IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF MISSISSIPPI GREENVILLE DIVISION

ANDREA L. JOHNSON, Administratrix Of The Estate of Arthur Lee Johnson, Deceased, And On Behalf Of Themselves And All Others Similarly Situated **PLAINTIFFS**

UNICHEM PHARMACEUTICALS (USA), INC.; CVS MISSISSIPPI PHARMACY, LLC; And CVS PHARMACY, INC. **DEFENDANTS**

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

I. Introduction

1. Plaintiff brings this Class Action Complaint for claims against the named defendants and their affiliates related to the marketing, designing, manufacturing, producing, supplying, inadequately inspecting, inadequately testing, selling, and distributing dangerous, defective, adulterated and misbranded hydrochlorothiazide (HCTZ) 25 mg tablets sold to Arthur Lee Johnson (the decedent) at the CVS pharmacy located in Greenville, Washington County, Mississippi that were voluntarily recalled by the named defendants on July 31, 2015. Unfortunately for the decedent, he was found lying on the floor of his home in a pool of blood on July 15, 2015 prior to the voluntary recall.

II. Parties

A. The Named Plaintiff

- 2. The named plaintiff is an adult resident citizen of Greenville, Washington County, Mississippi, is the daughter of the decedent and is the duly court appointed Administratrix of the decedent's estate. Letters of the Administration were issued to the plaintiff as Administratrix on December 14, 2015 by the Washington County, Mississippi Chancery Court in Civil Action No. 2015-2016. A copy of the letters of Administration is attached hereto as Exhibit 1. Pursuant to Miss. Code Ann. 91-7-233 (Rev. 2004), plaintiff brings a survival claim as administratrix of the estate and brings a wrongful death claim on behalf of the decedent's statutory heirs at law and a wrongful death claim on behalf of the decedent's statutory heirs at law and wrongful death beneficiaries. The decedent's statutory wrongful death beneficiaries are his three (3) children, named: Andrea L. Johnson, daughter of Greenville, Washington County, Mississippi; and (3)Terence C. Johnson, son of Greenville, Washington County, Mississippi.
- 3. This Class Action Complaint is brought on behalf of the decedent's estate and all other similarly situated individuals who were prescribed hydrochlorothiazide (HCTZ) 25 mg tablets to control their hypertension, but were sold bottles containing clopidodogrel pills by the named defendants and ingested adulterated, misbranded and recalled pills that caused and contributed the decedent's injuries and death.

B. The Named Defendants

4. Defendant Unichem Pharmaceuticals (Unichem) is a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place

of business in Morristown, New Jersey and maybe served with process of this Court by and through is registered agent for process at its principal place of business and headquarters located at 777 Terrace Avenue, Suite 102, Hasbrouck Heights, New Jersey 07604. At all times relevant to this Complaint, Unichem was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing HCTZ 25 mg tablets and Unichem regularly transacted, solicited and conducted business in Mississippi, including the marketing, promoting, testing, selling and/or distribution for the sale of hydrochlorothiazide 25 mg tablets.

- 5. CVS Mississippi Pharmacy, LLC (CVS Mississippi) is a Mississippi LLC incorporated under the laws of the State of Mississippi process of this Court by and through is registered agent for process CT Corporation System, 645 Lakeland East Drive, Suite 10, Flowood, Mississippi 39232. At all times relevant herein, CVS Mississippi Pharmacy, LLC was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing HCTZ 25 mg tablets manufactured by Unichem and regularly transacted, solicited and conducted business in Mississippi, including the marketing, promoting, selling and/or distribution for the sale of HCTZ 25 mg tablets manufactured by Unichem.
- 6. CVS Pharmacy, Inc. is a Rhode Island company licensed to do business in this state and maybe served with process of this Court by and through is registered agent for process CT Corporation System, 450 Veterans Memorial Parkway, Suite 7a, East Providence, Rhode Island O2914. At all times relevant herein, CVS, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing HCTZ 25 mg tablets

manufactured by Unichem. At all times relevant herein, CVS, Inc. regularly transacted, solicited and conducted business at its pharmacy stores in Mississippi, including the marketing, promoting, selling and/or distribution for the sale of HCTZ 25 mg tablets manufactured by Unichem.

III. Jurisdiction

- 7. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a), as there is complete diversity jurisdiction in this civil action and is authorized pursuant to 28 U.S.C. § 1332(d), as minimal diversity exists if there are more than 100 class members, and the amount in controversy is in excess of \$5 million.
- 8. This suit is brought to pursuant to 28 U.S.C. Section 1331, 1332 (d)(2) (Class Action Fairness Act) 1343(3). This class action seeks, inter alia, actual damages, punitive damages, attorney's fees, and the costs of this suit.

IV. Venue

9. Pursuant to 28 U.S.C. Section 1391 (b) (1) and (2), venue is proper in the Northern District of Mississippi under 28 U.S.C. § 1391(b)(l) and (2) because a substantial part of the events giving rise to this action occurred in Washington County Northern District of Mississippi.

V. Class Action Allegations

10. Plaintiff brings this action individually and as representatives of all those similarly situated pursuant to Rule 23 F.R.C.P. on behalf of the below-defined Classes:

National Class: All persons in the United States that purchased the

Product.

Mississippi Subclass: All persons in the State of Illinois that purchased the Product.

Excluded from the Classes are the Defendants and its affiliates, parents, subsidiaries, employees, officers, agents, and directors. Also excluded are any judicial officers presiding over this matter and the members of their immediate families and judicial staff.

- 11. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of their claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.
- 12. Numerosity Federal Rule of Civil Procedure 23(a)(1). The members of the Classes are so numerous that their individual joinder herein is impracticable. On information and belief, Class members number in the hundreds to thousands. The precise number of Class members and their addresses are presently unknown to Plaintiff, but may be ascertained from the named defendants' books and records. Class members may be notified of the pendency of this action by mail, email, Internet postings, and/or publication.
- 13. Commonality and Predominance Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3). Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Such common questions of law or fact include:
 - a. The true nature and content of the recalled drug product;
 - b. Whether the quality control, packaging, labeling for the recalled product complied with FDA rules and regulations

- or was adulterated and misbranded;
- c. Whether the named defendant's actions violate FDA rules and regulations?
- d. Whether the named defendants were unjustly enriched at the expense of the plaintiff and Class Members; and
- e. Whether the named defendants's actions and conduct constitute product liability claims on behalf of the plaintiff and Class Members.
- 14. The named defendants engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff, on behalf of the decedent and his estate and the other Class members.
- 15. Typicality Federal Rule of Civil Procedure 23(a)(3). Plaintiff's claims are typical of the claims of the other members of the Class because, among other things, all Class members were comparably injured through the named defendants' actions and conduct described hereinabove. Further, there are no defenses available to the named defendants that are unique to the Plaintiff.
- 16. Adequacy of Representation Federal Rule of Civil Procedure 23(a)(4). Plaintiff is an adequate Class representative because the decedent's and his estate interests do not conflict with the interests of the other Class members and the decedent's estate seeks to represent and the estate has retained counsel competent and experienced in complex class action litigation and will prosecute this action vigorously. The Class's interests will be fairly and adequately protected by Plaintiff and her counsel.
 - 17. Insufficiency of Separate Actions Federal Rule of Civil Procedure 23(b)(1).

Absent a representative class action, members of the Class would continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual HCTZ pharmacy consumers, the resulting multiplicity of lawsuits would cause undue hardship and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated purchasers of the recalled drug product, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct of the named defendants. The proposed Class thus satisfy the requirements of Fed. R. Civ. P. 23(b)(1).

- 18. Declaratory and Injunctive Relief Federal Rule of Civil Procedure 23(b)(2). The named defendants have acted or refused to act on grounds generally applicable to Plaintiff and the other members of the Class, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to the members of the Class as a whole.
- 19. Superiority Federal Rule of Civil Procedure 23(b)(3). A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The injuries, wrongful deaths, if any, and other recoverable damages or other financial detriment suffered by Plaintiff and the other members of the Class are relatively small compared to the burden and expense that would be required to individually litigate their claims against the named defendants, so it would be impracticable for Class members to individually seek redress for the named defendants' wrongful actions and conduct. Even if Class members could afford individual litigation, the court system could not. Individualized litigation creates a potential for

inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

VI. Factual Allegations

A. The Drug - HCTZ

- 20. The named defendants designed, researched, tested, manufactured, advertised, marketed, promoted and/or sold HCTZ 25 mg tablets manufactured by Unichem Pharmaceuticals.
- 21. HCTZ 25 mg tablets are widely prescribed and used in the treatment of hypertension. The United States Food and Drug Administration (FDA) approved the medication to be manufactured, distributed and sold for the treatment of hypertension.
- 22. HCTZ 25 mg tablets manufactured by Unichem are approved only for sale and distribution in the United States.
- 23. Each HCTZ 25 mg tablets manufactured by Unichem tablet is approved by FDA only for sale and distribution if it contains the labeled amount of HCTZ.
- 24. HCTZ 25 mg tablets manufactured by Unichem have a narrow therapeutic index, and have a limited margin between effectiveness and toxicity.

B. Important Recall Information

25. On July 31, 2015, the FDA issued a notice regarding a voluntary recall of HCTZ 25 mg tablets manufactured by Unichem and advised as follows:

This recall was issued as a precaution because a clopidogrel tablet was found in a bottle of the product. Taking a clopidogrel tablet instead of a HCTZ tablet could cause side effects which include bleeding and/or bruising people who are allergic to clopidogrel or any of its ingredients may experience more serious side effects. Additionally, missing a dose of HCTZ could result in uncontrolled blood pressure or swelling caused by excess fluid.

This may represent a potential health hazard or safety risk to patients who may be using product affected by this recall.

Our records show you may have received a prescription for this product recently through your CVS/pharmacy.

HCTZ 25 mg tablets are light orange, circular tablets, with "U" and "128" on one side and plain on the other side. Clopidogrel tablets are light orange/pink circular unmarked tablets.

Please note: Product affected by this recall went in distribution on May 21, 2015. If you received hydrochlorothiazide 25 mg tablets before May 21, 2015 it is not affected by this recall, if you received product after May 21, 2015, please contact the pharmacy that filled your prescription.

Please call your doctor right away for advice if you may be using affected product. Your doctor is familiar with your medical history and can suggest the best treatment option for you and you need a prescription for a different medicine, please contact your doctor.

If you are currently using HCTZ 25 mg tablets and have not discussed this with your pharmacist or doctor, our team is available to help you. Please call your CVS/pharmacy at 662-332-1518. We will provide you with more information and help with arrangements for the return and replacement of any affected product.

For more information, please call Unichem Customer Service toll-free at 1-866-931-0700 Monday through Friday, 8:00 AM to 7:00 PM (CT). You may also call the FDA consumer inquiry free at 1-888-INFO-FDA (1-88-463-6332) or visist their Web site at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalForm456881.htm.

Sincerely,

CVS/pharmacy Medical Affairs

- 26. The July 31, 2015 Voluntarily Nationwide Recall Letter is available at http://www.fda.gov/foi/warning_letters/archive/g6235d.htm. A copy of the Recall Letter is attached hereto as Exhibit "2".
- 27. The named defendants' manufacturing, production, testing processing and inspection processes do not meet the current Good Manufacturing Practice Regulations as defined by the 21 C.F.R. §210 C.F.R. §211.
- 28. The FDA's Good Manufacturing Practice regulations describe the methods, controls, equipment, and facilities that must be in place for the manufacture of pharmaceutical products to ensure consumer safety and that the products are consistent with the purported identity, strength, quality, and purity.
- 29. Upon information and belief, there were numerous deficiencies in the named defendants' operations of the quality control unit, which included instances where the unit failed to package the correct medication, prior to shipping the product to its distributors.
- 30. The named defendants' failure to timely provide the medical community, the public, the patient and with full, complete and adequate information about recalled HCTZ 25 mg tablets is consistent with the safety violations which led the FDA to issue the July 31,2015 Warning Letter.
- 31. The named defendants' consistent failure to meet the FDA's current Good Manufacturing Practice Regulations include:
 - (a) deviating, without written justification, from the named defendants' own written

- specifications, test procedures, and laboratory mechanisms, 21 C.F.R. §211.160(a);
- (b) failing to establish the accuracy, specificity, and reproducibility of the test methods that the defendants employed, 21 C.F.R. §211.165(d);
- (c) maintaining incomplete laboratory records of all testing data, 21 C.F.R. § 211.194(a)(4);
- (d) failing to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. §211.194(a)(2);
- (e) failing to investigate unexplained out-of-specification testing results for drugs, 21C.F.R. §211.192;
- (f) failing to follow the defendants' own written stability testing program, 21 C.F.R. § 211.166(a);
- (g) failing to record and justify deviations from the defendants' own written production and process control procedures, 21 C.F.R. §211.100(b)
- (h) failing to examine and test samples to ensure that in-process materials conform to their specifications, 21 C.F.R. §211.110(b);
- (i) failing to follow the named defendants' own written quality control procedures, 21 C.F.R. §211.22(d);
- (j) failing to ensure that all data was reviewed and laboratory deviations were fully investigated and resolved prior to the release of drugs into commercial distribution, 21 C.F.R. §211.22(a);

- (k) failing to have laboratory controls sufficient to ensure that components, in—process materials, and finished drug products have the appropriate standards of identify, strength, quality, and purity and conform to their written specifications, 21 C.F.R. §211.160(b); and
- (I) failing to reject products that do not meet established standards or specifications and any other relevant quality control criteria, 21 C.F.R. §211.165(f).
- 32. Upon information and belief, the FDA inspected and found quality assurance and product safety issues with the HCTZ 25 mg tablets produced, manufactured, tested, marketed, distributed and sold or otherwise placed into the stream of commerce by the named defendants.
- 33. After the voluntary recall for all-lots, all-doses of HCTZ 25 mg tablets bearing labels of the named defendants' production lines were stopped.
- 34. Throughout the above time-line, the named defendants have repeatedly emphasized their reputations for quality manufacturing in publically available corporate documents and corporate run website despite the above information.
- 35. The named defendants under-reported, underestimated and/or downplayed the serious dangers and the defective nature of HCTZ 25 mg tablets manufactured by Unichem that included clopidogrel tablets.
- 36. Upon information and belief, the named defendants have a history of releasing drug products for public consumption that have been adulterated or misbranded.

- 37. Upon information and belief, the named defendants have a history of failing reliably to establish the identity, strength, quality and purity of drug products they release for public consumption.
- 38. At all times relevant to this action, the named defendants knew, and/or had reason to know that the voluntary recalled HCTZ 25 mg tablets included clopidogrel tablets and were not safe for the patients for whom the clopidogrel was not prescribed could cause serious medical problems such as bleeding and, catastrophic injuries and death.
- 39. At all times relevant to this Complaint, the HCTZ 25 mg tablets were in an unsafe, defective, and inherently dangerous condition which were unreasonably dangerous to its users, because the labeling, packaging, and warnings were insufficient to alert consumers, including the decedent, of the dangerous risks and reactions associated with the recalled HCTZ 25 mg tablets, including but not limited to failure to timely and adequately warn that clopidogal had been placed in HCTZ 25 mg tablet containers.
- 40. The clopidogrel tablets placed in HCTZ 25 mg tablet containers distributed and sold or otherwise placed into the stream of commerce by the named defendants were in a dangerous and defective condition and posed a threat to anyone that ingested the product. The decedent was in a class of persons that the named defendants should have considered to be subject to the harm caused by taking clopidogrel tablets instead of a HCTZ 25 mg tablets.
- 41. The named defendants knew, or should have known, at all times relevant herein, through quality control procedures, testing, adverse event reporting or otherwise that HCTZ 25 mg tablets manufactured by Unichem that included clopidogrel tablets were in a defective

condition, were inherently dangerous and unsafe and created a high risk of bodily injury and serious harm, to persons not prescribed clopidogrel tablets.

- 42. The label, warnings, and dosage information provided with the voluntary recalled HCTZ 25 mg tablets were not timely or accurate, and the named defendants failed to provide adequate and timely warnings or instructions regarding the inclusion of clopidogal tablets in HCTZ 25 mg containers.
- 43. The decedent and his prescribing physicians reasonably relied upon the skill, superior knowledge and judgment of the named defendants.
- 44. The named defendants had a continuing duty to warn the decedent and all patients of the dangers associated with the voluntarily recalled HCTZ 25 mg tablets.
- 45. If the decedent had time been made aware of the voluntary recall and the information regarding the risks of ingesting clopidogrel, he would not have used it. The voluntary recall notice was untimely and came fifteen (15) days after the decedent's death.
- 46. As a direct and proximate result of the named defendants' acts and omissions, the decedent sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.
 - VI. First Cause of Action: Mississippi Product Liability Act Claims (MPLA)
- 47. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

- 48. The MPLA governs "any action for damages caused by a product, including but not limited to, any action based on a theory of strict liability in tort, negligence or breach of implied warranty" Miss. Code Ann. § 11-1-63 (Rev. 1991). Further, the Mississippi Supreme Court has held that the MPLA subsumes claims of negligence, breach of implied warranty, breach of express warranty, fraud, negligent misrepresentation, negligent infliction of emotional distress, and strict liability.
- 49. MPLA claims are subject to the general three-year statute of limitations of Miss. Code Ann. § 15-1-49(1) (Rev. 1989). MPLA claims accrue when the plaintiff discovers, or by reasonable diligence should have discovered, the injury. Miss. Code Ann. § 15-1-49(2); (Rev. 1989).
 - VII. Second Cause Of Action: Wrongful Death Claim
- 50. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 51. The named defendants' actions, inactions, conduct, omissions as set forth hereinabove were the proximate cause of the decedent's death. Pursuant to Miss. Code Ann. § 11-7-13 (Rev. 2012), a statutory cause of action for wrongful death is expressly allowed and permitted by Mississippi law.
 - VIII. Third Cause Of Action: Punitive Damages
- 52. The averments of the foregoing paragraphs are incorporated herein as if set forth at length below.
 - 53. Pursuant to Miss Code Ann. §11-1-65, punitive damages are warranted in the

case at hand because the named defendants' acted with such gross negligence that showed a willful, wanton, and/or reckless disregard for the safety of the decedent and other pharmacy customers. The named defendants' negligence proximately caused the decedent's injuries and death.

54. At all times relevant hereto, the defendants' through their agents' and conduct and omissions in failing to provide the decedent and all other similarly situated individuals who were prescribed HCTZ 25 mg tablets were grossly negligent and of such outrageous, egregious and offensive character and so offensive to community standards as to subject the named defendants' to punitive damages.

IX. Fourth Cause Of Action: Survival Claims Of The Decedent

55. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

56. Pursuant to Miss. Code Ann. § 91-7-233 (Rev. 2004), the named defendants' agent's, employees and servants' deviations from FDA rules and regulations, actions, conduct, inactions, omissions caused and contributed to the decedent and all other similarly situated individuals who were prescribed and ingested HCTZ 25 mg tablets, pain, suffering, emotional distress, loss of enjoyment of life and other damages the decedent would have been entitled to before his death.

PRAYER FOR RELIEF

WHEREFORE, the named plaintiff and all similarly situated class members seeks judgment favor against the named defendants as follows:

- 1. Economic and non-economic damages in an amount in excess of \$5,000,000 as provided by CAFA and to be supported by the evidence, after discovery and at trial;
- 2. For the equitable relief requested;
- 3. For compensatory damages according to proof;
- 4. For punitive damages;
- 5. For judgment that the named defendants' are liable to plaintiff and all other similarly situated persons for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by the named defendants' wrongdoing;
- 6. For disgorgement of profits;
- 7. For an award of attorneys' fees and costs;
- 8. For prejudgment interest and the costs of suit; and
- 9. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff and the class members hereby demands a trial by jury as to all claims in this action.

SO COMPLAINED, this the 11th day of July, 2018.

Respectfully submitted,

ANDREA L. JOHNSON, Administratrix of the Estate of Arthur Lee Johnson, Deceased

By: s/Ellis Turnage
ELLIS TURNAGE, Attorney for
Plaintiff And All Other Similar
Situated Individuals

OF COUNSEL:

ELLIS TURNAGE, MSB # 8131 TURNAGE LAW OFFICE POST OFFICE BOX 216 108 NORTH PEARMAN AVENUE CLEVELAND, MS 38732

Tel: (662) 843-2811 Fax: (662) 843-6133 eturnage@etlawms.com Case: 4:18-cv-00140-DMB-JMV Doc #: 1-1 Filed: 07/11/18 1 of 1 PageID #: 19

LETTERS OF ADMINISTRATION

STATE OF MISSISSIPPI COUNTY OF WASHINGTON CAUSE NO. 2015 - 1066

BY THE CHANCERY COURT OF SAID COUNTY

Whereas, ARTHUR L. JOHNSON, Deceased, late of said County, died interstate, as we are informed, having whilst he lived and at the time of his death divers, goods and chattels, rights and credits within this state, and we desiring that the said goods and chattels, rights and credits, may be well and truly administered, converted and disposed of, hereby grant unto ADREA L. JOHNSON, full power, by the tenor of these presents, to administer the goods an chattels, rights and credits which to the said deceased in his lifetime and at the time of his death, did belong to ask, levy, recover and received the same, and pay the debts which the deceased stood bound, so far as the goods, chattels, rights, credits, lands, tenements and hereditaments of the said deceased will extend, according to their rate and the order of the law, to make a true and perfect inventory of said goods and chattels, rights and credits, and the same to exhibit in the office of the clerk of this Court, at or before the expiration of three months from the date hereunto legally required, and the said ADREA L. JOHNSON is hereby ordained administrator of all and singular the goods and chattels, rights and credits of said deceased.

Witness the Honorable Marie Wilson Chancellor of the Ninth District, this the 18th day of ________, 2015 and the seal of said Court hereunto affixed.



MARILYN HANSELL, CHANCERY CLERK

D.C.

You are viewing an archived web page, collected at the request of <u>U.S Food and Drug Administration (http://archive-it.org/organizations/1137)</u> using <u>Archive-It (http://archive-it.org/)</u>. This page was captured on 7:25:54 Jan 12, 2017, and is part of the <u>FDA.gov (http://archive-it.org/public/collection.html?id=7993)</u> collection. The information on this web page may be out of date. See <u>All versions (http://wayback.archive-it.org/7993/*/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2015/ucm456877.htm)</u> of this archived page. Note that this document was downloaded, and not saved because it was a duplicate of a previously captured version (0:20:43 Oct 23, 2016). HTTP headers presented here are from the original capture.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Unichem Pharmaceuticals (USA), Inc. Issues a Voluntary Nationwide Recall of Hydrochlorothiazide Tablets Due to the Potential Presence of Foreign Tablets

Contact:

Consumer:

1-866-931-0704.

regaffairs@unichemusa.com (mailto:regaffairs@unichemusa.com)

FOR IMMEDIATE RELEASE – July 30, 2015 – Rochelle Park, New Jersey – Unichem Pharmaceuticals (USA), Inc. (Unichem) is voluntarily recalling one lot of Hydrochlorothiazide Tablets 25 mg 1000-count bottle to the consumer level. This recall has been initiated as a precautionary measure due to the identification of a Clopidogrel tablet found in a bottle of the product.

The risk associated with mistakenly taking a Clopidogrel tablet instead of a Hydrochlorothiazide tablet is the increased probability of experiencing Clopidogrel's side effects which include bleeding and/or bruising. Patients with active bleeding or who are allergic to Clopidogrel or any component of the formulation may experience more serious adverse health consequences as a result of unknowingly consuming Clopidogrel. Additionally, missing a dose of Hydrochlorothiazide could result in uncontrolled blood pressure or swelling caused by excess fluid (edema). As per Unichem's internal investigation, this episode is an isolated event noted at one pharmacy and confined to the recalled lot. Unichem has not received any reports of adverse events related to this recall to date.

Hydrochlorothiazide tablets are indicated for the management of high blood pressure and edema and are packaged in 1000-count bottles. The affected Hydrochlorothiazide tablets include Lot # GHYL15028 - Expiration April, 2018, and was distributed nationwide directly to wholesalers, retailers, and pharmacies from May 21 - 28, 2015.

Unichem is notifying its distributors and customers by letter, overnight FedEx and emails. Unichem is also arranging for return of all recalled products. Consumers should not consume Hydrochlorothiazide Tablets 25 mg 1000's from the lot GHYL15028 which is being recalled and should return to place of purchase.

Consumers with questions regarding this recall can contact Unichem Pharmaceuticals (USA), Inc. by e-mail regaffairs@unichemusa.com or call customer service at: 1-866-931-0704, Monday through Friday 8:30 AM - 5:00 PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. If the consumer is not sure they received the recalled lot, they should contact the pharmacy that dispensed the product to them.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm (http://way-back.archive-it.org/7993/20170112072554/http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm (http://way-back.archive-it.org/7993/20170112072554/http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

RSS Feed for FDA Recalls Information

(/7993/20170112072554/http://www.fda.gov/AboutFDA/ContactFDA/StayIn-

formed/RSSFeeds/Recalls/rss.xml) [what's this?

(/7993/20170112072554/http://www.fda.gov/AboutFDA/ContactFDA/StayIn-

formed/RSSFeeds/default.htm)]

Photo: Product Labels (/7993/20170112072554/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2015/ucm456878.htm)

Recalled Product Photos Are Also Available on FDA's Flickr Photostream. (http://wayback.archive-it.org/7993/20170112072554/https://www.flickr.com/photos/fdaphotos/sets/72157650046427065/)

More in 2015

(/7993/20170112072554/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2015/default.htm)

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet.

purpose of initiating the civil to	locket sheet. (SEE INSTRUC	CHONS ON NEXT PAGE C	OF THIS FO	DRM.)							
I. (a) PLAINTIFFS	I. (a) PLAINTIFFS				DEFENDANTS UNICHEM PHARMACEUTICALS; CVS MISSISSIPPI PHARMACY,						
ANDREA L. JOHNSON, Administratrix Of The Estate of Arthur Lee Johnson And On Behalf Of Themselves And All Others Similar Situ (b) County of Residence of First Listed Plaintiff				LLC, and CVS PHARMACY, INC							
		ACEC)		County of Residence of First Listed Defendant							
(EXCEPT IN U.S. PLAINTIFF CASES)				(IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.							
(c) Attorneys (Firm Name, Address, and Telephone Number) Turnage Law Office				Attorneys (If Known)							
P.O. Box 216, Cleveland (662) 843-2811	d, Mississippi 38732										
II. BASIS OF JURISD	ICTION (Place an "X" in (One Box Only)		TIZENSHIP OF P (For Diversity Cases Only)	RINCIP	AL PARTIES					
☐ 1 U.S. Government				TF DEF		and One Box for	Dejenac PTF	DEF			
Plaintiff (U.S. Government Not a Party)			Citize	en of This State	11 0 1	Incorporated or Pr of Business In	rincipal Place	□ 4	□ 4		
☐ 2 U.S. Government Defendant	☐ 4 Diversity (Indicate Citizens)	hip of Parties in Item III)	Citize	en of Another State	12 🗇 2	Incorporated and of Business In		□ 5	5		
				en or Subject of a	13 🗆 3	Foreign Nation		□ 6	□ 6		
IV. NATURE OF SUI						c here for: Nature			_		
CONTRACT		ORTS		ORFEITURE/PENALTY		NKRUPTCY	OTHER ST		ES		
☐ 110 Insurance ☐ 120 Marine	PERSONAL INJURY ☐ 310 Airplane	PERSONAL INJUR 365 Personal Injury -	Y □ 62	5 Drug Related Seizure of Property 21 USC 881	☐ 422 App ☐ 423 With	eal 28 USC 158	☐ 375 False Clair				
☐ 130 Miller Act	☐ 315 Airplane Product	Product Liability	□ 69	0 Other		JSC 157	376 Qui Tam (3729(a))	31 USC			
140 Negotiable Instrument	Liability						☐ 400 State Reap	portion	nent		
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 320 Assault, Libel & Slander	Pharmaceutical Personal Injury	- 1		PROPE	RTY RIGHTS	410 Antitrust				
☐ 151 Medicare Act	☐ 330 Federal Employers'	Product Liability			☐ 820 Cop: ☐ 830 Pate	yrights nt	☐ 430 Banks and ☐ 450 Commerce		ğ		
☐ 152 Recovery of Defaulted	Liability	368 Asbestos Personal				nt - Abbreviated	☐ 460 Deportatio				
Student Loans	☐ 340 Marine	Injury Product				Drug Application	☐ 470 Racketeer				
(Excludes Veterans) ☐ 153 Recovery of Overpayment	☐ 345 Marine Product Liability	Liability PERSONAL PROPER	TV	LABOR	☐ 840 Trad	emark SECURITY	Corrupt Or 480 Consumer		ons		
of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 370 Other Fraud		0 Fair Labor Standards	☐ 861 HIA		490 Cable/Sat				
160 Stockholders' Suits	☐ 355 Motor Vehicle	☐ 371 Truth in Lending		Act	☐ 862 Blac	k Lung (923)	☐ 850 Securities/		dities/		
☐ 190 Other Contract ☐ 195 Contract Product Liability	Product Liability 360 Other Personal	☐ 380 Other Personal Property Damage	D 72	0 Labor/Management Relations	☐ 863 DIW	C/DIWW (405(g))	Exchange 890 Other Statu		29		
☐ 196 Franchise	Injury	☐ 385 Property Damage	□ 74	0 Railway Labor Act	☐ 865 RSI		☐ 891 Agricultura	al Acts	tions		
	☐ 362 Personal Injury -	Product Liability	□ 75	l Family and Medical		i datte	☐ 893 Environmen	ntal Matt			
REAL PROPERTY	Medical Malpractice CIVIL RIGHTS	PRISONER PETITION	IS 7 79	Leave Act Other Labor Litigation	FEDER	AL TAX SUITS	☐ 895 Freedom of	f Inform	ation		
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	_	l Employee Retirement		es (U.S. Plaintiff	896 Arbitration				
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	1	Income Security Act		efendant)	☐ 899 Administra		cedure		
☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land	☐ 442 Employment	☐ 510 Motions to Vacate				-Third Party	Act/Review		eal of		
245 Tort Product Liability	☐ 443 Housing/ Accommodations	Sentence 530 General			26 (ISC 7609	Agency De 950 Constitutio		c		
☐ 290 All Other Real Property	☐ 445 Amer. w/Disabilities -			IMMIGRATION	1		State Statut		£		
	Employment	Other:	□ 462	Naturalization Application			CASCASO FLORIDORIAL				
	☐ 446 Amer. w/Disabilities - Other	☐ 540 Mandamus & Othe ☐ 550 Civil Rights	r 46:	Other Immigration Actions							
	☐ 448 Education	☐ 555 Prison Condition	- 1	ricuons							
		☐ 560 Civil Detainee -									
		Conditions of Confinement									
V. ORIGIN (Place an "X" is	One Ren Onto	- Community									
	CONTRACTOR AND ADMINISTRATION OF THE PROPERTY AND A	D1-16							720		
	te Court	Appellate Court	J 4 Reins Reop	ened Anothe (specify)	r District	 6 Multidistr Litigation Transfer 	- Li	ultidist tigation rect File	n -		
	Cite the U.S. Civil Sta	tute under which you are	e filing (D	o not cite jurisdictional state	utes unless di	versity):					
VI. CAUSE OF ACTIO	Brief description of ca	iuse:		D							
VII. REQUESTED IN		Misbranded Pharma				THOU THE			CO :		
COMPLAINT:	UNDER RULE 2	IS A CLASS ACTION 3, F.R.Cv.P.	DE	CMAND \$		HECK YES only URY DEMAND:		mplain No	t:		
VIII. RELATED CASE											
IF ANY	(See instructions):	JUDGE			DOCKE	T NUMBER					
7-11-20	10	SIGNATURE OF ATT	ORNEY O	F RECORD							
	1 6	Ellis	10	ge							
FOR OFFICE USE ONLY											
RECEIPT # AN	MOLINT	ADDI VING IED		HIDGE		MAG IIID	GE.				

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Lawsuit Filed Against Unichem, CVS Claims Mislabeled HCTZ Caused Death of Mississippi Man</u>