UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF GEORGIA

ATLANTA DIVISION

CITY OF MARIETTA, on behalf of itself and all others similarly situated,

Plaintiff,

v.

MALLINCKRODT ARD LLC, *formerly known as* MALLINCKRODT ARD, INC., *formerly known as* QUESTCOR PHARMACEUTICALS, INC.

Defendants.

COMPLAINT - CLASS ACTION FOR UNJUST ENRICHMENT

JURY TRIAL DEMANDED

Plaintiff City of Marietta (the "City"), by and through the undersigned attorneys, files this Complaint against Defendant Mallinckrodt ARD LLC, formerly known as Mallinckrodt ARD, Inc., formerly known as Questcor Pharmaceuticals, Inc., (hereafter collectively "Mallinckrodt or "Defendant"), on behalf of itself and all others similarly situated.

Except as to the allegations of Plaintiff's experiences, which are based on personal knowledge, all other allegations are based on information and belief and are formed based on an inquiry reasonable under the circumstances.

NATURE OF THE ACTION

1. This class action for unjust enrichment arises out of the exorbitant and unconscionable prices that Defendant charged, and continues to charge, for the drug H.P. Acthar, NDC No. 63004871001 ("Acthar").

2. Acthar used to cost $40, but Mallinckrodt has raised the price of the drug to over $*39,000* per vial. This eye-popping 97,500% price increase is the result of unlawful and unfair conduct by Mallinckrodt and its predecessor Questcor Pharmaceuticals, Inc. ("Questcor"). Defendant's actions include preventing competition from entering the market that could have lowered the price of the drug.

3. Defendant's conduct is particularly outrageous and ongoing with respect to entities, such as the City, which have self-funded health plans, paid for by tax revenues, that include prescription coverage for Acthar. The City has expended over $2 million for Acthar for just *one* patient covered by the City's self-funded health plan. The City and other members of the Class paid more for Acthar than they otherwise would have paid in the absence of Mallinckrodt's unlawful conduct and continue to do so.

4. Mallinckrodt is not entitled to enrich itself unjustly at the expense of Plaintiff and the Class.

5. Accordingly, the City, on behalf of the Class, has determined to challenge Mallinckrodt's outrageous price gouging for Acthar.

PARTIES

6. The City of Marietta employs more than 700 benefits-eligible individuals in the service of its citizens and also provides health insurance benefits to more than 300 retired individuals. A family member of one such individual has a serious medical condition, for which Acthar was indicated as the treatment. The City, which pays the health care benefits of its employees, including specialty pharmacy drugs, has paid, and continues to pay, for administrations of Acthar.

7. Mallinckrodt ARD LLC is a biopharmaceutical company incorporated in California, with offices located at 675 McDonnell Blvd., Hazelwood, Missouri 63042. Mallinckrodt ARD LLC has locations in Hampton, New Jersey and Bedminster, New Jersey. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc. Questcor was acquired by Mallinckrodt on August 14, 2014 for $5.9 billion. Following the acquisition, Questcor became a wholly-owned subsidiary of Mallinckrodt and its name was changed to Mallinckrodt ARD Inc. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC, and it continues to market Acthar to this day.

8. Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt plc, an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames, Surrey, TW18 3 AG.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because the Plaintiffs and members of the Class are diverse from the Defendant and over two-thirds of the Class is situated outside of Georgia. Due to the exorbitant prices charged by

Defendants for Acthar to the Class, the aggregate amount in controversy far exceeds $5,000,000.

10. This Court has personal jurisdiction over the parties because the Defendant conducts substantial business in this State, has had systematic and continuous contacts with this State, and has agents and representatives that can be found in this State.

11. This Court has jurisdiction over the Defendant because it has had sufficient minimum contacts with and/or have purposefully availed itself of the laws and markets of the State of Georgia through, among other things, its distribution, marketing and sales of Acthar to the residents of Georgia.

12. Venue is proper in the Northern District of Georgia pursuant to 28 U.S.C. § 1391 because Defendant transacts substantial business in this District and a substantial part of the events or omissions giving rise to Plaintiff's claims arose here. Defendant has engaged in substantial conduct relevant to the claims of the Plaintiff and the Class and caused harm to Plaintiff and members of the Class in this District.

13. Acthar is sold in interstate commerce and the unlawful activities alleged in this Class Action Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

FACTUAL BACKGROUND

Acthar

14. Acthar is the only therapeutic adrenocorticotropic hormone (ACTH) product sold in the United States. Acthar's active ingredient is extracted from pig pituitary glands. It was invented in 1948 by the pharmaceutical division of the Armour meatpacking and processing company as a byproduct of pork-processing operations. At the time, Acthar was considered a miracle drug because it stimulated the body's production of cortisol, provoking a natural anti-inflammatory response that was beneficial for the treatment of various conditions. Acthar was given broad approval by the FDA in 1952 to treat a wide range of ailments at a time when such broad approvals did not require support from clinical trials.

15. The original form of ACTH had a half-life of only 10 minutes, Acthar was developed for clinical use by creating a repository gel tailored to a patient's individual needs. The gel must be refrigerated and is applied through either an intramuscular or a subcutaneous depot injection (i.e., an injection that deposits the drug in a localized mass, which is gradually absorbed by the body over an extended period).

16. Acthar was approved to treat multiple sclerosis ("MS") in 1979. ACTH is now the standard care treatment for infantile spasms, a rare but extremely

serious disorder involving seizures in the first two years of life. Acthar also has 19 different "indications," which means that the drug can be used to treat 19 different ailments, including Lupus, kidney disorders, rheumatoid arthritis, multiple sclerosis and various dermatological diseases.

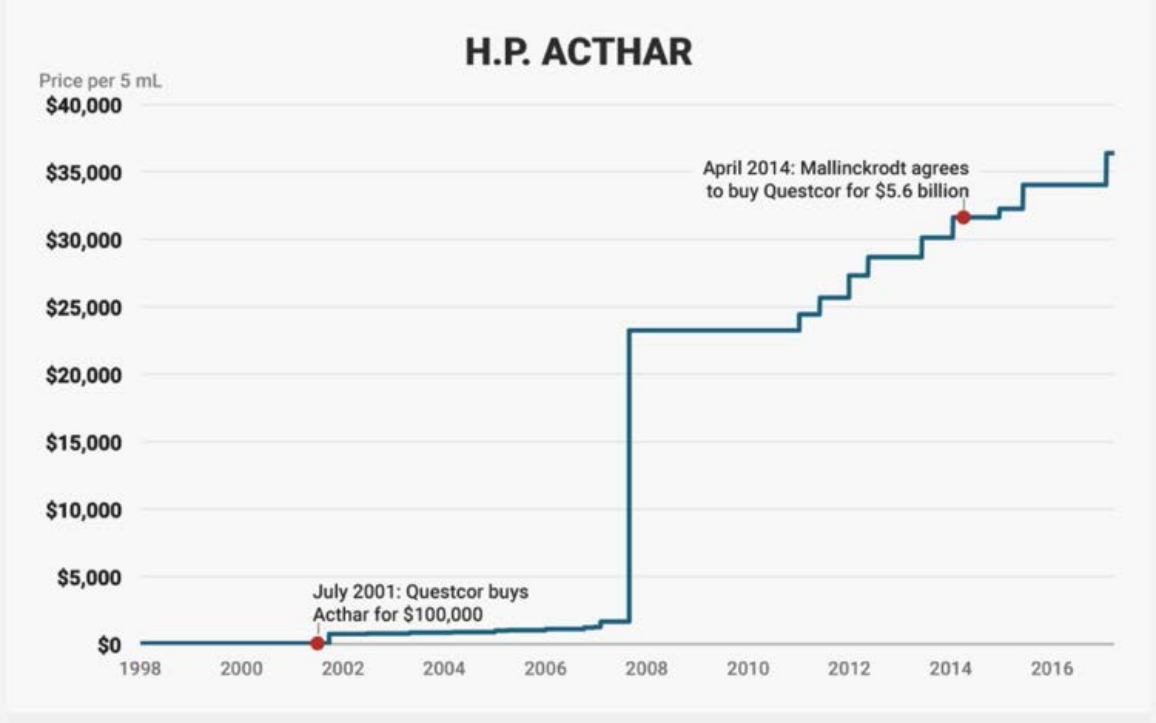
17. Acthar was first owned by Armour Pharmaceutical Company, then by Rhone-Poulenc Rorer, and until 2001 by Aventis Pharmaceuticals, Inc. (now Sanofi). To that point, the drug was priced competitively with other anti-inflammatories. But since it was expensive to produce, difficult to apply, and (except for certain indications such as infantile spasms) not known to be more effective than simpler, cheaper, and more widely available drugs, Aventis considered discontinuing production.

18. Questcor acquired worldwide rights to sell and manufacture Acthar from Aventis in July 2001. In view of what would come, the price was a bargain: $100,000, plus modest royalties. When Mallinckrodt acquired Questcor in 2014, it also acquired the rights to Acthar, At the time of the Mallinckrodt acquisition, Questcor's only product sold in the United States was Acthar.

19. At the time Questcor purchased Acthar, the average price of a vial of the medication was about $40. Mallinckrodt has since raised Acthar's price to over $39,000 per vial – a 97,500% increase.

20. Immediately after acquiring the rights to sell Acthar, Mallinckrodt's predecessor company Questcor increased the price from approximately $40 per vial to nearly $750 per vial. On August 27, 2007, Questcor increased the price of Acthar by more than 1,300%, from $1,650 to $23,269 per vial. On January 3, 2011, Questcor raised Acthar's price to over $24,430 per vial. Six months later, it raised the price again to over $25,600 per vial. In December 2011, it raised the price to over $27,300 per vial. In May 2012, it raised the price to over $28,680 per vial. In June 2013, it raised the price to over $30,100 per vial. In January 2014, it raised the price to over $31,600 per vial. In December 2014 it raised the price to over $32,200 per vial. By 2018, the price of Acthar was $38,892 in 2018. Since treatment with Acthar usually requires at least three vials, a single course of treatment can cost nearly $120,000.

21. The following chart shows the price increases for Acthar:



Mallinckrodt's Improper Conduct

22. Mallinckrodt was able to keep Acthar's price artificially high by, among other things, eliminating the only viable competition to Acthar. Mallinckodt acquired, and then shelved, the rights to Synacthen Depot ("Synacthen"), Acthar's much cheaper synthetic equivalent.

23. Mallinckrodt (then known as Questcor) purchased the rights to Synacthen, an alternative to Acthar, from drug giant Novartis AG. Questcor then determined not to bring Synacthen to market and not to seek FDA approval of Synacthen. This conduct allowed Questcor/Mallinckrodt to maintain Acthar as the

only viable product on the market for infantile spasms and other conditions and to raise the price of Acthar exponentially.

24. Specifically, by 2013, the only significant alternative to Acthar was Synacthen, a synthetically derived, preclinical ACTH medication manufactured by Novartis. Novartis was already selling Synacthen in Europe, Asia, and Latin America, but the drug was not approved for use in the United States.

25. Synacthen posed a nascent competitive threat to Questcor's drug, Acthar. Acthar and Synacthen have very similar biological activities and pharmacological effects, and the active ingredient in both is drugs is an ACTH molecule.

26. In 2009, Questcor unsuccessfully attempted to buy the rights to Synacthen in a defensive move to prevent competitors from acquiring the drug and developing it as a competitor to Acthar.

27. In October 2012, Questcor learned that at least one other company was attempting to buy the rights to Synacthen from Novartis to compete with Questcor in the ACTH drug market in the United States. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing the precise formulation for Synacthen and the drug's manufacturing process. In possession of the Synacthen assets, a buyer would not

need to create a synthetic ACTH drug for formulation or testing protocols from scratch.

28. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements. Each firm planned to commercialize Synacthen in the United States to compete directly with Acthar, having taken affirmative steps to do so by independently conducting due diligence, and crafting business plans and regulatory approval strategies. Each of these firms expected to capture a significant share of the U.S. market by pricing Synacthen well below the price for Acthar.

29. In 2013, Novartis agreed to sell the rights of Synacthen to Retrophin, Inc., for $16 million. However, on June 11, 2013, the day Retrophin was to sign its contract with Novartis, Mallinckrodt swept in at the eleventh hour and agreed with Novartis to pay a minimum of $135 million, a bid several multiples higher than the other bidders, for the exclusive rights to Synacthen.

30. Unlike the three alternative bidders, Mallinckrodt had only incomplete plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

31. On June 11, 2013, Questcor and Novartis entered into formal agreements pursuant to which Questcor gained the exclusive rights to develop,

market and sell Synacthen in the United States and in over 35 other countries.

32. Upon purchasing the rights to Synacthen, Mallinckrodt chose not to bring it to market. Mallinckrodt never sought FDA approval for Synacthen. Acthar was and continues to be the only viable product in the market for infantile spasms and certain other conditions.

33. Moreover, because ACTH drugs require Food and Drug Administration approval to be sold to consumers, there are significant barriers to entry for ACTH drugs. Developing a long acting, depot injection formulation of a drug product containing ACTH that is stable, safe and effective would require significant cost, time, and effort with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained release depot injection formulation, scaling production to clinical scale and successfully conducting clinical trials necessary for FDA approval.

34. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar.

35. Neither Questcor nor Mallinckrodt made more than superficial efforts to pursue commercialization of Synacthen, however. Instead, Mallinckrodt chose to shelve the asset and thereby to protect Acthar monopoly pricing.

36. In January 2014, Retrophin sued Mallinckrodt for antitrust violations in the United States District Court for the Central District of California. Retrophin alleged that there was no procompetitive aspect of Mallinckrodt's acquisition of Synacthen. Mallinckrodt eventually settled the Retrophin lawsuit for $15.5 million.

37. The Federal Trade Commission also sued Mallinckrodt on January 18, 2017, similarly alleging that Mallinckrodt exercised, and continued to exercise, monopoly power in the United States and did so unlawfully based, in part, on the Synacthen acquisition. The Complaint, filed by the government and three state attorneys general, alleged that Questcor thwarted attempts by competitors to introduce similar drugs into the marketplace by out-bidding them in attempts to acquire Synacthen. Mallinckrodt eventually settled the FTC lawsuit for $100 million.

38. Mallinckrodt's conduct as alleged herein with respect to the Synacthen acquisition injured Plaintiff and members of the Class by forcing them to pay higher costs for Acthar than they would have but for Defendant's conduct. Malinckrodt was unjustly enriched based on this conduct alone.

39. In addition, in lawsuits filed by whistleblowers and then joined by the government, Mallinckrodt has been accused of engaging in a kickback scheme

with doctors who prescribed Acthar in situations in which it was not called for, which also contributed to the high prices for Achthar.

40. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – with the intent to induce a health care provider to prescribe a drug reimbursed by Medicare. This prohibition extends to such practices as "wining and dining" doctors to induce them to write Medicare prescriptions of a company's products. However, in violation of the anti-kickback statute, Mallinckrodt maintained artificially high demand for Acthar through a pervasive scheme to bribe doctors to prescribe Acthar.

41. The government alleged that, from 2009 to 2013, twelve Questcor sales representatives marketing Acthar provided illegal remuneration to health care providers in the form of lavish meals and entertainment expenses. The company paid this remuneration, the government alleges, with the intent to induce Acthar Medicare referrals from those health care providers, resulting in a violation of the Anti-Kickback Statute and the submission of false claims to Medicare.

42. These bribes were necessary because Acthar is an expensive drug that requires refrigeration and injection, and it is not the first-line treatment for most of its indicated conditions. Instead, much cheaper and more effective treatments are

recommended. Under the guise of "education" and "marketing," Mallinckrodt paid millions of dollars to thousands of doctors, and particularly large sums to a smaller number of doctors who then prescribed a disproportionate amount of Acthar.

43. On September 13, 2019, Mallinckrodt paid more than $15 million to the United States Justice Department to settle claims that it paid illegal kickbacks to doctors to prescribe Acthar.

44. In another lawsuit filed in June 2019, the government alleges that Mallinckrodt used a foundation as a conduit to illegally pay patients' co-payments in violation of the Federal Anti-Kickback Statute, which prohibits a pharmaceutical company from paying anything to induce Medicare patients to buy a company's drugs. In this way, Mallinckrodt could prop up demand for Acthar, raise the price of the drug, negate concerns about the high cost of the drug, and market the drug as "free." In fact, the monies that Mallinckrodt routed to these funds drove Acthar pricing and allowed Mallinckrodt to continually raise the price of the drug.

45. Specifically, when a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or a deductible (collectively, "copays"). Congress included copay requirements in the Medicare

program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value—to induce Medicare patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

46. The government alleges that Mallinckrodt used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar, so it could market the drug as "free" to doctors and patients despite increasing Acthar's price astronomically. Mallinckrodt allegedly paid these illegal subsidies through three funds that it established at the foundation to the exclusion of other drugs. Mallinckrodt was the sole "donor" to these funds and routed Acthar patients there to receive virtually guaranteed copay subsidies to counteract doctor and patient concerns about the drug's high cost. By doing so, Mallinckrodt marketed Acthar as "free" to patients and caused the submission of millions of dollars in false Acthar claims to Medicare. The subsidies it routed through these funds drove Acthar prescribing and was a proven method that negated concerns about the cost of the drug, allowing Mallinckrodt to continually raise its price. "Illegal inducements increase the costs paid by the American taxpayer and distort the market forces that

otherwise could control those costs," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "This lawsuit and prior enforcement actions make clear that the Department will hold accountable drug companies that pay illegal kickbacks to facilitate increased drug prices."

47. In short, Mallinckrodt purchased its only competitor for an inflated sum to foreclose any potential for competition, hiked the price of its Acthar product nearly a thousand times over, and then bribed doctors to prescribe the drug, all while marketing the drug to patients as "free." Based on the any or all of the foregoing unlawful conduct, Acthar was unjustly enriched.

CLASS ACTION ALLEGATIONS

48. Plaintiff incorporates by reference each of the preceding paragraphs as though fully set forth herein.

49. Plaintiff brings this class action pursuant to Federal Rules of Civil Procedure, Rules 23(a), (b)(2) and (b)(3) on behalf of itself and members of the Class as defined below.

50. Plaintiff's proposed Class consists of and is defined as follows:

> All third-party payors and their beneficiaries and people without insurance in the United States and its Territories that paid for Acthar from four years prior to the filing of the Complaint until the date of trial (the "Class").

51. Plaintiff's proposed Sub-Class consists of and is defined as follows:

> All third-party payors and their beneficiaries and people without insurance in Georgia that paid for Acthar from within four years prior to the filing of the Complaint until the date of trial (the "Class").

52. Excluded from the Class and Sub-Class are Defendant, and its subsidiaries and affiliates; its current and former officers, directors, and employees (and members of its immediate families); and the legal representatives, heirs, successors or assigns of any of the foregoing; its officers, directors, management and employees; judges assigned to this case and any members of their immediate families; all persons or entities who purchased Acthar directly from Defendant or via legal contract with Defendant; all persons or entities who suffered no economic injury as a result of Defendant's wrongful conduct (such as insured consumers who paid a flat co-pay) or who purchased in states, if any, where a cause of action for

unjust enrichment requires direct privity, where a separate claim for unjust enrichment is not recognized or where the unjust enrichment law is not the same or similar to Georgia law; and all persons or entities who purchased pursuant to an agreement whereby Express Scripts Holding Company or any of its wholly-owned subsidiaries is, or was, the exclusive distributor of Acthar.

53. Plaintiff reserves the right to redefine the Class and to add subclasses as appropriate based on further investigation, discovery, and specific theories of liability.

54. As required by Fed. R. Civ. P. 23(a)(2) and (b)(3), there are questions of law and fact common to the Class, and those common questions predominate over any questions affecting only individual members. Among the common questions of law and fact include:

(a) Whether the Defendant artificially inflated the prices of Acthar;

(b) Whether Plaintiff and members of the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of the unlawful conduct of Defendant;

(c) Whether the Defendant has been unjustly enriched by its unlawful conduct;

(d) Whether Plaintiff and members of the Class are entitled to declaratory

and injunctive relief as to Defendant's conduct;

(e) Whether Plaintiff and members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;

(f) The proper measure of damages; and

(g) Whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs.

55. Numerosity: As required by Fed. R. Civ. P. 23(a)(1), the members of the Class are so numerous that joinder of all Class members would be unfeasible and impractical, and the resolutions of their claims through the procedure of a class action will be of benefit to the Parties and the Court. The membership of the entire Class is unknown to Plaintiff at this time; however, the Class is estimated to be greater than one hundred (100), including public and private payors located throughout Georgia and the United States, based on the fact that Mallinckrodt has sold thousands of vials of Acthar in each quarter over the last few years alone. Thus, the Class is so numerous that joinder of all of its members is impractical. Individuals and the identity of such membership is readily ascertainable by inspection of Defendant's records.

56. Typicality: As required by Fed. R. Civ. P. 23(a)(3), Plaintiff's claims

are typical of the claims of all members of the Class since Plaintiff and all members of the Class suffered damages as result of Defendant's fraudulent concealment and wrongful conduct set forth herein.

57. Adequacy: As required by Fed. R. Civ. P. 23(a)(4), Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has no interests adverse or antagonistic to those of the Class and has retained counsel competent and experienced in class action litigation who will zealously prosecute this matter on behalf of the Class to its conclusion.

58. Superiority: As required by Fed. R. Civ. P. 23(b)(3), the nature of this action makes the use of a class action adjudication superior to other methods. A class action will achieve economies of time, effort, and expense as compared with separate lawsuits, and will avoid inconsistent outcomes because the same issues can be adjudicated in the same manner and at the same time for the entire Class.

59. Defendant keeps extensive computerized records of its customers. Defendant has one or more databases through which a significant majority of Class members may be identified and ascertained, and it maintains contact information, including email and home mailing addresses, through which notice of this action could be disseminated in accordance with due process requirements.

60. Class certification of Plaintiff's claims is also appropriate pursuant to Fed. R. Civ. P. 23(b)(2) because Defendant has acted or refused to act on grounds generally applicable to Plaintiff and the Class, making appropriate both declaratory and injunctive relief with respect to Plaintiff and the Class.

FIRST CLAIM FOR RELIEF

Unjust Enrichment

61. Plaintiff incorporates by reference each of the preceding paragraphs as though fully set forth herein.

62. Plaintiff and members of the Class provided a benefit to Defendant by purchasing Acthar at inflated prices. Defendant profited from the individual demands of consumers, including Plaintiff and its employee who required the drug paid for by Plaintiff. Defendant's benefit and Plaintiff's detriment flowed from Defendant's alleged misconduct.

63. By engaging in the conduct described herein, Mallinckrodt has knowingly obtained benefits from Plaintiff and members of the Class through collecting grossly inflated revenue from its sale of Acthar under circumstances such that it would be inequitable and unjust for Mallinckrodt to retain such benefits. In so doing, Mallinckrodt has been unjustly enriched by the amount charged for Acthar.

64. Plaintiff and each member of the Class are entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendant by means of the above-described actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all those similarly situated, as set forth above, prays for relief and judgment against Defendant as follows:

1. Plaintiff, on behalf of himself, and members of the Class, requests the Court to enter judgment against Defendant as follows:

(a) An order certifying the proposed Class designating Plaintiff as named representative of the Class, and designating Plaintiff's Counsel as Class Counsel;

(b) A declaration that the acts and practices alleged herein are unlawful, enjoining the Defendant from committing the acts alleged herein, and restoring the status quo before the unlawful conduct took place;

(c) Entry of judgment against Defendant for the violations alleged herein;

(d) An award of the actual damages incurred by Plaintiff and the

members of the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;

(e) An award of punitive damages;

(h) An award to Plaintiff of the costs of this action, including reasonable attorneys' fees, and, where applicable, expert fees; and

(i) An award of such other and further relief as the Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procure, Rule 38(b), Plaintiff hereby demands a trial by jury as to all claims so triable.

Dated: February 6, 2020

By: /s/ Douglas R. Haynie

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