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8 Attorney for Plaintiffs

United States District Court for the Western District of Oklahoma

9 1) Dennis W. Brennan,  
10 Plaintiff

11 vs.

- 12 1) United State of America  
13 Department of Health and Human  
14 Services,  
15 2) Sylvia Mathews Burwell, Secretary  
16 of Health and Human Services, in  
17 her official capacity  
18 3) Agency for Healthcare Research and  
19 Quality,  
20 4) Centers for Medicare and Medicaid  
21 Services (CMS),

Defendants

Case No. CIV

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Dennis W. Brennan, by and through his attorney, brings this civil action for declaratory and injunctive relief, and alleges as follows:

INTRODUCTION

1. In this action plaintiff, Dennis Brennan seeks to declare defendant Centers for Medicare and Medicaid Services (CMS), an agency of Health and

1 Human Services actions refusing to provide for CT lung screening invalid and  
2 unconstitutional in conflict with defendant Agency for Healthcare Research and  
3 Quality, an agency of Health and Human Services requirements that the  
4 recommendations of U.S. Preventive Services are the force of law under the  
5 Patient Protection and Affordable Care Act, Public Law 111-148 and permanently  
6 enjoin the enforcement of Medicare to provide CT lung screening for high risk  
7 asymptomatic individuals.

#### 8 JURISDICTION AND VENUE

9 2. This Court has jurisdiction over this subject matter pursuant to 28  
10 U.S.C. § 1331. This action arises under the Constitution of the United States,  
11 Amendment 14 which Federal Courts have read to be judicially enforceable  
12 against the Federal Government.

13 3. Venue lies in the District of Oklahoma pursuant to 28 U.S.C. § 1402 (a)  
14 (1). Plaintiff resides in the Western District of the State of Oklahoma.

#### 15 PARTIES

16 4. Plaintiff Dennis Brennan is a Medicare recipient, Medicare number xxx-  
17 xx-6485A, redacted pursuant to FRCP 5.2, and is an asymptomatic high risk  
18 individual for lung cancer with a smoking history of equal to or greater than 30 pack  
19 years with less than 15 years cessation.

20 5. Defendant, Health and Human Services is an executive department of  
21 the United States of America.

22 6. Defendant, Sylvia Mathews Burwell, is the Secretary of the Department  
23 of Health and Human Services, and is being sued in her official capacity.

24 7. Defendant Agency for Healthcare Research and Quality is an agency of  
25 defendant Department of Health and Human Services.

1 8. Defendant, Centers for Medicare and Medicaid Services is an agency of  
2 Defendant Health and Human Services.

3 FACTUAL ALLEGATIONS, CAUSE OF ACTION AND CLAIMS FOR RELIEF

4 FIRST CLAIM FOR RELIEF

5 9. Plaintiffs incorporate paragraphs 1 through 8 of the petition as if fully stated  
6 herein.

7 10. According to defendant Agency for Healthcare Research and Quality, the  
8 work of the U.S. Preventive Services Task Force is central to the preventive benefits  
9 covered under the Patient Protection and Affordable Care Act. Under the Patient  
10 Protection and Affordable Care Act, Public Law 111-148, Sec 2713, in new plans  
11 and policies preventive services with a Task Force rating of A or B will be covered  
12 with no cost sharing requirements and these requirements are administered by the  
13 Secretary of the Department of Health and Human Services.

14 11. The U.S. Preventive Services Task Force in December, 2013 has issued  
15 a rating of B concerning lung screening to all asymptomatic individuals with a  
16 smoking history of equal to or greater than 30 pack years with less than 15 years  
17 cessation. See Exhibit 1.

18 12. Under the provisions of Patient Protection and Affordable Care Act, Public  
19 Law 111-148, Sec 2713, U.S. Preventive Services Task Force ratings of A or B  
20 become law requiring the CT Lung Screening to all asymptomatic individuals with a  
21 smoking history of equal to or greater than 30 pack years with less than 15 years  
22 cessation with no cost sharing requirements on insurance companies.

23 13. This action that U.S. Preventive Services Task Force recommendations  
24 rating A or B become law under the Patient Protection and Affordable Care Act,  
25 Public Law 111-148, Sec 2713, results in a Federal Government mandate that

1 private insurances companies provide the CT lung caner screening to appropriate  
2 asymptomatic individuals with a smoking history of equal to or greater than 30 pack  
3 years with less than 15 years cessation without a deductable or co-pay.

4 14. Defendant Medicare and Medicaid Services issued a Proposed Decision  
5 Memo for Screening for Lung Cancer with Low Dose Computed Tomography  
6 (LDCT) (CAG-00439N) on November 10, 2014.

7 15. Defendant Medicare and Medicaid Services has refused to provide CT  
8 lung screening for asymptomatic Medicare individuals with a smoking history if older  
9 than 74 whereas the U.S. Preventive Services Task Force's recommendations  
10 having the force of law under the Patient Protection and Affordable Care Act, Public  
11 Law 111-148, Sec 2713, on private health insurance companies to provide for CT  
12 lung screening for individuals and Medicare's refusal to provide the CT lung  
13 screening for individuals without deductable for those 55 through 80 insured through  
14 private insurance.

15 16. The effect of the U.S. Preventive Services Task Force's  
16 recommendations having the force of law under the Patient Protection and  
17 Affordable Care Act, Public Law 111-148, Sec 2713, on private health insurance  
18 companies to provide for CT lung screening for individuals and Medicare's refusal to  
19 provide the CT lung screening for individuals without deductable or co-pay has  
20 created two classes of citizens, those 55 through 80 insured through private  
21 insurance, and those 65 and older covered by Medicare.

22 17. Under the Patient Protection and Affordable Care Act, Public Law 111-  
23 148, Sec 4105, the Secretary of Health and Human Services has authority to modify  
24 coverage of all Medicare existing preventive services, consistent with U.S.  
25 Preventive Services Task Force's recommendations.

1 18. For the above reasons, the Federal Government, through defendant  
2 Health and Human Services refuses to provide equal protection of its citizens,  
3 private insured individuals who meet the requirements are covered for CT lung  
4 screening and Medicare individuals who would meet the requirements are not  
5 covered for CT lung screening.

6 19. Defendant Health and Human Services actions requiring CT lung  
7 screening to certain citizens while refusing it to other citizens could be considered  
8 governmental schizophrenia.

9 20. The United States Constitution Amendment 14 provides, "...nor deny to  
10 any person within its jurisdiction the equal protection of the laws. The requirements  
11 of equal protection have been placed on the Federal Government through judicial  
12 decisions.

13 SECOND CLAIM FOR RELIEF

14 21. Plaintiff incorporate paragraphs 1 through 20 of the petition as if fully  
15 stated herein.

16 22. Defendants may allege or claim that U.S. Preventive Services Task Force  
17 is not an agency within the Health and Human Services or other executive branch  
18 agency of the United States of America.

19 23. If the U.S. Preventive Services Task Force is not a federal agency, the  
20 U.S. Preventive Task Force has no authority to issue recommendations that  
21 become federal law under Patient Protection and Affordable Care Act, Public Law  
22 111-148, Sec 2713.

23 24. Patient Protection and Affordable Care Act, Public Law 111-148, Sec  
24 2713 allows what may be a private entity to issue recommendations that become  
25 law under the Patient Protection and Affordable Care Act, Public Law 111-148

1 25. There are no provisions within the United States Constitution which allows  
2 a private entity make law or which allows a private entity's recommendations to  
3 become law or have the force of law on other private companies or individuals.

4 26. If Defendants claim or allege or claim that the U.S. Preventive Services  
5 Task Force is a private entity, then the provisions of Patient Protection and  
6 Affordable Care Act, Public Law 111-148, Sec 2713 is unconstitutional and without a  
7 severability clause within the Patient Protection and Affordable Care Act, Public Law  
8 111-148, the entire act should be declared unconstitutional.

9 THIRD CLAIM FOR RELIEF

10 27. Plaintiff incorporate paragraphs 1 through 26 of the petition as if fully  
11 stated herein.

12 28. Plaintiff alleges that Defendant may approve Medicare lung cancer  
13 screening at a reduced payment rate less than adequate for the performance of the  
14 services and less than what private insurers are mandated to pay which will result in  
15 hospitals and physicians refusal to perform CT lung screening services.

16 FORTH CLAIM FOR RELIEF

17 29. Plaintiff incorporate paragraphs 1 through 28 of the petition as if fully  
18 stated herein.

19 30. Defendant Sylvia Mathews Burwell, Secretary of the Department of  
20 Health and Human Services, refuses to comply with Patient Protection and  
21 Affordable Care Act, Public Law 111-148, Sec 2713 which requires the secretary to  
22 establish a minimum interval between the date in which recommendations of the  
23 United States Preventive Task Force were adopted and the date the date they are  
24 effective.

25 PRAYER FOR RELIEF

1 WHEREFORE, Plaintiff requests the following relief:

2 1. Declaratory relief that defendant Health and Human Services is not  
3 providing equal protection of the law where certain asymptomatic individuals for  
4 those 55 through 80 years of age with a smoking history of equal to or greater than  
5 30 pack years with less than 15 years cessation are provided private healthcare  
6 coverage, without deductible or co-pay for CT lung screening by the demands of  
7 the Patient Protection and Affordable Care Act, Public Law 111-148, Sec 2713, and  
8 Medicare individuals through defendant Centers for Medicare and Medicaid  
9 Services (CMS) are not provided healthcare coverage for CT lung screening for  
10 those 75 through 80 without deductible or co-pay.

11 2. A permanent injunction requiring the Secretary of the Department of  
12 Health and Human Services through Centers for Medicare and Medicaid  
13 Services (CMS) to provide for asymptomatic individuals with a smoking history of  
14 equal to or greater than 30 pack years with less than 15 years cessation CT lung  
15 screening without deductible or co-pay to meet the recommendations of the U.S.  
16 Preventive Services Task Force as it pertains to CT Lung Cancer Screening as  
17 permitted under Patient Protection and Affordable Care Act, Public Law 111-148,  
18 Sec 4105.

19 3. That if a permanent injunction is not issued, declaratory relief that without  
20 equal protection for CT lung Screening to all citizens of the United State, the Patient  
21 Protection and Affordable Care Act, Public Law 111-148 is unconstitutional, invalid,  
22 null and void.

23 4. That Medicare be ordered to compensate hospital and physicians for CT  
24 lung cancer screening equal to the same rate paid by private insurers.

25





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18 3) Agency for Healthcare Research and  
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20 4) Centers for Medicare and Medicaid  
21 Services (CMS),

Defendants

Case No. CIV

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff John Hamlin brings this civil action for declaratory and injunctive relief, and alleges as follows:

INTRODUCTION

1. In this action plaintiff seeks to declare defendant Centers for Medicare and Medicaid Services (CMS), an agency of Health and Human Services actions

1 in defining radiology eligibility to interpret low dose CT lung scans for screening  
2 purposes have no statutory authority.

### 3 JURISDICTION AND VENUE

4 2. This Court has jurisdiction over this subject matter pursuant to 28  
5 U.S.C. § 1331. This action arises under the Constitution of the United States.

6 3. Venue lies in the District of Oklahoma pursuant to 28 U.S.C. § 1402 (a)  
7 (1). Plaintiff resides in the Western District of the State of Oklahoma.

### 8 PARTIES

9 4. Plaintiff is a licensed physician in the State of Oklahoma with a national  
10 provider number of xxxxxx4554, redacted pursuant to FRCP 5.2 and a board  
11 certified diagnostic radiologist.

12 5. Defendant, Health and Human Services is an executive department of  
13 the United States of America.

14 6. Defendant, Sylvia Mathews Burwell, is the Secretary of the Department  
15 of Health and Human Services, and is being sued in her official capacity.

16 7. Defendant Agency for Healthcare Research and Quality is an agency of  
17 defendant Department of Health and Human Services.

18 8. Defendant, Centers for Medicare and Medicaid Services is an agency of  
19 Defendant Health and Human Services.

### 20 FACTUAL ALLEGATIONS, CAUSE OF ACTION AND CLAIMS FOR RELIEF

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covered under the Patient Protection and Affordable Care Act. Under the Patient

1 Protection and Affordable Care Act, Public Law 111-148, Sec 2713, in new plans  
2 and policies preventive services with a Task Force rating of A or B will be covered  
3 with no cost sharing requirements and these requirements are administered by the  
4 Secretary of the Department of Health and Human Services.

5 11. The U.S. Preventive Services Task Force in December, 2013 has issued  
6 a rating of B concerning low dose computed tomography lung screening to all  
7 asymptomatic individuals with a smoking history of equal to or greater than 30 pack  
8 years with less than 15 years cessation. See Exhibit 1.

9 12. Under the provisions of Patient Protection and Affordable Care Act, Public  
10 Law 111-148, Sec 2713, U.S. Preventive Services Task Force ratings of A or B  
11 become law requiring low dose computed tomography lung screening to all  
12 asymptomatic individuals with a smoking history of equal to or greater than 30 pack  
13 years with less than 15 years cessation with no cost sharing requirements on  
14 insurance companies.

15 13. This action that U.S. Preventive Services Task Force recommendations  
16 rating A or B become law under the Patient Protection and Affordable Care Act,  
17 Public Law 111-148, Sec 2713, results in a Federal Government mandate that  
18 private insurances companies provide the low dose computed tomography lung  
19 caner screening to appropriate asymptomatic individuals with a smoking history of  
20 equal to or greater than 30 pack years with less than 15 years cessation without a  
21 deductible or co-pay.

22 14. Defendant Medicare and Medicaid Services issued a Proposed Decision  
23 Memo for Screening for Lung Cancer with Low Dose Computed Tomography  
24 (LDCT) (CAG-00439N) on November 10, 2014 in which it is setting forth regulations  
25 designating who can interpret low dose computed tomography lung screening

1 studies that it restricts which licensed physicians and radiologists can interpret low  
2 dose computed tomography lung screening studies.

3 15. There are no designations under the U.S. Preventive Task Force low  
4 dose CT lung screening for private insurance as to who can interpret the studies.

5 15. Since the completion of plaintiff's residency in diagnostic radiology and  
6 nuclear medicine, plaintiff has interpreted many computed tomography studies of  
7 the lung, whether with or without contrast, including high resolution computed  
8 tomography of the lung.

9 16. Defendants have never designated the differences between regular  
10 computed tomography of the lung or high resolution computed tomography of the  
11 lung and have not set a different compensation for the Medicare professional  
12 component between regular computed tomography of the lung and high resolution  
13 computed tomography of the lung.

14 11. Radiologists have been interpreting standard computed tomography lung  
15 studies since the role out of CT machines in the 1970's including the original axial  
16 computed tomography studies, the more recent helical single slice computed  
17 tomography studies, and the recent helical multislice computed tomography studies  
18 all of which may or may not have included high resolution computed tomography  
19 slices.

20 15. The practice of medicine is governed by state laws and the US  
21 government has never licensed physicians or designated which physicians can  
22 practice what medicine other than mammography as set for by federal statute  
23 Mammography Quality Standards Act of 1992, Pub. L. 102-539, Oct. 27, 1992,  
24 which defined by law requirements physicians had to meet to be eligible to interpret  
25 mammography exams as set forth in 42 U.S.C. sec. 263b(f). See Exhibit 2.



1 computed tomography of the chest who now interpret low dose computed  
2 tomography of the chest for lung nodule screening.

3 3. That this court award other relief it deems just and proper.

4 4. That this court award plaintiff his costs of suit and a reasonable  
5 attorney's fee.

6 Dated this 31<sup>st</sup> day of January, 2016.

7  
8 /s/ John Hamlin

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