinckrodt agrees to settle for \$100 million. As part of the settlement, Mallinckrodt also agrees to sell the rights to Synacthen to another company.