

U.S. DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

JUN 25 2014

CHRIS R. JOHNSON, Clerk
By

Deputy Clerk

Elizabeth West; §
§
Catherine Kiger; and §
§
C. J., a minor by and through §
her mother and guardian Amie §
Ledmen, §
PLAINTIFFS, §

CIVIL ACTION No.

v. §

14-5191

John Selig, §
in his official capacity as §
Director of Arkansas §
Department of Health §
Services; §
§

Jury Trial Demanded

Dawn J. Zekis, §
in her official capacity as §
Interim Director of Medical §
Services Arkansas Medicaid; §
§

William Golden, M.D., §
in his official capacity as §
Medical Director of the §
Division of Medical Services §
Arkansas Medicaid; and §
§

Suzanna Bridges, P.D. §
in her official capacity as §
Director of Pharmacy Programs §
Arkansas Medicaid, §
§

DEFENDANTS. §
§

FIRST AMENDED COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT:

The plaintiffs, Elizabeth West (an adult feme sole), Catherine Kiger (an adult feme sole) and C.J. (a minor) are qualified Arkansas Medicaid beneficiaries who seek to enjoin the defendants

from denying medically necessary Medicaid services to which they are each entitled under Title XIX of the Social Security Act.

I. JURISDICTION.

1. The United States District Court for the Western District of Arkansas has federal question jurisdiction over this cause of action under 28 U.S.C. §1331 because the plaintiffs allege under 42 U.S.C. §1983 that the defendants have violated their rights and entitlements under the Medicaid amendments to the Social Security Act (codified at 42 U.S.C. §1396a et seq.) and allege that the defendants have violated their rights to Due Process and Equal Protection under the Fourteenth Amendment of the United States Constitution.

2. This Court has federal civil rights jurisdiction under 28 U.S.C. §1343(a)(3) because the plaintiffs claim a deprivation of federal Medicaid rights and entitlements by the defendants acting under the color of state law in violation 42 U.S.C. §1983 and the Fourteenth Amendment of the United States Constitution.

3. This Court has supplemental jurisdiction under 28 U.S.C. §1367 for any and all violations of the state Medicaid statute because such claims are so closely related to the federal claims that they form part of the same case or controversy.

4. The defendants in their official capacity are not immune from the jurisdiction of this Court under Ex parte Young, 209 U. S. 123, 28 S. Ct. 441 (1908).

II. VENUE

5. Venue is proper in this Court under 28 U.S.C. §1391(a) and §1391(b) because all the defendants are subject to this Court's personal jurisdiction; because each defendant resides in or can be found in this federal district; because at least one plaintiff resides in this federal district; and because the operative facts and violations of law that give rise to this civil action occurred in this federal district.

III. PARTIES.

6. The plaintiff Elizabeth ("Lizzy") West is an adult Medicaid beneficiary who resides at:

509 Seventh Street
St. Charles, Arkansas County, Arkansas 72140

7. The plaintiff Catherine Kiger is an adult Medicaid beneficiary who resides at:

5000 Boys Ranch Road
Lavaca, Sebastian County, Arkansas 72941

8. The plaintiff C.J. is a minor and Medicaid beneficiary who is the ward of her mother Ms. Amie Ledmen, residing in:

Lawrence County, Arkansas.

9. Defendant John Selig, is an official of the Arkansas Department of Health Services serving in the capacity of Director. He may be served with process by U. S. Mail at:

Arkansas Department of Health Services
Donaghey Plaza
P.O. Box 1437
Little Rock, Arkansas 72203

and he may be found for service of process at:

Arkansas Department of Health Services
Donaghey Campus
700 Main Street
Little Rock, Arkansas 72201

10. Defendant Dawn J. Zekis is an official of the Arkansas Department of Health Services serving in the capacity of Interim Director of Medical Services of Arkansas Medicaid. She may be served with process by U. S. Mail at:

Arkansas Department of Health Services
Donaghey Plaza
P.O. Box 1437
Little Rock, Arkansas 72203

and she may be found for service of process at:

Arkansas Department of Health Services
Donaghey Campus
700 Main Street
Little Rock, Arkansas 72201.

11. Defendant William Golden, M.D. is an official of the Arkansas Department of Health Services serving in the capacity of Medical Director of Arkansas Medicaid. He may be served with process by U. S. Mail at:

Arkansas Department of Health Services
Donaghey Plaza
P.O. Box 1437
Little Rock, Arkansas 72203

and he may be found for service of process at:

Arkansas Department of Health Services
Donaghey Campus
700 Main Street
Little Rock, Arkansas 72201.

12. Defendant Suzanna Bridges, P. D. is an official of the Arkansas Department of Health Services serving in the capacity of Director of Pharmacy Programs for Arkansas Medicaid. She may be served with process by U. S. Mail at:

Arkansas Department of Health Services
Donaghey Plaza
P.O. Box 1437
Little Rock, Arkansas 72203

and she may be found for service of process at:

Arkansas Department of Health Services
Donaghey Campus
700 Main Street
Little Rock, Arkansas 72201.

IV. FACTS.

A. Each Plaintiff has Cystic Fibrosis.

13. Each plaintiff was born with cystic fibrosis. Cystic fibrosis is a genetic disease that affects the lungs, pancreas, liver, and other organs. Cystic fibrosis is a progressive, degenerative disease. If not properly treated, cystic fibrosis will lead to death, most commonly by respiratory failure and usually before age 30.

B. Cystic Fibrosis is a Life Threatening Disease.

14. Cystic fibrosis is characterized by abnormally thick and sticky mucous in the lungs and digestive organs.

15. In the respiratory system, viscous mucous clogs the airways and sinuses, making it difficult to breathe. Bacteria easily grows in the mucous, leading to life-threatening sinus and lung infections that permanently scar lung tissue, causing irreversible loss of pulmonary function. Individuals with cystic fibrosis are prone to pneumonia, bronchiectasis, hemoptysis, sinus infections, pulmonary exacerbations and other complications, requiring frequent physician interventions and hospitalizations.

16. In the digestive system, viscous mucus clogs the liver, pancreas and other organs, preventing normal digestion. This causes pancreatic insufficiency and may cause malnutrition, acute bowel obstructions and other complications.

17. People with cystic fibrosis also may also experience cystic fibrosis related diabetes, poor growth, infertility and other adverse affects of the disease.

C. Abnormal Function of CFTR Protein.

18. In cystic fibrosis patients, the genetic defect causes the abnormal production and abnormal function of a protein called the *cystic fibrosis transmembrane-conductance regulator* or "CFTR".

19. In a person without cystic fibrosis, the CFTR protein regulates the movement of chloride and sodium ions across epithelial membranes of cells. In a person with cystic fibrosis, the CFTR protein is abnormal. The abnormal CFTR cannot properly regulate chloride and sodium ions and causes a fundamental

disjunction in the cells. This fundamental disjunction in cystic fibrosis patients results in the secretion of the characteristic viscous mucous, which causes the other symptoms and complications of the disease.

D. Plaintiffs' Medical Need Can Only Be Met with Kalydeco™.

20. Each of the plaintiffs need a medicine that improves the function or potentiates their defective CFTR protein, so that they will have more normal function of the chloride channels in their cells and have more normal secretions in their respiratory and digestive organs.

21. Only one drug is available to potentiate the CFTR protein in CF patients like Lizzy, Catherine and C.J.. It is Kalydeco™. Kalydeco is not experimental; it is proven to be safe and effective to treat cystic fibrosis. Kalydeco is FDA approved.

22. Kalydeco is the standard-of-care for individuals with cystic fibrosis who are over age 6 years and who have the G551D genetic mutation. It is highly likely that Kalydeco™ will substantially improve the health of the plaintiffs and others like them.

23. Kalydeco is widely available to cystic fibrosis patients in the United States, except for those enrolled in Arkansas Medicaid.

E. Prescription Drugs are a Covered Medicaid Service.

24. Prescription drugs are a covered service in Arkansas's Medicaid program. Arkansas Medicaid's prescription drug coverage ostensibly covers Kalydeco, and Kalydeco is listed among the covered prescription drugs in Arkansas Medicaid's published manual.

25. The plaintiffs are categorically needy individuals and eligible to receive medical assistance from Arkansas Medicaid. They are each entitled to receive the amount, duration and scope of covered services, including prescription drug services, that are medically necessary.

F. Kalydeco is Medically Necessary for Each Plaintiff.

26. The attending physicians of the plaintiffs (who are each Arkansas Medicaid Providers) have determined that each plaintiff has a G551D genetic mutation and that Kalydeco is medically necessary and appropriate to treat their cystic fibrosis. The plaintiffs' attending physicians have certified the medical necessity of Kalydeco for each of them. The plaintiffs' physicians have delivered to Arkansas Medicaid statements of medical necessity detailing the reasons that Kalydeco is medically necessary to treat or ameliorate their symptoms of cystic fibrosis and the causes of those symptoms.

G. Defendants have Denied Kalydeco for Each Plaintiff.

27. Each plaintiffs' request for prior authorization for Kalydeco was denied and continues to be denied by the defendants,

despite the certification that the drug is medically necessary and appropriate to correct or ameliorate the affects of cystic fibrosis.

V. CAUSES OF ACTION.

A. 42 U.S.C. §1983 Cause of Action for Deprivation of Federal Rights and Privileges.

28. Each of the defendants are persons who, acting under the color or authority of a statute, regulation, custom, or usage of the State of Arkansas have subjected the plaintiffs and continue to subject them (and other similarly situated persons within the jurisdiction of Arkansas) to deprivations of rights, privileges and immunities secured by Title XIX of the Social Security Act (42 U.S.C. §1396a et seq.) and under the Constitution of the United States.

1. Deprivation of Rights under Title XIX of the Social Security Act.

(a.) Failure to Provide Medically Necessary Services.

29. Under Title XIX of the Social Security Act (42 U.S.C. §1396a et seq.), Arkansas Medicaid is obligated to provide (and the plaintiffs have the right and privilege to receive) medically necessary treatment within a covered service area.

30. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of rights and privileges under the Medicaid Act:

- (i) by failing to provide medically necessary medical assistance within a covered service area;
- (ii) by establishing the custom, policy and practice of denying covered services without regard to medical necessity;
- (iii) by requiring the plaintiffs (and others like them) to undergo medically **unnecessary** treatments as condition for approval for the medically necessary treatment of Kalydeco;
- (iv) by establishing prior authorization criteria that impose an irrebuttable presumption that Kalydeco is not medically necessary; and
- (v) by establishing unreasonable standards for providing Kalydeco that do not allow for exceptions based on medical necessity or the established standards of care.

(b.) Failure to Provide Medically Necessary Services Sufficient in Amount, Duration and Scope to Achieve Medical Purpose.

31. Under Title XIX of the Social Security Act, Arkansas Medicaid is obligated to provide (and the plaintiffs have the right and privilege to receive) medically necessary treatment that is sufficient in an amount, duration and scope to meet their medical need.

32. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of their rights and privileges under the Medicaid Act by:

- (i) failing to provide the prescription drug Kalydeco™ in sufficient amount, duration and scope to achieve the purpose of the covered service;
- (ii) establishing limitations on providing Kalydeco that are not rationally based on medical necessity; and
- (iii) establishing limitations on providing Kalydeco that are not consistent with the standards of care in the medical community regarding the amount, duration and scope of the drug.

(c.) Arbitrary Denial of the Amount, Duration and Scope of Medically Necessary Treatment.

33. Under Title XIX of the Social Security Act, Arkansas Medicaid is prohibited from (and the plaintiffs have the right and privilege to be free from) the arbitrary denial or reduction of the amount, duration and scope of medically necessary treatment because of the diagnosis, type of illness or condition.

34. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of the rights and privileges under the Medicaid Act by:

- (i) arbitrarily denying the necessary amount, duration and scope of medically necessary treatment;
- (ii) establishing arbitrary standards for providing the medically necessary services; and
- (iii) providing medically necessary prescription drug services to other Medicaid beneficiaries with other diagnoses, types of illness or conditions, while failing to provide medically necessary prescription drug services to the plaintiffs.

(d.) Failing to give Proper Weight and deference to the Treating Physician.

35. Under Title XIX of the Social Security Act, Arkansas Medicaid must give deference to (and must not disregard) the determinations of medical necessity of a treating physician.

36. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of the rights and privileges under the Medicaid Act by failing to give any weight or deference to the determinations of medical necessity of a treating physician, even when such determinations are based on objective medical testing and established standards of care in the medical community.

(e.) Denying Medically Necessary Services Because of Cost.

37. Arkansas Medicaid is obligated under Title XIX of the Social Security Act to assure that a lack of adequate funds from local sources, if any, will not result in a lower amount, duration and scope or quality of care available under the state Medicaid plan.

38. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of the rights and privileges under the Medicaid Act by denying Kalydeco when medically necessary because of its cost.

2. Deprivation of Due Process.

39. The Fourteenth Amendment of the U. S. Constitution guarantees that no State shall deprive any person of life, liberty, or property, without due process of law.

40. As qualified Medicaid beneficiaries, the plaintiffs and other similarly situated persons have been denied a tangible property interest in medically necessary covered Medicaid services without due process of law.

41. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of their entitlement to Kalydeco by depriving the plaintiffs of a meaningful opportunity to be heard with prior authorization criteria that impose an irrebuttable presumption that Kalydeco is not medically necessary.

42. The defendants, singularly and in combination, have deprived the plaintiffs (and other similarly situated individuals) of their entitlement to Kalydeco by depriving the plaintiffs of a meaningful opportunity to be heard with prior authorization criteria that do not allow for reasonable exceptions to the criteria based on medical necessity.

3. Deprivation of Equal Protection.

43. The Fourteenth Amendment of the U. S. Constitution guarantees that no State shall deny to any person within its jurisdiction the equal protection of the laws.

44. The defendants, singularly and in combination, have denied the plaintiffs (and other similarly situated individuals) the equal protection of the law by failing to provide a medically necessary prescription drug to them, while at the same time providing medically necessary prescription drugs to others who have different diagnoses, types of illness or conditions.

B. Violation of State Medicaid Statute.

45. The defendants are prohibited under the Arkansas Medical Assistance statute from establishing any prescription drug program guideline to control the provision of prescription drug services that conflict with any federal law.

46. The defendants, singularly and in combination, have violated the Arkansas Medical Assistance Statute by establishing prescription drug program guidelines to control the provision of

prescription drug services that conflict with federal law by establishing prior authorization criteria that deny prescription drug services even when such drugs are medically necessary.

C. Attorney Fees in a 42 U.S.C. §1983 Action.

47. Under 42 U.S.C. §1988, the plaintiffs may recover reasonable attorney fees as part of costs in a civil action to enforce federal civil rights, including a civil action under 42 U.S.C. §1983. Because this civil action is brought to enforce federal civil rights under 42 U.S.C. §1983, the plaintiffs allege a cause of action to recover reasonable attorney fees as part of costs.

VI. JURY DEMAND.

48. Under Rule 38 of the Federal Rules of Civil Procedure, the plaintiffs demand that all issues of fact be tried to a jury.

49. The plaintiffs further request an advisory jury under Federal Rule of Civil Procedure 39(c) for any issue that is not triable of right by a jury.

VII. PRAYER FOR RELIEF.

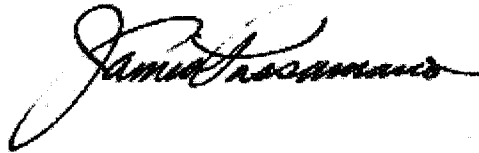
WHEREFORE, PREMISES CONSIDERED the plaintiffs respectfully pray that this court grant all relief in law and equity to which they may be entitled, including:

- A. Prospective injunctive relief ordering the defendants to not deny the plaintiffs (and other similarly situated individuals) Kalydeco when it is certified to be

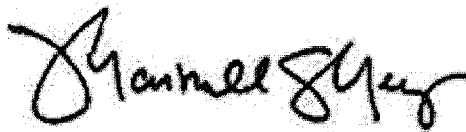
medically necessary by their treating physician;

- B. Declaratory relief stating that the prior authorization criteria for Kalydeco that the defendants have applied to the plaintiffs' request for prior authorization is unlawful because it is inconsistent with the purpose and substance Title XIX of the Social Security Act.
- C. Attorneys' fees; and
- D. Court costs.

Respectfully Submitted,



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