

Thomas P. McNamara Mayor Office of the Mayor

Date: September 29, 2020

To: United States House Committee on Oversight & Reform

From: Thomas P. McNamara, Mayor, City of Rockford, IL

Re: City of Rockford's Statement regarding Mallinckrodt & Express Scripts' Acthar Price Gouging Scheme

Introductory remarks

The problem of high-priced prescription drugs in America has grown to nearly epidemic proportions. The "new normal" appears to be one of prescription drug companies charging whatever they can for a drug, regardless of what the drug costs to develop and bring to market, or its actual therapeutic value. This has happened with new drugs,¹ as well as old, so-called "orphan" drugs, like Acthar.²

A report issued by America's Health Insurance Plans found that orphan drugs cost 26 times more than they did 20 years ago.³ Leading such explosive growth was Mallinckrodt's Acthar Gel. Acthar cost just \$40 when Mallinckrodt acquired it in 2001. Now Mallinckrodt charges over \$46,000.00 for Acthar. Nothing has changed about Acthar's makeup since it was discovered in 1952, except the price.

Rockford's Acthar Litigation Against Mallinckrodt and Express Scripts

In 2017, Rockford decided to push back against such high drug pricing for orphan drugs.

Two years earlier, the City had spent nearly \$500,000 on Acthar when it was prescribed to two of its employee's children who had been diagnosed with rare infant epilepsy disorders. Acthar is a naturally derived extract from the pituitary glands of pigs. It has been commonly used to treat these epilepsy disorders for decades.

The money that cities like Rockford spend on high priced drugs impacts our ability to provide vital services that our taxpayers deserve. For Rockford, the \$500,000 we spent on a few vials of Acthar is the equivalent to:

-Hiring 4 or 5 police officers;

-Installing 350 street lights;

-Resurfacing streets for 43 neighborhood blocks;

-Replacing 2 miles of sidewalks;

-Planting approximately 2,000 trees; or

-Purchasing 6,000 tons of road salt

² Rockford paid nearly \$500,000 in 2015 for Acthar for just 2 patients.

³ "The Rise of Orphan Drugs", AHIP, September 2019.

¹ Rockford paid over \$2.5 million for Humira, and nearly \$200,000 for Gleevec for 1 patient, between August 2013 and July 2020.

Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is its sole provider. Thus, Mallinckrodt is a monopolist.

Mallinckrodt attained its Acthar monopoly in 2001 when it paid \$100,000 to purchase the drug from Aventis.⁴ In 2013, Mallinckrodt also purchased the drug Synacthen (a competitor to Acthar) for about \$130 million, but never brought that product to market. Mallinckrodt did so to maintain its high prices for Acthar, its flagship product.

It is important to note that at the time Mallinckrodt purchased Achtar and Synacthen, the company was known as Questcor Pharmaceuticals. Questcor became Mallinckrodt ARD in 2014. Mallinckrodt has previously attempted to deflect its decision to withhold Synacthen from the market by claiming it was the decision of Questcor Pharmaceuticals, in an apparent attempt to avoid the fact the companies are one in the same.⁵

Acthar is a "specialty pharmaceutical" and is distributed only through "specialty pharmacy distributors". One of the largest specialty pharmacy distributors in America is Curascript, a subsidiary of the pharmacy benefit manager Express Scripts. Ironically, Rockford had contracted with Express Scripts as its PBM to assist the City in *lowering* its drug costs, but it came to learn that Express Scripts had actually conspired and agreed with Mallinckrodt to *raise* the price of Acthar as part of Mallinckrodt's "new strategy" to distribute the drug.

In 2007, Mallinckrodt embarked on this "new strategy" by agreeing to distribute Acthar exclusively through Curascript rather than existing networks available to specialty drugs. In effect, Mallinckrodt contracted with Express Scripts to create an exclusive arrangement whereby both companies would share the financial rewards of the Acthar monopoly.

Immediately after signing the exclusive agreement, Mallinckrodt and Express Scripts agreed to raise the price of Acthar nearly 1,400% from \$1,980 to \$27,927.80 per vial. Mallinckrodt and Express Scripts agreed to raise the price of Acthar multiple times thereafter, charging inflated prices to Express Scripts' clients, including Rockford.

By 2014, the value of the Acthar monopoly was \$5.9 billion.

The City of Rockford has filed a class-action suit against Mallinckrodt and Express Scripts for conspiring to overcharge patients and payors of Acthar and for maintaining a monopoly over the drug.

⁴ Questcor purchased Acthar from Aventis in 2001. Questcor's only product was Achtar. Questcor became Mallinckrodt ARD in 2014 after being acquired by its parent company.

⁵ For example, when this Committee previously questioned Mallinckrodt about "the threat of competition posed by Synacthen and the decision by the company to acquire Synacthen" – a direct question posed in our litigation as well – Mallinckrodt avoided the questioning by responding that "[t]he decision to acquire Synacthen Depot and any associated analysis of potential competition from Synacthen Depot related to the acquisition would have been made solely by Questcor Pharmaceuticals prior to Mallinckrodt's acquisition of Questcor Pharmaceuticals." What Mallinckrodt failed to advise the Committee is that Questcor Pharmaceuticals became Mallinckrodt ARD after the 2014 merger. Mallinckrodt ARD is the Defendant in our litigation and a wholly-owned subsidiary of Mallinckrodt PLC. So, its no answer that Questcor decided to acquire Synacthen. Questcor n/k/a Mallinckrodt ARD failed to bring Synacthen to market until the January 2017 settlement with the FTC that ordered that Synacthen be licensed to a competitor company.

In denying the Defendants' motions to dismiss our case last year, the federal court wrote as follows: ⁶

[T]he court finds that a reasonable inference could be drawn that defendants conspired to unlawfully boost the price of Acthar, restrict its output, and eliminate competition in violation of federal antitrust law when Mallinckrodt instituted its "new strategy." The goal of the exclusive dealing arrangement was "to lock patients into receiving Acthar through one channel and prevent a competitive product from entering the market." SAC ¶ 222 (emphasis added). Express Scripts employed its market power to effectuate these goals, allowing Mallinckrodt to maintain its monopoly, thereby increasing both their profits, and prevent competitors from challenging that monopoly. Thus, Mallinckrodt's decision to purchase the rights to Synacthen "at the eleventh hour" only to "shelve" the product upon acquiring it was simply an intended goal of the ASAP, effectuated by both defendants. Id. ¶¶ 111-114, 145, Specifically, Express Scripts agreed not to push back on Mallinckrodt's decisions to inflate Acthar's price beyond the competitive level, in contrast to when Express Scripts took the opposite approach in 2015 with respect to Turing's drug, Daraprim.⁷

We are assembling documentary evidence to prove these companies violated the law and lied to the public about it. To the extent we can assist the Committee in its efforts, we will seek permission from the court to release any documents or information the Committee requests.

We have uncovered documents from Mallinckrodt acknowledging how incredibly lucrative the "orphan drug pricing strategy" can be. Mallinckrodt boasts that over 100 of its employees became millionaires as a result of its Acthar pricing scheme.

Concluding remarks

Companies like Mallinckrodt know what they are doing is wrong. They need to be stopped. In Questcor COO Steve Catt's presentation to Mallinckrodt CEO Mark Trudeau prior to their merger, Mr, Catt advised that to "ensure appropriate access to Acthar" and "protect current coverage", Mallinckrodt should "Let sleeping dogs lie' – avoid highlighting Acthar coverage if the payer is paying." In other words, if the payor's eyes are shut to the reality of the drug company's fraudulent pricing schemes, then let them lie as they are, and continue to pay the high prices. Under Mr. Trudeau, Mallinckrodt has been more than willing to continue its price-gouging scheme at the expense of the American public.

For Rockford, no more.

⁶ At the Defendants' request, the Court entered a Confidentiality Order permitting the defendant companies to stamp their documents "Confidential" or "Attorneys' Eyes Only", prohibiting the City from sharing any documents so marked. *City of Rockford v. Mallinckrodt ARD, Inc.*, Dkt No. 145 (N.D.III.). Unfortunately, virtually every document produced by the Defendants in the litigation have been so marked, rendering it impossible for us to share the evidence that the Defendants did what Rockford says they did. By the time of trial next year, we hope to have the Court weigh in on the propriety of the Defendants' stamping of discovery documents and depositions. That is why having public hearings about these issues is so important to the cause of truth.

[&]quot;The way to right wrongs is to shine the light of truth on them." Ida B. Wells (a prominent, African-American journalist, activist and researcher in the late 19th and early 20th centuries. *See*

 $https://www.womenshistory.org/education-resources/biographies/ida-b-wells-barnett\).$

⁷ City of Rockford v. Mallinckrodt ARD, Inc., 360 F.Supp. 3d 730, 749 (N.D. Ill. Jan. 25, 2019).