IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BARBARA SMITH
19147 Woodworth
Redford, MI 48240,

and

CHERYL KORT
5378 Silo Ridge
Colorado Springs, CO 80917,

and

LORRAINE KOVNAT
1515 The Fairway, Apt. H-103
Rydal Park
Jenkintown, PA 19046-1435,

Plaintiffs,

-v.-

Civil Action No. _____

SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of the United States Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201,

and

CENTERS FOR MEDICARE AND MEDICAID SERVICES
200 Independence Avenue SW
Washington, DC 20201,

Defendants.

COMPLAINT

Plaintiffs Barbara Smith, Cheryl Kort, and Lorraine Kovnat ("Plaintiffs") in their Complaint against Defendants Sylvia Mathews Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services ("the Secretary"), the United States Department of Health and Human Services ("HHS"), and the Centers for Medicare and Medicaid Services ("CMS," and, together with the Secretary and HHS, the "Defendants" or the "Agency"), hereby allege as follows:

NATURE OF ACTION

1. Defendants have established a nationwide rule that the Medicare program will never cover the use of an innovative new procedure used in the diagnosis of Alzheimer's Disease for any patient, regardless of the patient's medical circumstances or the health care provider's judgment, except in a clinical trial. *See* Exh. A, Decision Memo for Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (CAG-00431N) (Sept. 27, 2013) (the "Decision"). Nearly a year after issuance of the Decision, no qualifying national clinical trial that would support coverage exists at this time. This is an action to hold unlawful and set aside that Decision.

2. Positron Emission Tomography ("PET") beta-amyloid imaging is a groundbreaking diagnostic procedure that enables a PET scan to measure the accumulation of beta-amyloid neuritic plaques in a patient's brain. The presence of such plaques in a patient's brain is a "virtually necessary" element of Alzheimer's and is "require[d]" for the "'gold standard'" diagnosis. Decision at 13–14. Thus, a negative scan "virtually excludes" an Alzheimer's diagnosis. *Id.* at 63. Similarly, a positive scan, when combined with a clinical assessment of a patient's symptoms, can lead to an Alzheimer's diagnosis. *Id.* at 13–14.

3. PET beta-amyloid scans provide patients and their physicians the opportunity, for the first time, to identify the biological marker of Alzheimer's during a patient's lifetime. This is a substantial and critically important improvement over prior diagnostic methods. Previously, the presence or absence of beta-amyloid neuritic plaques could only be detected in a patient's brain upon autopsy. *Id*. at 13–14. Thus, the diagnosis of Alzheimer's in a living patient was predicated solely upon a clinical assessment of the patient's symptoms, a necessarily imperfect process.

4. As the Decision admits, "[u]nfortunately, despite being the 'cornerstone' of diagnosis, clinical assessment of [Alzheimer's] remains poor." *Id.* at 12 (citing T. Beach, et al., Accuracy of the Clinical Diagnosis of Alzheimer's Disease at National Institute on Aging Alzheimer's Disease Centers, 2005–2010, 71 Journal of Neuropathy & Experimental Neurology 266–73 (2012)). Studies acknowledged by the Decision report that "significant limitations remain in the speed and accuracy of initial diagnosis"; as a consequence, as many as 20% of patients clinically diagnosed with probable Alzheimer's during life do not, in fact, have the disease. *See* M. Grundman, et al., Potential Impact of Amyloid Imaging on Diagnosis and Intended Management in Patients With Progressive Cognitive Decline, 27 Alzheimer Dis. Assoc. Disord. 4 (2013); Decision at 12 (citing this study). Indeed, the Decision itself specifically credits a finding that the misdiagnosis rate is even higher—30% for patients given an Alzheimer's diagnosis based on a clinical assessment alone. Decision at 12 (reporting study finding the "clinical diagnosis of [Alzheimer's] by expert neurologists to be 81% sensitive and 70% specific compared to neuropathy" (citing D. Knopman, et al., Practice Parameter: diagnosis of dementia (an evidence-based review), Report of the Quality Standards Subcommittee of the American Academy of Neurology, 56 Neurology 1143–53 (2001))); *id.* at 61 (explaining that

"[s]ensitivity asks what portion of diseased persons will be identified as positive," while "[s]pecificity asks what portion of non-diseased persons will be identified as negative").

5. Despite this, Defendants' Decision—a nationwide rule—refuses to provide coverage for PET beta-amyloid scans in any case, for any patient, except in certain qualifying clinical trials. Decision at 1–3. Nearly a year after issuance of the Decision, there are no national clinical studies approved.

6. The Decision insists that, to qualify for coverage under the Medicare program, a diagnostic service must change the treatment of a patient's disease—*i.e.*, it must "improve health outcomes" or alter the patient's "disease management." *Id*. at 2, 17, 38. This unprecedented condition to coverage is fundamentally inconsistent with the plain language of the controlling statute.

7. Title XVIII of the Social Security Act—typically referred to as the Medicare Act, 42 U.S.C. § 1395 *et seq.*—specifies the coverage that Defendants must provide under the Medicare program. That statute imposes no "health outcomes" or "disease management" limitation on the coverage of diagnostic agents. In fact, the statute makes unambiguously clear that coverage must be provided for any medical item or service that is "reasonable and necessary" to *either* "diagnosis *or* treatment." *Id.* § 1395y(a)(1) (emphasis added).

8. By purporting to permit coverage for diagnostic services only when they "improve health outcomes" or alter "disease management," the Decision attempts to rewrite the statute to cover diagnostic services only when they are reasonable and necessary for "diagnosis *and* treatment." The Decision thus exceeds the Secretary's statutory authority and jurisdiction and is void under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(C).

9. In addition, the condition to coverage imposed by the Decision is fundamentally irreconcilable with longstanding Agency practice. Defendants consistently cover items and services designed to diagnose incurable illnesses for which no disease-modifying therapy is available. These determinations, which Defendants and their contractors act upon every day to pay Medicare claims for other services, establish that the diagnostic value of a procedure, standing alone, is a basis for its coverage. The Decision is flatly inconsistent with these prior determinations. Defendants cannot simultaneously have one coverage standard for PET beta-amyloid scans and another, conflicting standard for other diagnostic services. The Decision's condition to coverage is therefore arbitrary, capricious, an abuse of discretion, and void under the APA. *Id.* § 706(2)(A).

10. Finally, even if Defendants have the statutory authority to require diagnostic services to "improve health outcomes" or alter "disease management" as a condition to coverage, the Decision applies that standard in an entirely arbitrary and capricious manner. Medical evidence that is conceded in the Decision—and thus not in dispute—demonstrates that, for instance, negative PET beta-amyloid scans produce valuable diagnostic information that trigger precisely the sort of improvements in patient health and changes in disease management that the Decision contends are necessary for coverage. The Decision's conclusion that no PET beta-amyloid scan can ever "improve health outcomes" or alter "disease management" for any patient in any circumstance cannot be reconciled with the Decision's own admissions and with longstanding Agency practice. The Decision is therefore arbitrary, capricious, an abuse of the Secretary's discretion, and void under the APA. *Id.*

11. Plaintiffs are Medicare beneficiaries who suffer from cognitive impairment. Plaintiffs' symptoms are consistent with Alzheimer's, as well as one or more other neurological

disorders. Plaintiffs' symptoms preclude a reliable diagnosis based solely on a clinical assessment. Therefore, Plaintiffs would benefit from a PET beta-amyloid scan.

12. Defendants' refusal to authorize coverage of any PET beta-amyloid scan in any circumstance outside of a clinical trial has caused Plaintiffs substantial injury. Plaintiffs rely on Medicare coverage to meet their health care needs. None of the Plaintiffs are eligible for any PET beta-amyloid trial.

13. Accordingly, Plaintiffs seek an order setting aside the Decision because the condition to coverage the Decision imposes exceeds the Secretary's statutory authority and jurisdiction, 5 U.S.C. § 706(2)(C), and because the Decision is an arbitrary and capricious exercise of the Secretary's authority and an abuse of the Secretary's discretion, *id.* § 706(2)(A).

14. Plaintiffs further seek injunctive relief (1) barring Defendants from enforcing, implementing, or otherwise applying the Decision or any other Agency action that purports to require a PET beta-amyloid scan to "improve health outcomes" or alter "disease management" as a condition to coverage, and (2) barring Defendants from enforcing, implementing, or otherwise applying the condition to coverage articulated in the Decision through any agency action that purports to conclude that a PET beta-amyloid scan can never be a reasonable and necessary diagnostic service for any patient in any medical circumstance outside of a clinical trial.

15. Lilly USA, LLC ("Lilly"), the manufacturer of Amyvid™ (F-florbetapir), a radiopharmaceutical product used in PET beta-amyloid scans, has provided assistance to Plaintiffs in preparing this challenge, including providing financial support for the costs of this litigation. *See* CMS, Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63692, 63695 (Nov. 7, 2003) ("[B]eneficiaries may seek assistance from knowledgeable physicians, suppliers, providers, manufacturers, and

attorneys in developing the individual's request for review [and] [t]he individual is free to consult with these individuals and to follow those suggestions, recommendations, or advice.").

JURISDICTION AND VENUE

16. This Court has jurisdiction over this matter under 28 U.S.C. § 1331 and 28 U.S.C. § 1346, because it involves the interpretation and application of the laws of the United States, including the APA and the Medicare Act, and because it involves an agency of the United States as a defendant.

17. Plaintiffs' claims are ripe for judicial review pursuant to 42 U.S.C. § 1395ff(f)(3), because their challenge to the Decision does not involve any dispute of material fact and raises only the legal question whether the Decision is invalid. The Decision constitutes final agency action.

18. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because at least one defendant in this action resides in this district, and because a substantial part of the events giving rise to Plaintiffs' claims occurred in this district.

PARTIES

19. Plaintiff Barbara Smith is a resident of Michigan, who is eligible for benefits under the Medicare program on the basis of age, as previously determined by the Secretary.

20. Plaintiff Cheryl Kort is a resident of Colorado, who is eligible for benefits under the Medicare program on the basis of age, as previously determined by the Secretary.

21. Plaintiff Lorraine Kovnat is a resident of Pennsylvania, who is eligible for benefits under the Medicare program on the basis of age, as previously determined by the Secretary.

22. Defendant Sylvia Mathews Burwell is sued in her official capacity as the Secretary of the United States Department of Health and Human Services. As Secretary, Ms.

Burwell has ultimate responsibility for the activities of the Department, including those actions complained of herein. Secretary Burwell maintains an office at 200 Independence Avenue SW, Washington, DC 20201.

23. Defendant United States Department of Health and Human Services is the federal agency charged with the administration of the Medicare program, as established under the Medicare Act, and is headquartered at 200 Independence Avenue SW, Washington, DC 20201.

24. Defendant Centers for Medicare and Medicaid Services is the federal agency within HHS that administers the Medicare program, and is located at 200 Independence Avenue SW, Washington, DC 20201.

GENERAL ALLEGATIONS

I. Alzheimer's Disease.

25. An estimated 5.4 million Americans have been diagnosed with Alzheimer's Disease. Advancing age is the strongest risk factor for the disease. Indeed, an overwhelming majority of those individuals—more than 5.2 million—are over age 65 and, thus, eligible for the Medicare program on that basis alone.

26. Recently, Congress passed the National Alzheimer's Project Act, 42 U.S.C. § 11225, to "build upon and leverage HHS programs and other federal efforts to help change the trajectory of [Alzheimer's disease and related dementias]." HHS, National Alzheimer's Project Act, http://aspe.hhs.gov/daltcp/napa/#NAPA (last visited Sept. 5, 2014). Defendant HHS has operationalized its response to this new initiative by creating a National Plan to Address Alzheimer's Disease, laying out five goals considered of primary importance in meeting the needs of patients, families, physicians, and health systems suffering under the weight of Alzheimer's Disease and related dementias. Within that National Plan, HHS notes that ensuring

patient access to timely and accurate diagnoses is a necessary step toward enhancing the quality and efficiency of care patients receive. Specifically, HHS has stated:

> Far too many people with Alzheimer's disease are not diagnosed until their symptoms have become severe. Timely diagnosis gives people with the condition, and their families, time to plan and prepare for the future, leading to more positive outcomes for both. . . . Even with access to affordable care for individuals, the health care workforce needs tools that can help ensure timely and accurate diagnoses. Research has helped identify some assessment tools that can be used to detect cognitive impairment that may indicate the need for a comprehensive diagnostic evaluation for Alzheimer's disease.

Id.

27. As the Decision notes, at present, there is no treatment available to "prevent, stabilize, or reverse" Alzheimer's. Decision at 56. This situation is also true for many other illnesses, including "some cancers," *id.*, and numerous neurological conditions, including multiple sclerosis ("MS"), amyotrophic lateral sclerosis ("ALS"), Creutzfeldt-Jakob disease, and Huntington's disease, for which Defendants routinely cover diagnostic services.

28. Despite the lack of a treatment to "prevent, stabilize, or reverse" Alzheimer's, as the Decision explains, there are several drug therapies available to Alzheimer's patients that mitigate, reduce, and/or delay the symptoms of the disease. *Id.* at 65. These drug therapies include memantine and cholinesterase inhibitors. *Id.*

29. As stated in the Decision, at present, definitive, pathological diagnosis of Alzheimer's is possible only upon autopsy, by identifying the presence of a moderate-to-frequent accumulation of beta-amyloid neuritic plaques—a "virtually necessary" element of Alzheimer's—in the brain tissue. *Id.* at 13–14.

30. Accordingly, the Decision notes that, during a patient's life, Alzheimer's is diagnosed based solely on a clinical assessment, a process the Decision describes as "poor." *Id.* at 12. In the absence of a diagnostic test for living Alzheimer's patients, approximately 20% of

patients clinically diagnosed with Alzheimer's during life are discovered to have no evidence of Alzheimer's pathology upon autopsy. *Supra* ¶ 3–4. Thus, nearly one in five Medicare beneficiaries presently being treated for Alzheimer's do not, in fact, have the disease.

31. The misdiagnosis of Alzheimer's in a patient who does not have the disease is an example of a circumstance in which Defendants' refusal to cover PET beta-amyloid scans in any situation outside a clinical trial will expose patients to substantial injury. These injuries include the prescription of unnecessary, ineffective, and even potentially harmful pharmaceutical therapies and other medical interventions to mistakenly-diagnosed Alzheimer's patients.

II. PET Beta-Amyloid Imaging.

A. The FDA Has Approved PET Beta-Amyloid Scans For Patients With Symptoms Of Cognitive Impairment.

32. PET beta-amyloid scans became clinically available for the first time in April 2012, when the Food and Drug Administration ("FDA") approved Amyvid™, a radiopharmaceutical product used in conjunction with PET scan technology to measure the accumulation, or lack thereof, of beta-amyloid neuritic plaques in the brain. Exh. B, FDA Label, Amyvid™ (issued Apr. 6, 2012). The FDA has approved Amyvid™ exclusively for "adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline."[1] *Id.* at 1.

33. As the Decision explains, the FDA-approved indication states that PET beta-amyloid imaging "effectively exclude[s]" an Alzheimer's diagnosis. Decision at 60. Specifically, the FDA indication states, among other uses of the product, that "[a] negative

[1] Certain FDA and Medicare documents refer to medical conditions and diagnostic procedures by acronym. This Complaint uses those acronyms when quoting such documents, but otherwise refers to the conditions and procedures using their full names.

Amyvid scan indicates sparse to no neuritic plaques and is *inconsistent with a neuropathological diagnosis of AD* at the time of image acquisition." FDA Label, Amyvid™ (emphasis added).

B. PET Beta-Amyloid Scans Provide Valuable Diagnostic Information That Leads To Improvements In Patient Health And Changes In Disease Management.

34. Facts acknowledged in the Decision demonstrate that PET beta-amyloid scans provide critically important diagnostic information that leads to the improvements in "health outcomes" and changes in "disease management" the Decision claims are required for coverage.

35. For example, as the Decision concedes, a negative PET beta-amyloid scan demonstrates that the patient lacks a "virtually necessary" biomarker for Alzheimer's that is "require[d]" for a "'gold standard'" diagnosis. Decision at 13–14. Thus, a negative scan enables the patient's treating physician to "virtually exclude" Alzheimer's as a diagnosis, indicating that symptoms of dementia must be attributed to another, potentially treatable, cause. *Id.* at 63.

36. A negative PET beta-amyloid scan's ability to "virtually exclude[]" Alzheimer's is an essential component of the scan's diagnostic value. As the Decision concedes, the only other diagnostic method available—a clinical assessment—is "poor" and creates at least a one in five chance of misdiagnosis. *Id.* at 12; *supra* ¶ 3–4.

37. By "virtually exclud[ing]" Alzheimer's as a diagnosis, a negative PET beta-amyloid scan "improves health outcomes" and alters "disease management" by providing the patient's treating physician with information that will spare the patient from the following risks associated with an Alzheimer's misdiagnosis, all of which are either conceded or not disputed in the Decision:

(a) Memantine and cholinesterase inhibitors, the drug therapies typically prescribed to Alzheimer's patients, are potentially toxic when administered to patients

misdiagnosed with Alzheimer's who are, in fact, suffering from certain other causes of cognitive decline, such as frontotemporal dementia ("FTD"). *Id.* at 65, 74.

(b) Patients misdiagnosed with Alzheimer's are deprived of the opportunity to receive appropriate treatment for the actual cause of their cognitive impairment. *Id.* at 74. This risk is especially critical for patients whose cognitive impairment derives from a reversible condition, such as vascular dementia, depression, hydrocephalus, high blood pressure, sleep apnea, or alcohol dependence syndrome.

(c) Patients misdiagnosed with Alzheimer's may undergo medically unnecessary therapeutic procedures and diagnostic tests that would not be appropriate for a patient diagnosed with another source of cognitive decline. *See id.* at 59 (acknowledging the existence of a study finding that PET beta-amyloid scans led to "decreased utilization of other tests, such as MRI and/or CT").

(d) As their FDA labels indicate, memantine and cholinesterase inhibitors, the common drug therapies for Alzheimer's patients, carry significant side effects. Side effects commonly associated with memantine include fatigue, dizziness, headache, sleepiness, constipation, vomiting, back pain, coughing, shortness of breath, and hallucination.[2] Side effects commonly associated with cholinesterase inhibitors include nausea, diarrhea, vomiting, abdominal pain, loss of appetite, weight loss, insomnia, fatigue, and muscle cramps.[3] Subjecting patients who do not, in fact, have Alzheimer's to the side effects of these drugs can create unnecessary health complications.

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[2] FDA Label, Namenda™ at 16 (issued Oct. 16, 2003), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021487lbl.pdf.

[3] FDA Label, Aricept® at 4–5 (approved Nov. 25, 1996; revised Sept. 6, 2013), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020690s037,021720s010,022568s007lbl.pdf.

38. By identifying a "virtually necessary" element of Alzheimer's, a positive PET beta-amyloid scan also provides useful diagnostic information that, when combined with appropriate clinical findings of dementia, will indicate that a patient has been appropriately diagnosed with Alzheimer's. Decision at 13–14.

39. The diagnostic information provided by a positive scan also "improves health outcomes" and alters disease "management." By way of example, for a patient diagnosed with Alzheimer's with the assistance of a positive scan, the procedure can help the patient and his or her treating physician to prepare for "future functional declines," including by planning for the patient's increased risk of falls, a very common cause of injuries—and, sometimes, fatalities—among Alzheimer's patients.[4]

III. The Medicare Program And Its Coverage Of Diagnostic Services.

40. Medicare is the federal health insurance program for the elderly and disabled. Medicare contains four distinct programs, referred to as "parts." Three of these programs are at issue in this case. Medicare Part A covers inpatient hospital services and various other institutional care. 42 U.S.C. §§ 1395c to 1395i-5. Medicare Part B covers outpatient care. *Id.* §§ 1395j to 1395w-5. Medicare Part C enables beneficiaries to receive services authorized under Parts A and B through managed-care plans. *Id.* § 1395w-22(a)(1)(A), (a)(1)(B)(i).

41. The Secretary is responsible for administering the Medicare program and exercises that authority through CMS.

42. CMS has executed this function through a variety of means, including the publication of substantive regulations in the Code of Federal Regulations and through informal rules and interpretations contained in a series of manuals.

[4] Alzheimer's Ass'n., 2012 Alzheimer's Disease Facts and Figures (2012), *available at* http://www.alz.org/downloads/facts_figures_2012.pdf.

43. CMS also executes its function through private contractors—carriers or intermediaries—known as Medicare Administrative Contractors. *Id.* §§ 1395h, 1395kk–1. Pursuant to contractual agreements with CMS, Medicare Administrative Contractors are responsible for, *inter alia*, (1) receiving Medicare funds and disbursing them to health care providers for services rendered to Medicare beneficiaries; (2) determining the amounts owed to such health care providers for covered items and services; and (3) auditing claims for Medicare reimbursement. *See* 42 C.F.R. §§ 421.200, 421.214.

44. Diagnostic services are among the items and services covered under Parts A, B, and C of the Medicare program. 42 U.S.C. §§ 1395d, 1395k(a), 1395x(s)(2)(c). Medicare's coverage of diagnostic services includes both the costs of the diagnostic procedure itself, and the use of "drugs and biologicals required in the performance of the [diagnostic] service[]." 42 C.F.R. § 410.28.

45. The Medicare Act excludes certain services from coverage. 42 U.S.C. § 1395y.

46. Only one such exclusion is potentially relevant here. The Medicare Act provides that Medicare shall not provide reimbursement for medical items and services that are "not reasonable and necessary for the diagnosis *or* treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A) (emphasis added).

47. Accordingly, the Medicare Act provides that diagnostic items and services are eligible for reimbursement under the Medicare program as long as they are "reasonable and necessary" for *either* the "diagnosis *or* treatment" of an illness or injury. If a "diagnostic service" or a drug "required in the performance of the service[]" provides information that is reasonable and necessary to diagnose a patient, coverage for the diagnostic service is required on that basis alone. *Id.* §§ 1395d, 1395k(a), 1395x(s)(2)(c); 42 C.F.R. § 410.28. Under the text of

the statute, the diagnostic service or related drug need not impact the treatment of a patient's disease.

48. The Medicare Act requires the Secretary to determine whether particular items or services meet the statutory criteria for coverage under the Medicare program. *See* 42 U.S.C. § 1395ff(a)(1).

49. The Secretary may fulfill this obligation by issuing a "national coverage determination" ("NCD"), which establishes an up-front, nationwide rule as to whether, and in what circumstances, a particular item or service is covered. *Id.* § 1395ff(f)(1)(B).

50. There is no means to provide coverage under the Medicare program where an NCD forecloses coverage. A Medicare Administrative Contractor cannot, for instance, deviate from an NCD, regardless of the needs of an individual patient. *Id.* § 1395ff(c)(3)(B)(ii)(I).

51. The Secretary is not required to issue such up-front rules for all items and services. In the absence of an NCD, coverage determinations are made in one of two ways.

52. As intermediaries of CMS, Medicare Administrative Contractors may issue "local coverage determinations," establishing whether, and in what circumstances, the use of an item or service will be covered on an intermediary- or carrier-wide basis. *Id.* §§ 1395ff(f)(2)(B), 1395u(a).

53. If neither an NCD nor a local coverage determination is in place, Medicare Administrative Contractors determine coverage of claims on a case-by-case basis to determine whether a particular use of an item or service is "reasonable and necessary" in light of the individual beneficiary's particular medical circumstances. 78 Fed. Reg. 48164, 48165 (Aug. 7, 2013).

IV. Defendants Already Cover Certain PET Imaging Scans To Assist In The Diagnosis Of Alzheimer's Disease.

54. CMS has issued multiple NCDs that approve the use of PET imaging technology to aid in the diagnosis of various conditions. Those NCDs are set forth in Section 220.6 of the Medicare National Coverage Determinations Manual.[5]

55. In 2004, CMS issued NCD 220.6.13, approving the use of a very specific type of PET imaging—PET scans with a radiopharmaceutical product, fluorodeoxyglucose ("FDG PET")—to aid in the differential diagnosis of Alzheimer's and frontotemporal dementia. Medicare Manual, NCD § 220.6.13.

56. NCD 220.6.13 concluded that fluorodeoxyglucose PET scans were "reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD." *Id.* NCD 220.6.13 also provided coverage for fluorodeoxyglucose PET scans in certain clinical trials. *Id.*

57. That same NCD provided that "[*a*]*ll other uses of FDG PET* for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage *continue to be noncovered*." *Id.* (emphasis added).

58. CMS has thus publicly stated its position that NCD 220.6.13 establishes a categorical, nationwide rule excluding all existing or future uses of PET imaging with radiopharmaceutical products besides fluorodeoxyglucose from coverage for any patients with

[5] *See* Positron Emission Tomography (PET) Scans, Medicare National Coverage Determinations Manual, Chapter 1, Part 4 § 220.6 ("Medicare Manual, NCD § 220.6"), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf.

symptoms of cognitive impairment, even if those radiopharmaceutical products did not exist at the time NCD 220.6.13 was adopted. *Id*.

59. To the extent that Defendants attempt to apply NCD 220.6.13 to PET beta-amyloid scans and deny coverage for the scans on that basis, such efforts are arbitrary and capricious, as Amyvid™ was not even approved by the FDA at the time that NCD 220.6.13 was issued, and, therefore, could not possibly have been considered by CMS in NCD 220.6.13.

60. The Medicare program does not in any way limit coverage of an item or service because some other item or service may be used in the same or a similar situation.

V. Requests for Medicare Coverage of PET Imaging Scans.

61. On June 1, 2012, approximately two months after the FDA approved Amyvid™ for clinical use, Lilly, the manufacturer of Amyvid™, submitted a formal request to CMS, asking the Agency to reconsider NCD 220.6, to provide coverage for the use of PET imaging in patients with symptoms of cognitive impairment beyond those uses allowed in NCD 220.6.13 (the NCD applicable to fluorodeoxyglucose PET scans). Exh. C, Ltr. From D. Skovronsky, MD, PhD, et al., Lilly USA, LLC, to L. Jacques, MD, Director, Coverage & Analysis Group, CMS (June 29, 2012). Specifically, Lilly asked CMS to expand NCD 220.6 to cover PET beta-amyloid scans for use as a diagnostic service for the limited population of "adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive decline." *Id.* at 2.

62. Lilly's request emphasized the limited nature of the coverage Lilly sought, explaining that Lilly was not seeking coverage of PET beta-amyloid scans for use as "screeners in asymptomatic patients, on patients that have no documentation of cognitive decline, or on patients that present with symptoms and clinical profiles that make diagnosis clear and confident without the scan in the judgment of the treating physician." *Id.*

63. Lilly's coverage request was consistent with the FDA-approved indication for Amyvid™.

64. Lilly's coverage request also was consistent with "Appropriate Use Criteria" recommendations for beta-amyloid testing created by a group of prominent U.S. experts in the evaluation and treatment of cognitive disorders assembled by the Alzheimer's Association and the Society for Nuclear Medicine and Molecular Imaging, two groups widely regarded as leaders in developing and identifying best practices for patients with Alzheimer's Disease and other forms of cognitive impairment. *See* Exh. D, K. Johnson, et al., Appropriate Use Criteria for Amyloid PET: A Report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer's Association. Alzheimer's & Dementia 1 (2013).

65. The Appropriate Use Criteria reflect wide agreement among this group of experts that PET beta-amyloid imaging is an appropriate diagnostic tool for patients with objective symptoms of cognitive impairment whose diagnosis remains uncertain after a comprehensive evaluation by a dementia expert.

66. On October 9, 2012, CMS commenced reconsideration of NCD 220.6 as it related to PET beta-amyloid scans.

67. A public comment period occurred, in which Lilly and many others urged that Medicare's coverage of PET beta-amyloid imaging in the circumstances defined in the Appropriate Use Criteria was warranted as a reasonable and necessary diagnostic service under the Medicare Act.

68. CMS convened a panel of the Medicare Evidence Development Coverage Advisory Committee ("MEDCAC") to review the reconsideration request. MEDCAC is a

committee "used to supplement CMS' internal expertise" on questions involving "'state of the art' technology and science."[6]

69. On January 30, 2013, a MEDCAC panel heard public testimony regarding coverage of PET beta-amyloid imaging.

70. CMS restricted the analysis provided by the MEDCAC panel by directing it to assess whether PET beta-amyloid imaging "improve[s] health outcomes for patients," a standard that is wholly inappropriate for a diagnostic agent and that is inconsistent with the Medicare Act. Decision at 33.[7]

71. Neither CMS nor the MEDCAC panel acknowledged that the Medicare Act does not impose this condition on the coverage of diagnostic services.

72. Neither CMS nor the MEDCAC panel addressed objections raised by Lilly and other commenters to the adoption and application of this condition to coverage.

73. On July 3, 2013, CMS issued a proposed decision. Exh. E, Mem. on Nat'l Coverage Analysis for Beta-Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N) ("Proposed Decision"). The Proposed Decision determined that coverage of PET beta-amyloid imaging should not be permitted for any patient in any circumstance outside a clinical trial because the evidence allegedly was "insufficient to conclude that the use of [PET beta-amyloid] imaging *improves health outcomes* for Medicare beneficiaries with dementia or neurodegenerative disease." *Id.* at 1 (emphasis added).

74. The Proposed Decision reached this conclusion, even though it conceded that "it is widely accepted that the presence of amyloid plaques in the human brain is virtually necessary

[6] CMS, MEDCAC, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html; *see* 68 Fed. Reg. 55634, 55640 (Sept. 26, 2003).

[7] *See also* MEDCAC Meeting Transcript at 24 (Jan. 30, 2013), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/id66d.pdf.

for the diagnosis of AD," *id.* at 12, that the FDA had concluded that "'a negative scan is inconsistent with the diagnosis of AD,'" *id.* at 48, and that CMS had reached its own conclusion that "a negative PET beta-amyloid scan could virtually exclude AD in many patients," *id.* at 49.

75. A public comment period followed the issuance of the Proposed Decision.

76. Lilly submitted comments that (1) objected to Defendants' adoption of a condition to coverage that a diagnostic service must "improve health outcomes" or alter "disease management" to qualify for coverage, (2) urged coverage of PET beta-amyloid imaging in the circumstances defined in the Appropriate Use Criteria based on the diagnostic value of the service, and (3) argued that PET beta-amyloid scans "improve health outcomes" and change "disease management" in any event. Exh. F, Ltr. from M. Nagy, Eli Lilly and Company, to L. Jacques, MD, Director, Coverage & Analysis Group, CMS (Aug. 2, 2013).

77. Additional comments were submitted by numerous patient and provider groups, establishing a consensus among them that PET beta-amyloid imaging should be covered in the circumstances defined in the Appropriate Use Criteria.

78. According to the Medicare Program Integrity Manual, a "consensus of expert medical opinion" is sufficient to demonstrate that an item or service is "reasonable and necessary."[8] Despite this, CMS has not provided coverage for PET beta-amyloid imaging.

VI. Defendants' Refusal to Cover PET Beta-Amyloid Scans.

79. On September 27, 2013, CMS issued the Decision, an NCD that establishes a nationwide rule that Medicare will not cover any PET beta-amyloid scan performed in any circumstance, except in the very limited, and as of now entirely theoretical, context of certain clinical trials.

[8] Evidence Supporting LCDs, Medicare Program Integrity Manual § 13.7.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf.

80. The Decision adopts this rule despite conceding that PET beta-amyloid scans provide substantial diagnostic value.

81. For example, the Decision repeatedly acknowledges that a negative PET beta-amyloid scan has strong diagnostic utility. Indeed, the Decision accepts as "given" the fact that "*a negative PET amyloid scan could virtually exclude AD in many patients*." Decision at 64 (emphasis added). *See also id.* at 40 (discussing the "power of a negative scan to help exclude Alzheimer's, which is consistent with the FDA-approved label and our own detailed assessment"); *id.* at 64 ("The first part of that equation—that presence of amyloid plaques is virtually necessary—reflects the FDA-approved label that 'a negative scan is inconsistent with the diagnosis of AD' . . . ."); *id.* at 74 (acknowledging that the "potential power of a negative scan to virtually exclude significant brain beta amyloid deposition could benefit Medicare beneficiaries").

82. The Decision further acknowledges the existence of a study finding that PET beta-amyloid scans aided physicians in differentiating between Alzheimer's and other causes of cognitive impairment. *Id.* at 58–59 (citing a recent study establishing that 112 out of 113 recipients of a positive scan received a clinical diagnosis of Alzheimer's, and 115 of 116 recipients of a negative scan received a clinical diagnosis other than Alzheimer's).

83. The Decision nonetheless refuses to authorize coverage of any PET beta-amyloid scan outside a clinical trial. The Decision takes the position that the diagnostic information provided by a PET beta-amyloid scan can never "improve health outcomes" or alter "disease management" for any patient at any time or in any circumstance.

84. For example, the Decision claims that—despite the "poor" quality of clinical diagnostic tools for Alzheimer's and the one-in-five risk of an Alzheimer's misdiagnosis, *id.* at

12—a negative PET beta-amyloid scan's ability to avoid an Alzheimer's misdiagnosis does not "improve health outcomes" or alter "disease management" because the principal drug therapies prescribed to Alzheimer's patients, memantine and cholinesterase inhibitors, in many instances, allegedly do not harm patients misdiagnosed with Alzheimer's who ingest those drugs. *Id.* at 65.

85. Yet the Decision concedes that these therapies may cause affirmative harm to certain patients who do not, in fact, have the disease. *See id.* (acknowledging the "potential for harm" these therapies present to patients with frontotemporal dementia because "[c]holinesterase inhibitors have been shown to exacerbate symptoms in some patients with FTD, and the use of memantine has correlated with greater functional and cognitive decline"); *id.* at 74 (acknowledging that PET beta-amyloid scans are "promising" for "prevent[ing] the harm of inappropriate use of potentially toxic medications"); *supra* ¶ 37(a).

86. Moreover, the Decision acknowledges evidence that PET beta-amyloid scans may help to decrease the utilization of other unnecessary therapeutic procedures and diagnostic tests for such patients. *See* Decision at 59; *supra* ¶ 37(c).

87. In addition, the Decision does not address a negative PET beta-amyloid scan's ability to provide a patient otherwise at risk for an Alzheimer's misdiagnosis with the opportunity to receive an accurate diagnosis and treatment for a reversible cause of cognitive impairment, such as vascular dementia, depression, hydrocephalus, high blood pressure, sleep apnea, or alcohol dependence syndrome.

A. The Decision Ignores the Plain Text of the Medicare Act.

88. The Decision ignores that the Medicare Act does not require diagnostic services to "improve health outcomes" or alter the "management" of a patient's disease, and does not authorize the Secretary to impose such a condition to coverage.

89. The Medicare Act provides for coverage of items and services that are "reasonable and necessary for the diagnosis *or* treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added).

90. The statute uses the disjunctive term "or" to separate items and services that are reasonable and necessary for "diagnosis" from those that are reasonable and necessary for "treatment."

91. This clearly and unequivocally establishes Congress' intent to give independent significance to the words "diagnosis" and "treatment," and to require coverage of items and services that are reasonable and necessary for *either* "diagnosis *or* treatment."

92. The Decision's adoption of a requirement that diagnostic services must "improve health outcomes" or alter the "management" of a patient's disease cannot be reconciled with this statutory text. The Decision converts the text "diagnosis *or* treatment" into a requirement for "diagnosis *and* treatment." This is fundamentally contrary to the statute.

B. The Decision Is Fundamentally Inconsistent With Its Own Admissions and Other Agency Determinations.

93. Even if Defendants have the authority to require a diagnostic service to "improve health outcomes" or alter "disease management" as a condition to coverage, the Decision's conclusion that PET beta-amyloid scans cannot be covered for any patient in any medical circumstance outside of a clinical trial cannot be reconciled with concessions in the Decision itself and with other Agency determinations making clear that the diagnostic information provided by the procedure, especially the information provided by negative PET beta-amyloid scans, leads to precisely the type of improvements in health outcomes and changes in disease management the Decision claims are required for coverage.

1. The Decision Is Inconsistent With Defendants' Actions Authorizing Coverage For Diagnostic Services That Prevent Burdensome Or Hazardous Medical Interventions.

94. First, the Decision's refusal to cover any PET beta-amyloid scan in any circumstance cannot be reconciled with Defendants' established position—which the Decision concedes—that diagnostic services should be covered if they enable "the avoidance of burdensome or hazardous interventions that will not ultimately help the beneficiary." Decision at 56.

95. The undisputed medical evidence demonstrates that PET beta-amyloid scans must be covered under this rule because, as the Decision acknowledges, negative scans "virtually exclude AD in many patients." *Id.* at 64. By excluding Alzheimer's as a possible diagnosis, negative scans eliminate the risk of an Alzheimer's misdiagnosis—which presently afflicts approximately 20% of the population diagnosed with Alzheimer's—and the disease mismanagement that results from such a misdiagnosis.

96. Despite this, the Decision contends that coverage of PET beta-amyloid imaging is still not warranted. That legal conclusion cannot be supported by facts that are conceded or not disputed in the Decision, which establish that Alzheimer's therapies and other interventions cannot "ultimately help" patients misdiagnosed with Alzheimer's—and in a number of cases may affirmatively harm them—for at least four independent reasons:

(a) Memantine and cholinesterase inhibitors are potentially harmful to patients suffering from certain other forms of cognitive decline, such as frontotemporal dementia. *Id.* at 65, 74; *see supra* ¶ 37(a). The Decision's refusal to cover PET beta-amyloid scans in any circumstances outside of a clinical trial cannot be reconciled with its concession that a negative scan, by reducing the risk of an Alzheimer's misdiagnosis, will eliminate this risk of harm to patients who could otherwise be harmed by Alzheimer's drug therapies.

(b) Prescribing an Alzheimer's-focused course of treatment to a patient misdiagnosed with Alzheimer's deprives that patient of the opportunity to receive appropriate treatment for the actual cause of his or her cognitive impairment. *See id.* at 74. This is especially critical for patients whose cognitive impairment derives from a reversible condition, such as vascular dementia, depression, hydrocephalus, high blood pressure, sleep apnea, or alcohol dependence syndrome. The Decision's refusal to cover PET beta-amyloid scans in any circumstances outside of a clinical trial cannot be reconciled with the fact that a negative scan avoids misdiagnoses which deny these patients the therapies that will "ultimately help" them best.

(c) Patients misdiagnosed with Alzheimer's may potentially be subjected to unnecessary and potentially harmful medical procedures and other interventions. *See, e.g.*, *id.* at 79. The Decision's refusal to cover PET beta-amyloid scans in any circumstances outside of a clinical trial cannot be reconciled with the fact that a negative scan can avoid exposing patients to these procedures which cannot "ultimately help" them.

(d) Memantine and cholinesterase inhibitors are subject to harmful side effects. *Supra* ¶ 37(d). The Decision's refusal to cover PET beta-amyloid scans in any circumstances outside of a clinical trial cannot be reconciled with the fact that a negative scan can avoid exposing patients misdiagnosed with Alzheimer's to the side effects of these drugs that cannot "ultimately help" them.

2. The Decision Is Inconsistent With Defendants' Prior Determination To Authorize Coverage For PET Scans With Fluorodeoxyglucose.

97. Second, the Decision ignores that, by providing coverage for fluorodeoxyglucose PET scans in NCD 220.6.13, Defendants have already determined that PET imaging is "reasonable and necessary" for the diagnosis of patients with symptoms of cognitive impairment

and, thus, is entitled to coverage for use in aiding in the diagnosis of Alzheimer's. *Supra* ¶¶ 55–56.

98. Defendants' issuance of NCD 220.6.13, upon which CMS and its contractors act every day in paying Medicare claims for other PET services, establishes Defendants' position that PET imaging justifies coverage for use in at least some Alzheimer's patients—*i.e.*, those "with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD." Medicare Manual, NCD § 220.6.13.

99. Defendants cover fluorodeoxyglucose PET scans under NCD 220.6.13 despite their claim, articulated in the Decision, that diagnostic services for Alzheimer's cannot "improve health outcomes" or alter "disease management" because Alzheimer's is incurable. Decision at 56 ("The clinical usefulness of AD testing, including [PET beta-amyloid scans], is limited by the current absence of therapies that meaningfully prevent, stabilize or reverse the progressive course of the condition.").

100. It is arbitrary, capricious, and an abuse of discretion for Defendants to simultaneously maintain one coverage standard for PET beta-amyloid imaging in the Decision and another standard for fluorodeoxyglucose PET imaging in NCD 220.6.13, when both services are designed for use in an overlapping patient population and both are subject to the same alleged limitations in their ability to influence health outcomes or disease management.

3. The Decision Is Inconsistent With Defendants' Actions Authorizing Coverage For Other Alzheimer's-Related Services That Do Not Halt The Progression Of The Disease.

101. Third, the Decision cannot be reconciled with Defendants' longstanding practice of covering Alzheimer's-related treatments and services, including the following examples, without requiring that they "prevent, stabilize, or reverse" Alzheimer's. Decision at 56.

(a) Defendants reimburse the costs of office visits for Alzheimer's patients. Like PET beta-amyloid scans, these office visits do not "prevent, stabilize, or reverse" Alzheimer's or lead to the prescription of such treatments, since no such treatments exist. *Id.* Yet Defendants consistently allow coverage for these visits.

(b) Defendants cover the prescription of memantine and cholinesterase inhibitors to Alzheimer's patients. These therapies mitigate the symptoms of Alzheimer's, *id*. at 65, but, like PET beta-amyloid scans, do not "prevent, stabilize, or reverse" the course of the disease, *id*. at 56. Nonetheless, Defendants consistently cover their use.

(c) Defendants cover counseling services for Alzheimer's patients and their families,[9] and cover mental health services for appropriate Alzheimer's patients struggling to cope with the implications of their disease.[10] Like PET beta-amyloid scans, these services do not prevent, stabilize, or reverse Alzheimer's or lead to the prescription of such treatments, since no such treatments exist. Nonetheless, Defendants routinely cover them.

102. It is arbitrary, capricious, and an abuse of discretion for Defendants to hold that the diagnostic information provided by a PET beta-amyloid scan can never provide diagnostic information that "improves health outcomes" or alters "disease management" in *any* case regardless of the patient's medical circumstances when Defendants simultaneously cover this wide array of Alzheimer's-related services. *See* Decision at 17, 38. All of these Alzheimer's-related services are subject to the same alleged limitation as PET beta-amyloid imaging—none can lead to the use of treatments that "prevent, stabilize, or reverse" Alzheimer's. *Id.* at 56.

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[9] *See* Medicare Manual, NCD § 70.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf.

[10] *See* Outpatient Mental Health Treatment Limitation, Application of the Limitation, Medicare Claims Processing Manual, Chap. 12, § 210.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.

103. Thus, the Decision has either imposed a condition on the coverage of PET beta-amyloid imaging that it has failed to impose on other Alzheimer's-related services (*i.e.*, the demand that the service "improve health outcomes" or alter "disease management") or the Decision has applied that condition differently against PET beta-amyloid imaging than it applies against these other services. In either case, the Decision is unlawful.

4. The Decision Is Inconsistent With Defendants' Actions Authorizing Coverage For Diagnostic Services For Other Incurable Diseases.

104. Fourth, the Decision ignores that, in numerous coverage determinations that are currently in effect, and in others that have been issued over the course of decades, Defendants do not require diagnostic services to "improve health outcomes" or alter "disease management" as a condition to coverage.

105. Specifically, Defendants, acting through CMS and its contractors, consistently have covered and reimbursed items and services designed to diagnose neurological conditions for which no cure or disease-modifying treatment is available. Notable examples include, but are not limited to, the following:

(a) Defendants have, since 1985, authorized coverage for brain magnetic resonance imaging ("MRI") scans used to diagnose MS, a debilitating neurological disorder for which there was no cure or disease-modifying treatment available at the time that this coverage was created.[11]

(b) Defendants, acting through CMS and its contractors, cover electromyography/nerve conduction studies designed to diagnose ALS, a progressive,

[11] *See* Magnetic Resonance Imaging, Medicare Manual, NCD § 220.2, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf.

debilitating neurological disorder for which no cure or disease-modifying treatment is available.[12]

(c) Defendants, acting through CMS and its contractors, cover services that aid in the diagnosis of Creutzfeldt-Jakob disease, a rapidly progressive and uniformly fatal neurological infection, for which there is no disease-modifying treatment or cure.[13]

(d) Defendants, acting through CMS and its contractors, cover genetic testing used in the diagnosis of Huntington's disease, a condition for which there is no available cure or disease-modifying therapy.[14]

106. It is arbitrary, capricious, and an abuse of discretion for the Decision to require PET beta-amyloid imaging to "improve health outcomes" or alter "disease management" as a condition to coverage when Defendants do not impose this condition on numerous other diagnostic services for incurable neurological conditions.

VII. Plaintiffs Are Denied Coverage And Reimbursement For PET Beta-Amyloid Scans.

107. Plaintiff Barbara Smith experiences symptoms of cognitive impairment. Smith's symptoms preclude a reliable diagnosis based solely on a clinical assessment. Accordingly, Smith would benefit from a PET beta-amyloid scan.

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[12] One example of a local coverage determination authorizing such coverage is Wisconsin Physician Service, Nerve Conduction Studies and Electromyography, LCD No. L31346 (Jan. 1, 2012), *available at* http://downloads.cms.gov/medicare-coverage-database/lcd_attachments/31346_6/L31346_NEURO005_CBG_010112.pdf.

[13] On example of a local coverage determination authorizing such coverage is Noridian Adm. Servs., MRI and CT Scans of the Head, Brain, and Neck, LCD No. L32848 (Mar. 5, 2013), *available at* http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?Date=04/08/2013&DocID=L32848.

[14] On example of a Medicare Administrative Contractor's policy statement authorizing such coverage is Healthnet Nat'l Med. Policy, Genetic Testing for Huntington's Disease, NMP138 (Dec. 2011), *available at* http://www.healthnet.com/static/general/unprotected/pdfs/national/policies/Genetic_Testing_Huntington_Disease_Dec_11.pdf.

108. Smith is unable to obtain Medicare coverage for the PET beta-amyloid scan pursuant to the Decision and Defendants' interpretation and application of NCD 220.6.

109. Smith is unable to obtain a PET beta-amyloid scan using her own funds.

110. Defendants' refusal to cover any PET beta-amyloid scan outside of a clinical trial injures Smith. Smith relies on Medicare coverage to meet her health care needs. Smith is not eligible for any PET beta-amyloid trial.

111. Plaintiff Cheryl Kort experiences symptoms of cognitive impairment. Kort's symptoms preclude a reliable diagnosis based solely on a clinical assessment. Accordingly, Kort would benefit from a PET beta-amyloid scan.

112. Kort is unable to obtain Medicare coverage for the PET beta-amyloid scan pursuant to the Decision and Defendants' interpretation and application of NCD 220.6.

113. Kort obtained a PET beta-amyloid scan and is financially liable for the service.

114. Defendants' refusal to cover any PET beta-amyloid scan outside of a clinical trial injures Kort. Kort relies on Medicare coverage to meet her health care needs. Kort is not eligible for any PET beta-amyloid trial.

115. Plaintiff Lorraine Kovnat experiences symptoms of cognitive impairment. Kovnat's symptoms preclude a reliable diagnosis based solely on a clinical assessment. Accordingly, Kovnat would benefit from a PET beta-amyloid scan.

116. Kovnat is unable to obtain Medicare coverage for the PET beta-amyloid scan pursuant to the Decision and Defendants' interpretation and application of NCD 220.6.

117. Kovnat obtained the PET beta-amyloid scan and is financially liable for the service.

118. Defendants' refusal to cover any PET beta-amyloid scan outside of a clinical trial injures Kovnat. Kovnat relies on Medicare coverage to meet her health care needs. Kovnat is not eligible for any PET beta-amyloid trial.

CLAIMS FOR RELIEF

COUNT I
(Violation of 5 U.S.C. § 706(2)(C))

119. Plaintiffs reallege and incorporate by reference paragraphs 1 through 118, as if set forth fully below.

120. Defendants' denial of coverage for PET beta-amyloid imaging pursuant the Decision and NCD 220.6 is premised on the conclusion that diagnostic services must "improve health outcomes" or alter "disease management" to be covered under the Medicare Act. Decision at 2, 17, 38.

121. The Medicare Act does not require a diagnostic service to "improve health outcomes" or alter disease "management," or authorize the Secretary to impose such a condition to coverage. The Act provides for coverage of items and services that are "reasonable and necessary for the diagnosis *or* treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added). The statute uses the disjunctive term "or" to separate items and services that are reasonable and necessary for "diagnosis" from those that are reasonable and necessary for "treatment." This unequivocally establishes Congress' intent to give independent significance to the words "diagnosis" and "treatment," and to require coverage of items and services that are reasonable and necessary for *either* "diagnosis *or* treatment."

122. The Medicare Act therefore establishes that the diagnostic value of a service, standing alone, is a sufficient basis for its coverage; a diagnostic service need not impact health outcomes or disease management to qualify for coverage.

123. Defendants' contrary conclusion is fundamentally inconsistent with the Medicare Act's plain language. Accordingly, the condition to coverage adopted by Defendants pursuant to the Decision and NCD 220.6 exceeds the Secretary's statutory jurisdiction, authority, and limitations, and is short of statutory right. 5 U.S.C. § 706(2)(C).

124. Accordingly, the Decision and NCD 220.6, as the latter is applied to PET beta-amyloid scans, are unlawful and must be set aside.

COUNT II
(Violation of 5 U.S.C. § 706(2)(A))

125. Plaintiffs reallege and incorporate by reference paragraphs 1 through 124 as if set forth fully below.

126. In adopting the requirement that a diagnostic service must "improve health outcomes" or alter disease "management," Defendants have reached legal conclusions based on undisputed facts that are fundamentally inconsistent with NCDs, local coverage determinations, and other coverage decisions issued by Defendants and their agents over the course of decades, and through which they currently provide coverage for many other diagnostic and other services.

127. Specifically, Defendants consistently cover items and services designed to diagnose diseases for which there is no cure or disease-modifying treatment available. These decisions demonstrate that a diagnostic service must be covered based on its diagnostic utility alone. Defendants' adoption of a condition to coverage that diagnostic services must "improve health outcomes" or alter "disease management" cannot be reconciled with these well-established and ongoing Agency positions.

128. Defendants have made no effort to reconcile the condition to coverage adopted in the Decision and their interpretation and application of NCD 220.6 with these conflicting precedents.

129. Although objections to Defendants' adoption of this condition were presented in comments submitted in the Agency record, the Decision failed to address those objections.

130. Defendants' conclusion pursuant the Decision and NCD 220.6 that PET beta-amyloid scans may never be covered in any circumstance except a clinical trial is thus arbitrary, capricious, an abuse of the Secretary's discretion, and otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

131. Accordingly, the Decision and NCD 220.6, as the latter is applied to PET beta-amyloid scans, are unlawful and must be set aside.

COUNT III
(Violation of 5 U.S.C. § 706(2)(A))

132. Plaintiffs reallege and incorporate by reference paragraphs 1 through 131 as if set forth fully below.

133. Even if Defendants have the statutory jurisdiction and authority to adopt a requirement that a diagnostic service must "improve health outcomes" or alter "disease management" as a condition to coverage, Defendants' application of that requirement is fundamentally inconsistent with NCDs, local coverage determinations, and other coverage decisions made by Defendants and their agents over decades, and through which they currently provide coverage for many other diagnostic and other services, and is inconsistent with facts acknowledged in the Decision.

134. First, this condition to coverage cannot be reconciled with the Agency's established position, conceded in the Decision, that diagnostic services should be covered if they

enable the "avoidance of burdensome or hazardous interventions that will not ultimately help the beneficiary." Decision at 56. Medical evidence conceded in the Decision demonstrates that PET beta-amyloid scans enable the avoidance of precisely this harm in patients otherwise at risk of being misdiagnosed with Alzheimer's.

135. Second, Defendants refuse to cover PET beta-amyloid scans for any patient in any circumstance outside of a clinical trial on the theory that the scans cannot "improve health outcomes" or alter "disease management" due to the incurable nature of Alzheimer's and the alleged absence of harm that misdiagnosis will cause Alzheimer's patients who do not, in fact, have the disease. This position cannot be reconciled with Defendants' decision in NCD 220.6 to approve the use of fluorodeoxyglucose PET scans for use in aiding in the differential diagnosis of Alzheimer's and frontotemporal dementia, despite the fact that fluorodeoxyglucose PET scans are subject to precisely the same alleged limitations.

136. Third, this condition to coverage cannot be reconciled with well-established Agency practice authorizing the coverage of numerous other Alzheimer's-related services, even though those services, like PET beta-amyloid scans, do not lead to treatments that "prevent, stabilize, or reverse" Alzheimer's.

137. Fourth, Defendants' refusal to cover any PET beta-amyloid scan outside of a clinical trial based on the scan's alleged inability to "improve health outcomes" or alter "disease management" cannot be reconciled with well-established Agency practice authorizing the coverage of services designed to diagnose incurable neurological conditions for which no cure or disease-stabilizing or disease-reversing treatment is available.

138. Defendants have made no effort to reconcile the condition to coverage adopted in the Decision and their interpretation and application of NCD 220.6 with these conflicting coverage decisions.

139. Defendants' conclusion that PET beta-amyloid scans may never be covered in any circumstance except a clinical trial is thus arbitrary, capricious, an abuse of the Secretary's discretion, and otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

140. Accordingly, the Decision and NCD 220.6, as the latter is applied to PET beta-amyloid scans, are unlawful and must be set aside.

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order setting aside the Decision on the following grounds:

(i) Defendants' adoption of a condition to coverage that requires PET beta-amyloid scans to "improve health outcomes" or alter "disease management" exceeds the Secretary's statutory jurisdiction and authority and is set aside pursuant to 5 U.S.C. § 706(2)(C);

(ii) Defendants' adoption of a condition to coverage that requires PET beta-amyloid scans to "improve health outcomes" or alter disease management" is arbitrary, capricious, an abuse of discretion, and not in accordance with law and is set aside pursuant to 5 U.S.C. § 706(2)(A);

(iii) Defendants' application of such condition to coverage as a basis to deny coverage for any use of any PET beta-amyloid scan in any patient regardless of the medical circumstances, except in certain clinical trials, is arbitrary, capricious, an abuse of discretion, is not in accordance with law, and is therefore set aside pursuant to 5 U.S.C. § 706(2)(A).

B. Issue injunctive relief:

(i) barring Defendants and their agents and contractors from issuing, enforcing, implementing, or otherwise applying the Decision, NCD 220.6, any decisions issued thereunder, or any other Agency action that purports to require PET beta-amyloid scans to "improve health outcomes" or alter "disease management" as a condition to coverage; and

(ii) barring Defendants and their agents and contractors from issuing, enforcing, implementing, or otherwise applying the Decision, NCD 220.6, any decisions issued thereunder, or any other Agency action that purports to conclude that the use of a PET beta-amyloid scan can never be a reasonable and necessary diagnostic service for any patient in any medical circumstance outside of a clinical trial.

C. Attorneys' fees and costs incurred by Plaintiffs as permitted by law.

D. Any other relief this Court deems appropriate.

Dated: September 5, 2014

Respectfully submitted,

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