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

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| Catherine Kiger;<br>Elizabeth West;<br>and<br>C. J., a minor by and through her mother and guardian Amie Ledman,<br>PLAINTIFFS,<br>v.<br><br>John Selig,<br>in his official capacity as Director of Arkansas Department of Health Services;<br><br>Dawn J. Zekis,<br>in her official capacity as Interim Director of Medical Services Arkansas Medicaid;<br><br>William Golden, M.D.,<br>in his official capacity as Medical Director of the Division of Medical Services Arkansas Medicaid; and<br><br>Suzanna Bridges, P.D.,<br>in her official capacity as Director of Pharmacy Programs Arkansas Medicaid,<br>DEFENDANTS. | §<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§ | CIVIL ACTION No. 14-2151<br><br>~~14-5191~~<br><br>Jury Trial Demanded |

**SETTLEMENT AGREEMENT**

**1.0 Parties.**

1.1 The parties to this agreement are:

- John Selig, in his official capacity as Director of Arkansas Department of Human Services;
- Dawn J. Zekis, in her official capacity as Director of the Division of Medical Services of the Arkansas Department of Human Services (hereinafter referred to as "Arkansas Medicaid");

- William Golden, M.D., in his official capacity as Medical Director of Arkansas Medicaid;
- Suzanna Bridges, P. D. in her official capacity as Director of Pharmacy Programs for Arkansas Medicaid;
- Catherine Kiger, in her individual capacity;
- Elizabeth West, in her individual capacity; and
- C. J. a minor in her individual capacity by and through her guardian Amie Ledman.

**2.0** **Continuing Jurisdiction of the Court.**

2.1 The parties agree (and the Court consents) that the United States District Court for the Western District of Arkansas, Fayetteville Division, shall have and may exercise continuing jurisdiction, within two years of the effective date of this agreement, over denials of authorization of Ivacaftor (Kalydeco) that do not comply with this agreement, as more fully described below in paragraph 6.0 of this agreement.

2.2 To facilitate the continuing jurisdiction of the Court, the parties consent to the jurisdiction of United States Magistrate Judge Erin L. Setser, or her successor. The parties agree to perform any further action (such as the execution of a consent to jurisdiction of the Magistrate document) that may be necessary to facilitate the Court's continuing jurisdiction solely for the period and purposes described below in paragraph 6.0 of this agreement.

2.3 At the end of the two year period described in paragraph 2.1 above, the Court's continuing jurisdiction under this agreement shall cease and this case dismissed with prejudice.

**3.0 Implementation of New Authorization Criteria for the Prescription Drug Ivacaftor.**

3.1 John Selig, Dawn J. Zekis, William Golden and Suzanna Bridges, all in their official capacities, (hereafter referred to as "the Defendants"), singularly and in combination, agree that not later than 30 days after the effective date of this settlement agreement they shall implement (or cause to be implemented) the prior authorization and re-authorization criteria as stated in the attachment to this agreement entitled "Authorization Criteria for Ivacaftor", which is marked as "Attachment A" and initialed by the counsel of record for the respective parties, and which may hereafter be referred to as the "New Authorization Criteria."

3.2 The New Authorization Criteria (along with any amendments permitted by this agreement) shall be the sole authorization criteria applied to requests to Arkansas Medicaid for prior authorization or re-authorization of Ivacaftor, subject to the recipient's Medicaid eligibility.

3.3 For two years after the date this settlement agreement is effective, the Defendants in their official capacities (or their successors) shall not alter the New Authorization Criteria, except that the defendants (or their successors) may add or delete criteria if such addition or deletion is identical to an addition

or deletion in the indications for use of Ivacaftor approved by the Food and Drug Administration (FDA) and stated on the FDA approved product label for Ivacaftor.

3.4 After two years has elapsed from the effective date of this settlement agreement, the defendants (or their successors) shall not alter the New Authorization Criteria (except for any changes identical to changes in the FDA labeling) without first giving written notice of a proposed change to the plaintiff's attorney at the address referenced below in paragraph 11.0; and (1) giving public notice of a proposed change in the authorization criteria, (2) providing for a period of public comment on the proposed change to the criteria, and (3) presentment to the Arkansas Medicaid Drug Utilization Review (DUR) Board for approval, all in accordance with applicable state law.

**4.0 Publication of Authorization Criteria.**

4.1 John Selig, Dawn J. Zekis, William Golden and Suzanna Bridges, in their official capacities, singularly and in combination, shall publish (or cause to be published) the New Authorization Criteria (along with any changes made pursuant to paragraphs 3.3 or 3.4 of this agreement) on the Arkansas Medicaid website, in a location where Medicaid customarily publishes such criteria.

**5.0 Fact Finding on Each Element of Authorization Criteria.**

5.1 When applying the New Authorization Criteria to a request for authorization of Ivacaftor, the defendants or their successors, singularly and in combination,

shall direct appropriate staff of Arkansas Medicaid to make a fact finding based on the medical evidence presented by the requestor on each element of the New Authorization Criteria (as it may be amended in accordance with this agreement) whenever a request for authorization of Ivacaftor is denied.

5.2 If the Arkansas Medicaid staff fail to make a finding of fact on each element of the new criteria (as it may be amended in accordance with this agreement), the person requesting authorization may make a written notice of a demand for review with the Medical Director of Arkansas Medicaid (or his or her designee) for the purpose of obtaining a fact finding on each element of the criteria. If the Medical Director (or his or her designee) has not made a fact finding on each element of the new criteria within 30 days after receiving a written demand for review, the person requesting authorization may invoke the continuing jurisdiction of the United States District Court and request a hearing on the issue.

5.3 Any request for a hearing shall be made to the Honorable Erin Setser, United States Magistrate Judge for the Western District of Arkansas, Fayetteville Division or her successor.

**6.0 Exercise of Continuing Jurisdiction of the United States District Court.**

6.1 When a request described in paragraph 5.2 above is made to the United States District Court within two years of the effective date of this agreement, the parties agree that the United States Magistrate Judge may schedule a hearing

only if the request is accompanied by evidence (by affidavit or otherwise) that (1) a request for authorization of Ivacaftor was made and denied; (2) the notice of the denial failed to make a fact finding on each element of the Authorization Criteria (as it may be amended in accordance with this agreement); (3) the person requesting the authorization made a written demand for review by the Medical Director of Arkansas Medicaid (or his or her designee); and (4) the review failed to yield a fact finding as described in section 5.0 within the time limits set forth therein.

6.2 The parties agree that the U. S. District Court shall not exercise its continuing jurisdiction over questions of the sufficiency of medical evidence supporting a request for authorization. Such disputes may be presented through state administrative procedure, through the procedure provided for below in paragraph 7.1, or both.

6.3 The Court may deny the request or grant the request in whole or in part, and may enter an order directing Arkansas Medicaid to make the required finding of fact.

**7.0 <u>Request for Reconsideration Directly to the Arkansas Medicaid Medical Director</u>.**

7.1 When a request for prior authorization or re-authorization for Ivacaftor is denied, the requestor may elect to present to the Medical Director of Arkansas Medicaid (and the Medical Director shall in good faith consider) a request for

reconsideration of the denial, along with any additional information the requestor may present.

7.2 Such a request for reconsideration made directly to the Medical Director shall not require any intermediate remedial procedures, nor shall the presentment of a request for reconsideration directly to the Medical Director preclude recourse to state administrative procedures or preclude recourse to any other remedial procedures that may be available to the requestor.

**8.0 Effective Date.**

8.1 This settlement agreement shall be effective on the date that it is signed by all parties.

**9.0 No Admissions by the Defendants.**

9.1 By entering into this settlement agreement, the defendants admit no fault, liability or wrongdoing.

9.2 Plaintiffs hereby release all claims against Defendants actually brought herein and those which could have been brought herein.

**10.0 Costs and Fees.**

10.1 The parties agree to bear their own costs.

10.2 The defendants acknowledge that the plaintiffs claim a bill of costs that exceeds $225,000. The plaintiff's attorney (James Passamano) and his law firm (Sufian & Passamano, L.L.P.) have provided professional services to the plaintiffs pro bono publico.

**11.0 Notices.**

11.1 Any notices required or permitted by this agreement shall be delivered:

(a) to a plaintiff at:

James A.Passamano
Sufian & Passamano, L.L.P.
712 Main Street, Suite 2130
Houston, Texas 77002
Facsimile: 713-224-1161

(b) to a defendant at:

J. Mark White
Director, Office of Policy and Legal Services
Arkansas Department of Human Services
P. O. Box 1437, Slot S260
Little Rock, AR 72203-1437

**12.0 Agreement to be Filed of Record.**

12.1 This agreement shall not be confidential and shall be filed of record with the Clerk of the United States District Court for the Western District of Arkansas, Fayetteville Division to be filed among the documents of this cause.

**12.0 Execution.**

12.1 SIGNED by the parties:

John Selig
in his official capacity as Director of the Arkansas Department of Human Services

Date: January ____, 2015

Dawn J. Zekis
in her official capacity as Director of the Division of Medical Services of the Arkansas Department of Human Services

Date: January 23, 2015

William Golden, M. D. in his official capacity as Medical Director of the Division of Medical Services of the Arkansas Department of Human Services

Date: January 22, 2015

~~Suzanna~~ Suzette Bridges, P. D.
in her official capacity as Director of Pharmacy Programs for the Division of Medical Services of the Arkansas Department of Human Services

Date: January 23, 2015

Catherine Kiger

Date: January 28, 2015

Catherine Kiger
in her individual capacity

Elizabeth West

Date: January 31 2015

Elizabeth West
in her individual capacity

Date: January 30 2015

C.J.a minor
in her individual capacity
by and through her guardian
[redacted]
Bill Jonas, Parent
AND GUARDIAN

**14.0 Approval as to Form.**

14.1 The below signed counsel of record approve as to the form of this agreement.

J. Mark White
Counsel of Record for the Defendants in
their Official Capacities

James A. Passamano
Counsel for the Plaintiffs

**15.0 Consent to Continuing Jurisdiction**

15.1 The Court consents to the nature and scope of continuing jurisdiction described in this agreement.

Erin L. Setser 2/6/15
Erin L. Setser
United States Magistrate Judge

## AUTHORIZATION CRITERIA FOR IVACAFTOR

**Prior Approval Criteria.**

Evidence showing each of the following:

1. Beneficiary must have a diagnosis of cystic fibrosis with gene testing positive for gene mutation in one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R;

2. Beneficiary must be established on the evidence-based standard of care for the treatment of Cystic Fibrosis;

3. Alanine transaminase (ALT) and aspartate transaminase (AST) tests performed before Ivacaftor therapy begins to establish a baseline, with re-testing every three months during the first year of Ivacaftor therapy and annually thereafter;

4. Beneficiary must not currently use tobacco products;

5. Beneficiary must be 6 years of age or older; and

6. Prescribed daily dose does not exceed one 150 mg tablet taken orally once every 12 hours.

**Re-authorization Approval Criteria.**

Evidence showing the following :

1. The Beneficiary is compliant with Ivacaftor therapy, as determined by refill claims history or as reported by requester;

2. The Beneficiary is not currently using tobacco; and

3. Documentation submitted showing any one of the following four items or any combination thereof:

   a. Stabilization or improvement in lung function (FEV1);

   b. Stabilization or improvement in weight gain;

   c. Reduction in exacerbations, hospitalizations, or both;

   **or**

   d. Other evidence of clinical benefit establishing medical necessity of continuation of Ivacaftor therapy.

Initials: Richard Rosen James Passamano

~~Mark White~~, Counsel for the Defendants

Richard Rosen

James A. Passamano counsel for the Plaintiffs