No. 20-1161

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AKEBIA THERAPEUTICS, INC.,

Plaintiff-Appellant,

v.

ALEX M. AZAR II, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA, AND CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Massachusetts, No. 1:19-cv-12132-ADB
Before the Honorable Allison D. Burroughs

BRIEF OF CENTER FOR MEDICARE ADVOCACY, INC. AS AMICUS CURIAE IN SUPPORT OF APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Center for Medicare Advocacy, Inc., states that it is a nonprofit, tax exempt organization operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code. The Center for Medicare Advocacy, Inc., has no parent corporation, nor has it issued shares or securities.

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RULE 29(a)(4)(E) STATEMENT

No party's counsel authored this brief in whole or in part. No party contributed money that was intended to fund preparing or submitting this brief. Only the Center for Medicare Advocacy, Inc., contributed money that was intended to fund preparing or submitting the brief.

INTRODUCTION AND ARGUMENT SUMMARY

A. Center for Medicare Advocacy, Inc. Statement of Interest

This amicus brief is submitted by the Center for Medicare Advocacy, Inc. ("CMA"), which is a national, private, non-profit organization, founded in 1986, that provides education and legal analysis, advocacy, and assistance nationwide to help older adults and people with disabilities access Medicare and necessary health care. CMA responds to over 7,000 calls and e-mails annually, produces educational materials, and provides training and technical assistance to advocates across the country on problems pertaining to Medicare. CMA also pursues Medicare coverage for beneficiaries in administrative and legislative forums, and serves as legal counsel in litigation of national significance to Medicare beneficiaries, especially on issues of import to people with low incomes and long-term conditions.

CMA has a substantial interest in the outcome of this case, as it strives to assist Medicare beneficiaries – and here, specifically, those with chronic kidney disease (CKD) – in securing critical medical treatment for which they are legally entitled to coverage. CMA files this amicus brief because the district court's decision rests on an erroneously restrictive interpretation of Medicare coverage law and impacts whether Medicare beneficiaries with CKD can currently access the medication Auryxia to treat a serious complication of the disease.

B. Summary Statement of Argument

CMA supports the position of Akebia in this appeal and urges the reversal of the district court's Order denying preliminary injunction in the proceeding captioned *Akebia Therapeutics, Inc., v. Alex M. Azar II,* Case No. 1:19-cv-12132 (D. Mass February 4, 2020). The district court held that Akebia was unlikely to succeed on the merits of its Administrative Procedure Act ("APA") claims. Specifically, it found that the Centers for Medicare & Medicaid Services's ("CMS") decision to exclude Auryxia from Part D drug coverage as a "mineral product" when used to treat iron deficiency anemia ("IDA") was neither contrary to the law nor arbitrary and capricious. As to the first claim, CMA strongly agrees with Akebia's argument and analysis that Auryxia is not a "mineral product" within the meaning of the statute, and that the government's interpretations of that term are unsupportable. In this brief, however, CMA will address only the claims regarding interpretation of the "mineral products" exclusion that are not dependent on Auryxia's composition, as well as the ramifications of CMS's decision for Medicare beneficiaries.

CMS's decision to exclude Auryxia from Part D coverage for treatment of IDA arbitrarily and capriciously deviates from its prior decisions to cover analogous drugs. The district court rejected this claim, finding the decision to be consistent with the agency's practice of excluding prescription vitamins and

mineral products from Part D coverage when used to treat a deficiency of the particular vitamin or mineral, but allowing coverage when prescribed for a different medical use. Appellant's Brief at Add. 15. The district court's analysis is incorrect and ignores material factors.

First, the district court's determination that CMS has similarly excluded other iron products from Part D coverage as "mineral product[s]" is based on erroneous examples. For instance, it referenced the agency's purported decision to exclude polysaccharide iron complex as a mineral product. In fact, though, polysaccharide iron complex is *statutorily* non-covered because, unlike Auryxia, it does not meet the definition of a "covered Part D drug." The opinion also cites the agency's consistency in excluding prescription iron supplements from Part D coverage, even though such supplements are likewise *statutorily* excluded from coverage. The opinion also likens CMS's treatment of Auryxia to its exclusion of certain injectable and IV iron drugs from Part D coverage as "mineral product[s]." But it is not for that reason that injectable and IV iron therapies are barred from Part D coverage; it is because they are properly covered by Medicare Part B. Notably, none of the examples that the district court relied upon provide a valid basis for finding that CMS's treatment of Auryxia was "[c]onsistent with other iron products[.]" Appellant's Brief at Add. 18.

Second and crucially, the district court incorrectly considered IDA to be the same medical condition as iron deficiency. Iron deficiency, however, is a nutritional disorder characterized by low iron stores, whereas IDA is a hematological disorder confirmed by low hemoglobin level as well as low iron stores. With IDA, the body cannot produce enough hemoglobin in the red blood cells to carry sufficient oxygen to the tissues and organs. Auryxia is a proven treatment for IDA because it functions to raise hemoglobin levels. Contrary to the district court's repeated assertion, Auryxia's medical use is *not* simply to treat iron deficiency. As such, CMS's exclusion of Auryxia is an arbitrary and capricious departure from its stated policy and demonstrated practice of covering "prescription vitamins and mineral products" when prescribed for a therapeutic use other than serving as a nutritional supplement or addressing a deficiency of that vitamin or mineral.

In addition to conflating IDA with iron deficiency, the district court's analysis also discounts the fact that Auryxia's FDA-approved and labeled indication is to treat IDA specifically in non-dialysis patients *with CKD*. The CKD diagnosis is material because deterioration of kidney function impairs the ability to absorb iron, which renders IDA in CKD patients poorly responsive to iron supplementation. But Auryxia *can* successfully treat IDA in CKD patients because it operates not merely to replace missing iron, but to effect its transport into the

blood to be incorporated into the hemoglobin. Auryxia's efficacy in non-dialysis CKD patients is further evidence that it serves a therapeutic capacity beyond that of an ordinary mineral supplement, and should be covered consistent with CMS's decisions in analogous contexts.

But for the district court's erroneous analysis, it would have determined that Akebia was likely to succeed on the merits and proceeded to evaluate and weigh the other factors in the preliminary injunction analysis. In doing so, it would have found that an injunction here strongly favors the public interest by allowing Medicare patients with IDA in CKD affordable access to a critical, and in some cases lifesaving, medical treatment.

Accordingly, CMA urges reversal of the Order.

ARGUMENT

A. Legal Standard

An appeal from the grant or denial of a preliminary injunction is reviewed for abuse of discretion. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 16 (1st Cir. 1996). Although the standard is deferential, "the trial court's discretion is not unbridled and '[a]buse occurs when a material factor deserving significant weight is ignored, when an improper factor is relied upon, or when all proper and no improper factors are assessed, but the court makes a serious mistake in weighing them.'" *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d

151, 158 (1st Cir. 2004), quoting *Indep. Oil & Chem. Workers of Quincy, Inc. v. Procter & Gamble Mfg. Co.*, 864 F.2d 927, 929 (1st Cir.1988).

B. CMS's Decision to Exclude Coverage of Auryxia Was Arbitrary and Capricious.

1. The District Court Erred in its Conclusion that CMS's Exclusion of Auryxia was Consistent with its Exclusion of Other Iron Products.

The district court determined that CMS's decision regarding Auryxia was not arbitrary and capricious because the agency "consistently treats iron products as not covered under Part D when used as an iron replacement." Appellant's Brief at Add. 10. Putting aside the district court's mistaken perception that Auryxia operates merely as an iron replacement, *see infra* pp. 14-15, the examples it relied upon all fail to validate CMS's treatment of Auryxia.

For instance, the court erroneously references polysaccharide iron complex as an example of an iron product that "is not covered under Part D because CMS has determined that it is a 'mineral product' and therefore excluded from coverage." In fact, polysaccharide iron complex cannot be a "covered Part D drug" in the first instance because (1) it is not "a drug that may be dispensed only upon a prescription" and (2) it has not been "approved for safety and effectiveness as a prescription drug" by the FDA. 42 U.S.C. §§ 1395w-102(e)(1); 1396r-8(k)(2). To be clear, it is labeled as an over-the-counter iron supplement. U.S. National Library

of Medicine, DailyMed, *Label: Polysaccharide-Iron capsule* (Dec. 23, 2019).[1] *See also infra* p. 9. That CMS at some point may have deemed polysaccharide iron complex to be an excluded "mineral product" is of no moment since it could never meet the statutory definition of a "covered Part D drug" to begin with. In light of this, the district court erred in considering it a valid precedent for excluding Auryxia, which, in contrast, *does* meet the statutory definition of a "covered Part D drug."

The district court likewise erred in crediting CMS's consistent treatment of injectable and IV iron products as "not covered under Part D because they are [p]rescription vitamin/mineral product[s]." Appellant's Brief at Add. 10. Neither the agency nor the exclusionary provision had any role in the matter. Rather, the reason why injectable and IV iron products cannot be considered covered Part D drugs is because coverage for them is available under Part B. 42 U.S.C. § 1395w-102(e)(2)(B). The cited iron therapies – Iron Dextran, Iron Sucrose, and Sodium ferric gluconate – generally must be administered by a physician in a clinical setting. Consequently, they are paid for by Part B, Medicare's outpatient benefit that covers drugs and biologicals that cannot be self-administered and are furnished incident to a physician's professional service. 42 U.S.C. §§ 1395k(a);

[1] https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a42168eb-180e-4b67-b8fd-641b0af32ff3&version=2

1395x(s)(2)(A). Their absence from the Part D formulary reference file is not attributable to CMS's purportedly consistent treatment of iron products.

If anything, the fact that these injectable and IV iron formulations *are covered* by Medicare for their labeled medical uses (and for certain off-label uses), provides precedent for covering Auryxia in this instance. Just like Auryxia, Iron Sucrose is approved as a safe and effective first line treatment for IDA in patients with CKD.[2] Sodium ferric gluconate's approved indication is to treat IDA in patients with CKD receiving hemodialysis.[3] Iron Dextran is FDA-approved to treat patients with iron deficiency "in whom oral administration is unsatisfactory or impossible."[4] The district court clearly erred in its assessment that CMS's exclusion of Auryxia is consistent with its treatment of injectable and IV iron products, given that the latter are covered (by Part B) and Auryxia is not. The agency regards them equally as "iron products" and "mineral products," yet has furnished no reasonable justification for their disparate treatment.

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[2] Venofer (iron sucrose injection, USP), Highlights of Prescribing Information (June 2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021135s020lbl.pdf

[3] Ferrlecit (sodium ferric glucomate complex in sucrose injection) for IV use, Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020955s013s015lbl.pdf

[4] INFeD (iron dextran injection USP), FDA Approved Label (July 2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017441s171lbl.pdf

Finally, the district court pointed to prescription iron supplements as another instance of where CMS has consistently excluded iron products from coverage under Part D. This again is a fundamentally flawed example because, unlike Auryxia, iron supplements do not legally qualify to be a "covered Part D drug" in the first place. They constitute dietary supplements, which are regulated as food products and not as drug products. Federal law does not require supplements to be reviewed or approved by the FDA for safety and effectiveness before they are marketed. 21 U.S.C. §§ 321(ff), 350. In contrast to drug products, which are legally defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," supplements may not be marketed as a treatment for a specific disease, or to alleviate the symptoms of a disease. *Id*. §§ 321(g)(1); 343(r)(6)(C). It follows that prescription iron supplements also fall squarely under the statutorily excluded product category of "[p]rescription vitamins and mineral products." A422-423. Thus, their exclusion from Part D drug coverage is uncontrovertibly established by statute rather than by administrative decision-making.

In all of the examples that the district court relied upon to find that CMS consistently excludes iron products from Part D coverage as "mineral products," the iron products were actually ineligible for Part D coverage for entirely different reasons, none of which apply to Auryxia. Hence, no basis exists for the court to

conclude that CMS's decision to exclude Auryxia is consistent with its exclusion of other iron products.

2. The District Court Ignored Material Facts in Finding that Excluding Auryxia was Consistent with CMS's Treatment of Analogous Vitamin and Mineral Products.

CMS's decision to exclude Auryxia (ferric citrate), a synthetic organic compound, is irreconcilable with its prior decisions to cover comparable drug products. Akebia presented four examples where the agency consistently determined that similar or less well-situated drug products did not fall within the statutory exclusion under Part D for vitamins and minerals and *are covered*: (1) synthetic mineral components combined with citric acid – e.g., lithium citrate, potassium citrate; (2) Vitamin D analogs, which are chemically-synthesized organic drugs, like Auryxia; (3) niacin-based products, where active ingredient is natural-occurring Vitamin B3; and (4) inorganic mineral salts. Akebia also raised the fact that CMS covers Auryxia when used to treat hyperphosphatemia in dialysis patients.

The district court, however, found that the agency's denial of coverage for Auryxia's IDA indication to be consistent with those prior determinations. The court accepted CMS's use-based interpretation of the statutory exclusion in those instances as a rational basis for denying coverage of a vitamin/mineral drug

product when used to treat a deficiency of the specific vitamin or mineral, while allowing its coverage when used for a different medical purpose.

Applying this reasoning, the district court should have found that CMS arbitrarily deviated from its own use-based interpretation in denying coverage for Auryxia's approved use to treat IDA in CKD, which is not equivalent to treating an iron deficiency. IDA and iron deficiency are clinically distinguishable conditions. Repeatedly throughout the opinion, however, the district court referred to them interchangeably, mistakenly regarding them as one and the same condition (*e.g.*, "Auryxia is not covered when used to treat iron deficiency, because it is a mineral product used to address a deficiency of that same mineral, but it is covered when used to treat something besides iron deficiency, specifically high levels of phosphorous due to chronic kidney disease." Appellant's Brief at Add. 15). Possibly flowing from this misconception is the district court's inaccurate notion that Auryxia functions simply as an iron replacement in the treatment of IDA (*e.g.*, "Again, this evidences CMS' consistency in denying Part D coverage to Auryxia, an iron replacement product, when used to treat iron deficiency anemia." *Id.* at Add. 12). The district court also gave little or no consideration to the unique challenges of treating IDA in the setting of CKD. These material errors in the district court's analysis warrant reversal of the Order.

a. *Iron Deficiency Anemia (IDA) and Iron Deficiency are Different Conditions.*

The district court erred in conflating IDA with iron deficiency. This error is relevant because pursuant to CMS's use-based interpretation of the mineral product exclusion, which the court adopted, Auryxia cannot be covered to treat iron deficiency. However, Auryxia's approved medical indication is *not* to treat iron deficiency, but to treat IDA, and specifically in non-dialysis CKD patients. Iron deficiency can set the stage for IDA, but the two are not the same medical condition. Iron deficiency is the depletion of total body iron stores, and can be present without anemia. IDA is characterized by iron deficiency so severe as to reduce the production of normal red blood cells to carry oxygen, which can critically impair the functioning of major organ systems. IDA is diagnosed by low serum concentrations of hemoglobin, hematocrit, and ferritin, in addition to low iron stores. Terri D. Johnson-Wimbley, *et al.*, *Diagnosis and Management of Iron Deficiency Anemia in the 21st century*, 4 Therapeutic Advances in Gastroenterology 177-184 (May 2011).[5]

It follows that IDA and iron deficiency belong to completely different clinical classifications. The International Classification of Diseases, 10th Revision [2020 ICD-10-CM], classifies IDA (diagnosis code D50.9) under "[d]iseases of the

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3105608/.

blood and blood-forming organs and certain disorders involving the immune mechanism" and within the Diagnostic Related Grouping of red blood cell disorders.[6] Iron deficiency (diagnosis code E61.1) is separately classified under "[e]ndocrine, nutritional and metabolic diseases," and more specifically, "[o]ther nutritional deficiencies."[7]

b. *Treating IDA in CKD Patients Presents Unique Challenges.*

The district court also erred in ignoring the complex nature of IDA in CKD, which was described in the declarations of Dr. Chertow, Chief of Nephrology at Stanford School of Medicine. A63-68, 657-660. IDA is a significant complication of CKD, and can be caused and exacerbated by multiple factors (e.g., blood loss, iron deficiency, use of erythropoietic stimulating agents). A835-842; *see also* Society for the Advancement of Blood Management, Inc., *Management of IDA in Chronic Kidney Disease* (Dec. 2018).[8] Adding to the difficulty is the fact that CKD patients suffer from both absolute iron deficiency (*i.e.*, absent or severely depleted iron stores) and functional iron deficiency, "where there is adequate or supra-

[6] https://www.icd10data.com/ICD10CM/Codes/D50-D89/D50-D53/D50-/D50.9.

[7] https://www.icd10data.com/ICD10CM/Codes/E00-E89/E50-E64/E61-/E61.1.

[8] https://www.sabm.org/wp-content/uploads/2019/01/3B-ChronicKidneyDisease.pdf.

adequate storage iron, but an inability of the body to utilize iron efficiently for erythropoiesis (the process of making red blood cells)." A658. Dr. Chertow explained that due to this characteristic, "[c]onventional (over-the-counter) formulations of iron … are generally ineffective at correcting IDA in patients with CKD." *Id.*

Had the district court properly considered this information, it would have understood that (a) IDA in CKD is qualitatively different from iron deficiency and even IDA by itself, and (b) iron replacement alone is not enough to treat IDA in many CKD patients.

c. *Auryxia Does More Than Replace Iron in CKD Patients with IDA.*

The district court erred in ignoring material evidence that Auryxia, when used to treat IDA in CKD, acts as more than just an iron replacement. The opinion does not reflect consideration of Auryxia's FDA-labeling information, clinical studies, or declarations by Dr. Chertow, that explain the mechanism by which the drug works for this specific patient population. These sources confirm that Auryxia does more than just replenish iron stores; it has been designed "to protect the ionized iron for transit and absorption in the body, resulting in substantially greater absorption and much more effective correction of IDA than can be achieved using conventional oral iron products." A65, A645-656. Notably, the FDA approved Auryxia's labeled use based on review of clinical trials that registered only patients

"who were intolerant of or ha[d] had an inadequate therapeutic response to oral iron supplement…." A183; *see also* A63-68, 657-660, 835-842. By enhancing the transport and absorption of iron, Auryxia is demonstrated to increase hemoglobin and ferritin levels in non-dialysis CKD patients. This is contrary to the district court's repeated assertions that Auryxia serves simply to replace iron.

In summary, CMS's decision to exclude Auryxia from coverage as a "mineral product" is arbitrary and capricious because it deviates from prior agency decisions. CMS covers synthetic organic drugs (e.g., lithium citrate, Vitamin D analogs) that are indistinguishable from Auryxia. To be clear, it even covers certain drugs that are obviously vitamin and mineral products (e.g., mineral salts, prescription niacin products), as well as covering Auryxia *itself* for a different medical use. Moreover, CMS has no logical basis to depart from these precedents with Auryxia, even under its own use-based interpretation of the vitamin and mineral product exclusion, which the court has endorsed. If CMS covered these other drug products based on their use for a medical purpose other than to treat a vitamin or mineral deficiency, then it must likewise cover Auryxia to treat IDA in patients with CKD. The district court reached a different conclusion because it ignored material facts and erred in its factual assessments concerning Auryxia's purpose and function, as well as the nature of IDA in CKD. Accordingly, its Order must be reversed.

C. The Public Interest Strongly Favors Injunctive Relief.

After finding that Akebia was unlikely to succeed on the merits, the trial court assessed whether Akebia would suffer irreparable harm absent injunctive relief, but did not consider the remaining two factors to be weighed in the preliminary injunction analysis: the balance of hardships as between the parties and the effect of an injunction on the public interest. With respect to the former, CMS offered no facts to support that it would incur hardship if enjoined to resume Part D coverage of Auryxia. As for the latter, Akebia and amici provided ample evidence that a large number of Medicare beneficiaries would suffer harm or hardship in being deprived of Part D coverage for this medication. *See* Dkt. 43; Dkt. 51.

Medicare beneficiaries are disproportionately low-income. *See, e.g.*, Gretchen Jacobson *et al.*, Kaiser Family Foundation, *Income and Assets of Medicare Beneficiaries, 2016-2035* (April 2017) (half had incomes below $26,200 in 2016).[9] Moreover, an estimated 14 million U.S. adults who are aged 65 and older have CKD. Centers for Disease Control, *Chronic Kidney Disease in the United States, 2019* (Mar. 2019).[10] CKD refers to five stages of kidney damage,

[9] https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/

[10] https://www.cdc.gov/kidneydisease/pdf/2019_National-Chronic-Kidney-Disease-Fact-Sheet.pdf.

from mild in stage 1 to complete kidney failure in stage 5, necessitating renal replacement therapy with dialysis, or kidney transplant surgery. As kidney function worsens over time, CKD patients become more prone to developing IDA. The prevalence of anemia increases from 8.4 percent at stage 1 to 53.4 percent at stage 5. IDA is associated with weakness, fatigue, insomnia, cognitive impairment, dyspnea, cardiovascular comorbidities (*i.e.*, angina, heart failure), CKD progression and higher mortality. Melissa E. Stauffer & Tao Fan, *Prevalence of Anemia in Chronic Kidney Disease in the United States*, PLOS ONE (Jan. 2014).[11]

Studies show that correction of IDA in CKD can improve overall quality of life, help avoid the need for blood transfusions, and slow the progression of renal disease. Susan Krikorian *et al.*, *Managing Iron Deficiency Anemia of CKD with IV Iron*, U.S. Pharmacist (Aug. 2013).[12] Despite its importance, managing IDA in CKD can prove difficult. As mentioned, many CKD patients cannot tolerate or adequately absorb oral supplemental iron. *Id.* Weekly IV iron therapy is a recommended alternative for such patients and those with severe IDA in stages 3-5. But iron infusions are expensive and onerous, taking 3-4 hours to administer. Compliance is often hindered by factors like weather, distance from a clinic, health

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3879360/.

[12] https://www.uspharmacist.com/article/managing-iron-deficiency-anemia-of-ckd-with-iv-iron-42386.

status, mobility, and the need for transport and assistance. Because infusions can pose too much of a hardship for patients with physical, mental, or financial limitations,[13] many go untreated. Moreover, attendant to IV infusions is an increased risk for iron toxicity, infection, arterial inflammation, and scarring of the veins – the latter a serious concern for those CKD patients who may later require vascular access for dialysis. *Id.*; *see also* A29-31.

Auryxia marked the advent of an effective oral treatment for IDA in non-dialysis CKD patients and for hyperphosphatemia in CKD patients on dialysis. Complaint ¶¶ 30-31 (A22-23). Leading renal organizations and physicians have recognized Auryxia's importance in offering a more conservative approach and convenient alternative to aggressive IV iron administration for these patients. *Id.* ¶ 49 (A31). Auryxia has been shown to correct IDA in CKD, which in turn can slow the progression of CKD to End Stage Renal Disease (ESRD). Clinical management of IDA also helps to avoid the need for emergent and costly blood transfusions and other CKD-related hospital admissions. A preliminary injunction ordering CMS to reinstate its prior Part D coverage policies for Auryxia would significantly aid in

[13] CKD is more prevalent among lower-income Medicare beneficiaries, namely dual eligibles (30.7 percent), than among non-dually eligible beneficiaries (22.3 percent). CMS, *Chronic Conditions, Prevalence State Level: All Beneficiaries by Medicare-Medicaid Enrollment and Age, 2007-2017*. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main at fifth download link.

the management of both IDA in CKD patients and hyperphosphatemia in dialysis patients, improving health outcomes nationally. Without injunctive relief, treatment options for Medicare patients suffering from these serious medical conditions are limited to oral iron supplements, which are often hard to tolerate and ineffective, and IV iron infusions, which are burdensome, risky, and expensive. Hence, a preliminary injunction weighs strongly in the public's interest.

CONCLUSION

For the foregoing reasons, amicus CMA respectfully urges the Court to reverse the Order below and preliminarily enjoin the government from denying, and otherwise constraining, Part D coverage for Auryxia's approved medical indications.

Dated: March 16, 2020

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This document complies with the word limit of Fed. R. App. P. 29(a)5 because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the brief contains 3993 words.
2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/Alice Bers
ALICE BERS
Dated: March 16, 2020

CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2020, a copy of the foregoing amicus brief of the Center for Medicare Advocacy in support of Plaintiff-Appellant Akebia Therapeutics, Inc. was electronically filed with the United States Court of Appeals for the First Circuit by using the Court's CM/ECF system. The following will be served by the CM/ECF system:

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