IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAROL A. LEWIS, and DOUGLAS B. SARGENT, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

Case No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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1. Plaintiff Carol A. Lewis and Douglas B. Sargent ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services, to obtain injunctive relief for violation of federal law. Plaintiffs make the following allegations based on the investigation of counsel and on information and belief, except as to allegations pertaining to Ms. Lewis and Mr. Sargent individually, which are based on personal knowledge.

I. EXECUTIVE SUMMARY

2. Millions of people in the United States suffer from diabetes and the complications from uncontrolled diabetes cost the United States hundreds of billions of dollars annually in direct expenses and lost productivity. Diabetes is a leading cause of blindness, lower limb amputation, kidney failure and cardiovascular disease among adults in the United States. Due to the public health care implications and associated costs, the Secretary urges Medicare beneficiaries to control their diabetes. For some individuals, the only practical means of monitoring and managing their diabetes is to use a continuous glucose monitor (CGM). As the name implies, a CGM continuously tests a diabetic's blood and notifies the user of changes in blood glucose levels. This allows the user to avoid many complications from diabetes, including slipping into a coma and possible death from having too low blood sugar. More than 98% of private insurance companies cover CGM devices both because of their life saving features and because they save money by avoiding expensive complications.

3. However, Medicare users face irrational resistance from the Secretary. When claims for Medicare CGM coverage are submitted, the Secretary tersely responds that "Medicare does not cover this device or service," thereby concealing the basis for the denial. Only

extensive litigation reveals that the Secretary denies claims on the nonsensical grounds that the life-saving CGM devices are not "primarily and customarily used to serve a medical purpose."

4. Because they do not know the true basis for the Secretary's denials, thousands of Medicare users do not further appeal the denial of their claims. As a result, people that are ill, or elderly (or both) are forced to pay for the full cost of these devices from their own, often limited, funds or forego this life saving technology.

5. For unknown reasons, the Secretary seeks to avoid the plain meaning of both the statutes and his own regulations as to what is covered. Instead, the Secretary substitutes his own terminology (*i.e.*, "precautionary" and "therapeutic") and issues denials based on terms that simply do not appear in the statutes or regulations. To date, the Secretary has never offered a definition of these terms or a reason why they could or should be added to the statutes or regulations.

6. Multiple courts and the Secretary's own ALJ's and civil remedies division have told the Secretary his position was wrong. However, the Secretary is impervious to reason and keeps issuing denials on the same nonsensical grounds, even to Medicare users in whose favor the courts have already ruled.

7. This suit is brought to right this wrong and to provide the coverage relief Congress specified in the Medicare program.

II. JURISDICTION

8. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) and 1395ff. Ms. Lewis is filing suit after a final decision of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of her Medicare claim (and, therefore, has exhausted her administrative remedies), the amount-in-controversy is more than $1,600 (42 U.S.C. §§

1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision. Likewise, Mr. Sargent is filing suit after final decisions of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of his Medicare claim (and, therefore, has exhausted his administrative remedies), the amount-in-controversy is more than $1,600 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision.

9. Pursuant to 28 U.S.C. § 1367(a), this Court has supplemental jurisdiction over claims of class members whose claims are not in excess of $1,600. Those claims are so related to Ms. Lewis and Mr. Sargent's claims that they form part of the same case or controversy.

10. The requirement to exhaust administrative remedies and/or bring suit within 60 days should be waived for class members who did not do so as a result of the Secretary's concealment of the reasons for denial of CGM coverage (as detailed below), futility, based on equitable principles, and/or in the interests of justice.

11. In addition to or in the alternative, this court also has jurisdiction under 28 U.S.C. §§ 1331 and 2201 to consider Plaintiffs' declaratory judgment claims.

12. Venue is proper in this district pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) because this action is being brought in the District of Columbia.

III. INTRODUCTION

13. Over a considerable period of time, the Secretary has defied Congress' will by refusing to provide Medicare coverage for diabetic patients needing continuous glucose monitors (CGMs). These FDA-approved, life-saving devices continuously test glucose levels and alert patients to changes. Without these devices, many diabetes patients suffer a risk of slipping into a diabetic coma and death.

14. Though these devices meet the requirements to be covered as durable medical equipment, the Secretary generally has refused to acknowledge this obvious conclusion. Instead, nonsensically, the Secretary contends that the FDA approved, life-saving devices are "nonmedical in nature" or "not used to serve a medical purpose" and therefore refuses to provide coverage as dictated by Congress.

15. As part of this effort, the Secretary has denied claims for CGM coverage because the devices are purportedly "precautionary" or "therapeutic." However, these terms do not appear in the governing statute or regulations as a bar to or limitation of coverage. To the contrary, these are terms coined by the Secretary that have no basis in the law and also have no defined meaning. Indeed, the Secretary's effort to deny claims for CGM coverage as "precautionary" has been rejected by one district court as arbitrary and capricious, unreasonable, and without substantial justification. Undeterred, the Secretary continues to issue denials on the same basis.

16. To enforce this irrational position, the Secretary employs a series of procedural and bureaucratic tactics designed to frustrate an elderly and frequently ill population in their effort to use the program enacted by Congress in the way Congress intended.

17. Just one component of this effort is the Secretary's requirement that every single claim for the same equipment to the same beneficiary be litigated anew. Thus, month after month, elderly and frequently ill beneficiaries are put to the Sisyphean task of repeatedly proving that the same equipment is eligible for coverage, only to repeat the same process when they submit the next claim.

18. So far, three beneficiaries (including Ms. Lewis) have had the resources and fortitude to challenge the Secretary's denials through district court. Each court that has

considered the matter has found that the Secretary's position was without merit and ordered coverage. Unfazed, the Secretary continues to issue the same denials.

19. Ms. Lewis, Mr. Sargent, and the Class Members are Medicare beneficiaries who have suffered from this conduct and bring this suit on their own behalf, to address the past denials, and to prevent the Secretary from using these same tactics against future Medicare beneficiaries.

IV. PARTIES

20. Plaintiff Carol A. Lewis is an individual and a resident of the State of Massachusetts. Ms. Lewis is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

21. Plaintiff Douglas B. Sargent is an individual and a resident of the State of Connecticut. Mr. Sargent is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

22. As detailed below, the proposed Class Members are citizens of the various States who have had their Medicare claims for CGM coverage denied.

23. Illustrative Class Members include:

a. Ronald Kilpack: Mr. Kilpack is an 86 year-old, retired machine tool salesman, father of 4, and grandfather to 8. Mr. Kilpack is a Korean War veteran and served six years in the submarine service. Along with his wife of 62 years (Marian), Mr. Kilpack currently lives in Bend, Oregon, where, in addition to other activities, Mr. Kilpack is an avid motorcycle enthusiast and a member of the Roadhouse Biker Church.

Mr. Kilpack has been a Type I diabetic for over 50 years and suffers from hypoglycemic unawareness. In the year before getting a CGM, Mr. Kilpack's family reports that

he had to be revived by family members, paramedics, or at the hospital more than 10 times for diabetes complications. Since getting a CGM, Mr. Kilpack has had no such instances. Mr. Kilpack has a single MAC decision denying his claim for Dexcom G5 coverage for a device supplied in May 2016.

b. Nancy Hawkins: Mrs. Hawkins is a 69 year-old, retired nurse, mother of 4, grandmother to 10, and league bowling champion. Along with her husband of 29 years (Dave), Mrs. Hawkins currently lives in Brunswick, Maine, where she is an active member of her church and a devoted sports fan.

Mrs. Hawkins is a Type I, brittle diabetic with hypoglycemic unawareness. Although Mrs. Hawkins' CGM was covered by her husband's employer, since being on Medicare, Mrs. Hawkins has had 7 ALJ decisions (6 favorable, 1 unfavorable) and has been to the MAC twice.

c. Vickie Brown: Mrs. Brown is a 63 year-old, retired health care executive and nurse. Along with her husband of 43 years (George), Mrs. Brown currently lives in Jacksonville, Florida where she is active in her church and keeps busy with volunteer work with the ASPCA, Goodwill, and the American Red Cross.

Ms. Brown was diagnosed with diabetes at the age of 29 and prescribed a CGM in 2011. Ms. Brown is a Type I, brittle diabetic who also suffers from hypoglycemic unawareness. Prior to receiving a CGM in 2011, on average, Ms. Brown suffered 2 or more events *each week* requiring medical intervention to revive her. A CGM reduced these incidents by more than 75%. Ms. Brown's CGM was covered by private insurance until she went on Medicare.

On Medicare, Ms. Brown submitted claims for coverage for Dexcom G4/G5 sensors provided in June, July, and August 2016 as well as January 30 and February 16, 2017. Though

denied at the initial levels, Ms. Brown received a fully favorable decision from an ALJ finding that all her CGM claims were covered as durable medical equipment. Nevertheless, in August 2018, the MAC issued a decision holding that the Dexcom G4/G5 sensors of June, July, and August 2016 were not covered durable medical equipment because they were not "primarily and customarily used to serve a medical purpose." At the same time, the MAC let stand the decision that the same sensors supplied in January and February 2017 were durable medical equipment because they were "primarily and customarily used to serve a medical purpose."[1]

24. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

V. FACTUAL BACKGROUND

25. Diabetes is a disease in which the body either does not produce any/enough insulin (Type I) or does not properly respond to/regulate blood glucose levels (Type II). As a result, the individual may experience high or low blood glucose levels for a prolonged period of time. High or low blood glucose levels for long periods lead to heart disease, stroke, kidney failure, ulcers (sometimes resulting in amputation), eye damage (sometimes resulting in blindness), and ultimately death. As of 2015, diabetes was the seventh leading cause of death in the United States.[2] Through 2012, the costs related to diabetes (healthcare and lost productivity) were estimated at $245 billion annually.[3]

26. In addition to monitoring through blood tests (see below), many diabetics feel physical symptoms such as blurred vision, fatigue, hunger, and increased thirst that alert them

[1] As noted below, CMS-1682-R is effective as to claims submitted for dates of service after January 12, 2017.

[2] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 10.

[3] *Id*.

their blood glucose levels are too high or too low. As a result, the diabetic is able to take corrective action (e.g., drinking orange juice).

27. However, the longer a patient lives with diabetes, the more they lose sensitivity to out of range glucose levels. That is, they no longer experience any physical sense that their glucose level may be too high or too low to indicate that corrective action must be taken. This is referred to as "hyperglycemic or hypoglycemic unawareness."

28. Further, the blood glucose levels of some diabetics are prone to wild and rapid swings either up or down. For example, in the span of minutes, glucose levels may drop precipitously low and the patient may fall into a diabetic coma that proves fatal. This is referred to as "brittle diabetes."

29. It is estimated that one in 20 individuals with diabetes dies each year in their sleep due to an undetected fatal low blood sugar. This is known as "dead in bed syndrome."[4]

30. For such individuals, to effectively monitor glucose levels, blood testing needs to be performed several times a day, even during the night.

A. Glucose Tests

31. Prior to the early 2000's, the most common method for patients to monitor blood glucose levels was by pricking a finger to draw blood. Blood was then placed on a test strip coated with glucose oxidase. Glucose in the blood and the glucose oxidase on the test strip react and, in doing so, consume oxygen. The oxygen consumption: 1) results in an electrical charge that is measured by a glucose meter; or 2) results in a color change on the test strip which is correlated with actual blood glucose levels.

[4] https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome (accessed October 9, 2018).

32. This method has several disadvantages. First, it requires patients to prick their fingers multiple (e.g., 12) times a day. Further, because some of those times will be when the patient is sleeping, the patient must awake throughout the night and cannot get a full night's sleep. Second, because it is done on relatively long intervals, brittle diabetes patients may suffer an episode between testing periods. Thus, a brittle diabetes patient fully compliant with this testing procedure may still die because the onset of symptoms is so quick.

B. Continuous Glucose Monitors

33. The disadvantages of finger prick/test strips led researchers to develop continuous glucose monitors which became available starting in the mid-2000s. When using a CGM, a disposable[5] sensor is placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells. These interstitial fluids contain glucose that has come from the blood and is on the way to the cells. Thus, interstitial glucose is correlated with the glucose in blood itself. Current CGM sensors last for a week and measure glucose levels every five to seven minutes (*i.e.*, more than 200 times a day) without requiring patient interaction, including when the patient is sleeping.

34. The output from a CGM sensor is transmitted, via a transmitter, to a CGM receiver/monitor or even a smart phone/tablet. A CGM transmitter typically lasts for several months. The CGM receiver/monitor or smart phone/tablet may monitor the detected glucose levels and report the results to the patient and/or a healthcare provider and/or trigger an alert. In addition, the CGM receiver may be connected to an insulin pump such that the amount of insulin delivered can be automatically controlled based on the sensed glucose levels. Further, when

[5] Pursuant to Medicare regulations, if one item is a system is durable medical equipment, payment is also available for supplies necessary to use that durable medical equipment. See Medicare Benefit Policy Manual, Chap. 15, Sec. 110.3.

using a smart phone or tablet, an application on the device can plot glucose trends and perform further analyses.

35. Typically, the CGM is calibrated by finger prick/test strip testing twice a day. Some newer CGM devices eliminate the need for calibration.

36. Accordingly, CGMs offer many advantages over finger prick/test strips. First, they monitor glucose levels much more frequently – more than 200 times a day, rather than 10 to 12 - meaning that brittle diabetes patients enjoy decreased risk of death from a rapid onset of symptoms. Second, even for non-brittle diabetes patients, the increased monitoring frequency leads to much finer glucose level control, thereby reducing diabetes related health complications. Third, the monitoring occurs without patient interaction, meaning that patients can sleep through the night and/or not interrupt their regular activities. Fourth, patients are not pricking themselves as frequently, meaning that they do not suffer from near continuous injuries and sources of infection and discomfort.

37. Fifth, because of the large number samples and short interval between them, the CGM provides granular trend information regarding how quickly glucose levels are dropping or rising. The trend information enables patients to exercise immediate short term management of their diabetes (*e.g.*, "Do I have time to make it to the lunch meeting or should I pull over now and drink juice?"), and are used by clinicians for the long term management of diabetes (*e.g.*, the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months).

38. Overall, these advantages lead to improved glucose monitoring, reduced costs, increased quality of life, and reduced risk of death or other complications.

39. Moreover, CGMs result in decreased health care costs and improved outcomes. Because complications related to glucose control are reduced/avoided, the overall expense of treating a diabetic patient is reduced. For example, many diabetic patients require ambulance transport to the hospital when they suffer an incident. In 2014, more than 450,000 emergency room visits were the result of hyperglycemic or hypoglycemic incidents among diabetics.[6] These episodes are very expensive and a CGM reduces their frequency. Of course, the ultimate cost is death and CGMs reduce the events that can lead to that result.

C. CGM Cost Coverage

40. Modern CGMs cost approximately $300-350/month for purchase of the CGM receiver, transmitter, disposable sensors, and test strip supplies for result calibration.

41. The advantages of CGMs over finger pricks/test strips are widely recognized in the health care field. Indeed, CGMs have become the standard of care for treating brittle diabetes. As a result, ~98% of private health care providers cover CGM related costs.[7]

42. For many patients, doctors describe a CGM as "life-saving."

43. Further, the FDA has approved one CGM device to completely replace finger pricks/test strips.[8]

44. Inexplicably, Medicare has resisted covering CGMs. Except with regard to a small number of CGM systems (lacking the features of non-covered CGMs), Medicare deems CGMs "not primarily and customarily used to serve a medical purpose" and, therefore, not covered durable medical equipment (DME).

D. Reasonable and Necessary – "Durable Medical Equipment"

[6] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 9.

[7] *See* https://provider.dexcom.com/reimbursement/commercial-reimbursement

[8] *See* Food and Drug Administration, Premarket Approval P120005/S041 (December 20, 2016).

45. Pursuant to the statutes, Medicare pays for items that are: 1) "reasonable and necessary for the diagnosis or treatment of illness or injury" (42 U.S.C. § 1395y(a)(1)(A)); and 2) that are within a defined benefit category such as "durable medical equipment" (42 U.S.C. 1395x(n) defining "durable medical equipment"); and 3) that are not otherwise excluded.

46. CGMs are available only upon a prescription from a doctor who has determined that a CGM is medically reasonable and necessary for the treatment of a patient's diabetic condition.

47. Only after receiving a prescription for a CGM can a beneficiary submit a claim for CGM coverage.

48. Thus, the fact that a beneficiary has submitted a claim for CGM coverage necessarily means that a doctor has determined that a CGM is medically reasonable and necessary for the beneficiary.

49. "Durable medical equipment" is defined in 42 U.S.C. § 1395x(n) in an open-ended fashion by way of examples of items that are durable medical equipment including "blood glucose monitors."

50. A CGM is a blood glucose monitor.

51. The Secretary has further issued regulations defining "durable medical equipment." *See* 42 C.F.R. 414.202. Pursuant to that regulation, and item is durable medical equipment if it meets the following conditions:

a. Can withstand repeated use;

b. Has a life expectancy of at least 3 years;

c. Is primarily and customarily used to serve a medical purpose;

d. Generally not useful to an individual in the absence of illness or injury; and

e. Is appropriate for use in the home.

52. A CGM can withstand repeated use.

53. A CGM (in particular, the Medtronic MiniMed and Dexcom devices) has a life expectancy of at least 3 years (in particular, the receivers of the devices).

54. A CGM is primarily and customarily used to serve a medical purpose.

55. A CGM is generally not useful to an individual in the absence of illness or injury.

56. A CGM is appropriate for use in the home.

57. CGM are not otherwise excluded from coverage.

E. CMS-1682-R

58. On January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS "final opinion and order" with regard to CGM coverage. By its own terms, that Ruling is "binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration …"

59. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

60. As set forth there, if a CGM does not completely replace finger prick/test strips, CMS considers the device not "primarily and customarily used to serve a medical purpose." This is so, CMS contends, because patients do not "mak[e] diabetes treatment decisions, such as

changing one's diet or insulin dosage based solely on the readings of the CGM[.]" See CMS-1682-R at 6-7. CMS calls these CGM's "non-therapeutic."[9]

61. The Ruling determines that one CGM that has been FDA approved to completely replace finger pricks/test strips is DME (the Dexcom G5). See CMS-1682-R at 7-10. In particular, the Ruling determines that the receiver/monitor portion of a CGM lasts more than 3 years and, including other factors, that the whole system is DME within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

62. Both before and after issuance of CMS-1682-R, the Secretary has refused coverage of CGM devices made by Medtronic and Dexcom (other than the Dexcom G5) on the grounds that they are not "primarily and customarily used to serve a medical purpose."

63. The Secretary has rejected claims for coverage of Dexcom G5 supplied weeks before issuance of CMS-1682-R on the grounds that the same device that is "primarily and customarily used to serve a medical purpose" on or after January 12, 2017, is not "primarily and customarily used to serve a medical purpose" on January 11, 2017 or before.

64. Further, as a result of CMS-1682-R, the discretion ALJs previously had to award coverage (even in the face of an alleged LCD) was eliminated. As a result, it is futile to submit claims for non-Dexcom G5 devices with dates of service after January 12, 2017. Because the ALJs no longer have discretion, those claims must be denied.

[9] This claim is demonstrably incorrect for at least some CGMs that do not completely replace finger sticks. For example, the Medtronic MiniMed 670G CGM includes an insulin pump. Based on the readings from the sensors, the CGM automatically controls or suspends the delivery of insulin. This is especially critical at night when the user is sleeping and the continued insulin doses could lead to a dangerous or fatal glucose low. Thus, the user delegates the treatment decision to the device and the decision of whether the administer insulin is based solely on the sensor readings.

65. Without notice and comment, CMS-1682-R was subsequently incorporated into LCD L33822 and Policy Article A52464, generally excluding CGMs.

66. Thus, the Ruling substituted the non-statutory/regulatory term "therapeutic" for the previous non-statutory/regulatory term "precautionary" as the criteria/basis for denials.

F. Other Litigation Related to CGMs

67. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. National Coverage Determination (NCD) 280.1. This is so, the Secretary contends, because CGMs are not "primarily and customarily used to serve a medical purpose."

68. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national or local coverage determination (NCD/LCD) excluding CGM coverage, a local coverage article (LCA) described CGMs as excluded as "precautionary." LCA A52464.

69. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

70. At the Medicare Administrative Law Judge ("ALJ") level, through the filing of this Complaint, more than 40 ALJs have considered the Secretary's position that a CGM is not "primarily and customarily used to serve a medical purpose" and rejected that claim more than 55 times. A listing of relevant ALJ decisions may be found at http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf.

71. With respect to the Secretary's effort to rely on/defer to the Article's description of CGM's as "precautionary" and, therefore, excluded, that was rejected as erroneous in *Whitcomb v. Burwell*, 2015 WL 3397697 (E.D. Wisc. May 26, 2015) (Duffin, J.) and *Finigan v.*

Burwell, 189 F.Supp.3d 201 (D. Mass. 2016) (Young, J.). In both cases, the district court held that reliance on/deference to the Article was erroneous.

72. As to the Secretary's base position that a CGM is not "primarily and customarily used to serve a medical purpose", that position has been rejected by three district courts.

73. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" was erroneous, not supported by substantial evidence, and in each case, ordered the Secretary to provide CGM coverage.

74. Further, in the *Whitcomb* case, the court found that the Secretary's position was "arbitrary and capricious" and "unreasonable." Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

75. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18.

G. The Secretary's Ongoing Efforts to Thwart CGM Coverage

76. In the face of the statute, regulations, and his numerous litigation defeats, the Secretary appears to be employing a four-pronged effort to thwart CGM coverage.

i. Initial Denials

77. The population Medicare serves is, by the terms of the statute, either elderly, suffering from significant medical issues, or both. Further, of course, the vast majority of Medicare beneficiaries are non-lawyers and are not represented by legal counsel in filing their

Medicare claims. Indeed, even if a Medicare beneficiary were represented by counsel, the Secretary's rules preclude the counsel from being paid until the fourth level of a five-level claim process. See 42 C.F.R. § 405.910(f)(1).

78. As indicated, Medicare employs a five-level claim appeal process. This involves (i) submission of a claim, (ii) an appeal of the denial (redetermination), (iii) an appeal of that (reconsideration), (iv) an appeal of that before an ALJ, and (v) an appeal of that to the Medicare Appeals Council. Thus, in many instances, unrepresented, elderly and/or ill persons are forced into a complex and laborious claims appeal process which can stretch out for years over a single claim.

79. At least partly as a result of the above, in FY2016, less than 3% of denied Medicare claims were appealed.[10] Thus, regardless of merit, an initial denial is likely to be final in virtually all cases because the Medicare beneficiary is not in a realistic position to appeal it.

80. While the above is true with regard to Medicare appeals generally, in the CGM context, the true basis for the Secretary's decisions denying coverage is concealed from the beneficiaries until well after the initial denial.

81. A Medicare beneficiary diligently pursuing his rights submits claims for coverage for a CGM according to Medicare rules. The Secretary responds with the bare statement: "Medicare does not cover this device or service." Likewise, on redetermination and reconsideration, the Secretary's denials are inscrutable.

82. As a result, the true basis for the Secretary's denial (*i.e.*, that Medicare contends that a CGM is not "primarily and customarily used to serve a medical purpose") is concealed

[10] *See* https://www.hhs.gov/sites/default/files/omha/files/medicare-appeals-backlog.pdf at 3 (accessed on October 9, 2018). In FY2016, 119 million Medicare claims were denied. Appeals of those denials totaled 3.5 million.

from the beneficiary. Relying on the belief that the Secretary is faithfully applying the statutes, all beneficiaries do not appeal the Secretary's denial.

83. The Class Members have diligently pursued their rights.

84. The Secretary has systematically misapplied the law with regard to whether a CGM is covered durable medical equipment.

85. The Secretary has concealed the basis for the denials which prevented the Class Members from knowing of a violation of their rights.

86. In the present case, the Secretary continues to issue CGM denials that are without basis and only a small fraction are appealed.

87. With respect to the small percentage that do appeal and are denied coverage before an ALJ, yet another tactic that frustrates beneficiaries is delays at the Medicare Appeals Council that far exceed the statutory mandate requiring decisions within 90 days. 42 U.S.C. § 1395ff(d)(2)(A).

88. For example, the appeal of one of the lead plaintiffs in this case (Ms. Lewis) was pending at the MAC for more than 2 years before Ms. Lewis was forced to invoke a procedure ("escalation", 42 C.F.R. §1132) requiring a decision or judicial review within five days. Likewise, one of the appeals of the other lead plaintiffs in this case (Mr. Sargent) was pending at the MAC for nearly a year.

89. Further, even with respect to the small percentage that do appeal and are victorious before an ALJ, frequently, the Secretary (using CMS) actually appeals the decision of his own ALJ. On so-called "own motion review", when an ALJ grants coverage of a CGM, frequently, CMS in effect appeals the decision to the MAC. As a result, having won before an

ALJ, the beneficiary is put through yet another level of appeal with the extraordinary delay described above.

ii. Failure to Follow Precedential Rulings

90. Yet another tactic employed by the Secretary is to consider each decision by an ALJ and the MAC non-precedential - *even with regard to the same device and same beneficiary*. See 42 C.F.R. §§ 405.1000, 405.1100. As a result, in addition to being put through the litigation process multiple times on the exact same facts/question, Medicare beneficiaries can and do receive inconsistent decisions depending upon which ALJ/MAC panel considers a particular claim.

91. For example, Ms. Lewis has litigated CGM coverage six times through an ALJ and three more times through the MAC. Even after Ms. Lewis' repeated victories, when Ms. Lewis submits a new claim for the next month's supplies, the Secretary pretends that he has never litigated the issue before, issues a denial, and inflicts his onerous process on Ms. Lewis yet again.

iii. Defiance

92. In addition to all of the above, the Secretary has engaged in a pattern of sheer defiance. After the numerous defeats from his own ALJs, his own Civil Remedies Division, and before three district courts, the Secretary continues to issue CGM denials on the grounds that a CGM is not DME.

93. For example, the beneficiary in the *Bloom v. Azar* case reported that he had been forced to litigate the issue of whether a CGM is DME through at least the ALJ stage thirteen (13) times. *See Bloom v. Azar*, Case No. 16-cv-121, Docket # 53 at 2 (D. Vermont) (Crawford, J.).

94. After district court rulings finding CGMs were covered benefits, the Secretary continues to issue denials asserting otherwise. For example, after Ms. Lewis received a district court decision in her favor regarding CGM coverage, the Secretary issued yet another denial to Ms. Lewis on the same grounds.

95. Likewise, after the beneficiary in the *Bloom* case received a district court decision in his favor, the Secretary continued to issue denials to the beneficiary. *See Bloom v. Azar*, Case No. 16-cv-121, Docket # 59 at 7.

96. In sum, the Secretary is using complexity/delay/litigation itself as a tactic to avoid compliance with the statute.

VI. Facts Specific to Ms. Lewis

97. Carol Lewis is a 72 year-old mother of three. Starting from a push cart in downtown Boston, Ms. Lewis has been a small business woman for the last 40 years, designing and selling women's apparel. In addition to the business that she operates with her daughter, Ms. Lewis volunteers with her church and at the local senior center. First diagnosed with Type I diabetes in 1985, Ms. Lewis is among the longest living brittle diabetics in the United States and one of the first to use CGM equipment.

98. As detailed above, Ms. Lewis has litigated the issue of coverage of her CGM equipment multiple times.

99. With regard to the specific denial forming the basis for this litigation, on October 26, 2015, Ms. Lewis received a Dexcom G5 CGM system comprising a receiver, transmitter, and sensors.

100. The total cost of these materials was $3,594.

101. Ms. Lewis' claim for coverage for these items was rejected on March 31, 2016 on the grounds that the items were "statutorily excluded" and that "Medicare does not pay for this item or service." Thereafter, Ms. Lewis sought redetermination.

102. Ms. Lewis' request for redetermination was denied on May 24, 2016, on the grounds that all of the items were "disposable" (including the receiver) and therefore could not withstand repeated use. Thereafter, Ms. Lewis sought reconsideration.

103. Ms. Lewis' request for reconsideration was denied on August 12, 2016, on the grounds that a CGM is "precautionary" and, therefore, not durable medical equipment. Thereafter, Ms. Lewis filed an appeal that was assigned to ALJ Holt.

104. After conducting a hearing in which CMS chose not to participate, on November 18, 2016, ALJ Holt issued a decision (ALJ Appeal No. 1-4852017030) holding that a CGM is "precautionary" and not "primarily and customarily used to serve a medical purpose." Thereafter, on December 7, 2016, Ms. Lewis filed an appeal at the MAC.

105. Medicare statutes require the MAC to issue a decision within 90 days of an appeal.

106. When no decision was received by November 2018 (*i.e.*, more than two years later), Ms. Lewis filed a request for escalation on November 26, 2018.

107. Through the filing of this Complaint, no response from the Secretary has been received. Accordingly, Judge Holt's decision is the Secretary's final decision.

VII. Facts Specific to Mr. Sargent

108. Douglas Sargent is a 73 year-old retired electrical engineer and volunteer firefighting Captain (35 years). Mr. Sargent also served six years in the Connecticut Air National Guard, rising to the rank of Staff Sargent before his honorable discharge. With his wife

of 46 years (Beth), Mr. Sargent is the father of three (3) and grandfather to eight (8) and currently lives in Portland, Connecticut. In his spare time, Mr. Sargent enjoys being with his family and supporting his grandchildren in their athletic endeavors.

109. Mr. Sargent is a Type I, brittle diabetic with hypoglycemic unawareness. Prior to using a CGM, paramedics/EMTs made more than twenty (20) visits to Mr. Sargent's house to revive him. After an initial teething period using a CGM, Mr. Sargent has not needed medical assistance in nearly18 months.

110. Through the filing of this Complaint, Mr. Sargent has received one favorable coverage decision at the reconsideration level and four ALJ decisions (three favorable and one unfavorable). CMS did not seek MAC review of two of the favorable ALJ decision but did seek review of one of them. Mr. Sargent sought MAC review of the unfavorable ALJ decision.

111. With regard to the specific denials forming the basis for this litigation, two MAC decisions are at issue.

A. MAC Appeal M-18-239

112. On August 9, 2016, Mr. Sargent received a 90 day supply of sensors for use with his Medtronic MiniMed CGM system. The total cost for these sensors was $1,419.

113. Mr. Sargent's claim for coverage of these sensors was rejected on September 9, 2016, on the grounds that the items were "statutorily excluded" and that "Medicare does not pay for this item or service." Thereafter, Mr. Sargent sought redetermination.

114. On February 27, 2017, Mr. Sargent's request for redetermination was rejected on the grounds that the sensors were "precautionary" and excluded by an LCD (L33822) as a result. Thereafter, Mr. Sargent sought reconsideration.

115. On April 21, 2017, Mr. Sargent's request was denied on the grounds that the sensors did "not meet Medicare's meaning of medical equipment." Thereafter, Mr. Sargent filed an appeal that was assigned to ALJ Jaya Shurtliff.

116. After conducting a hearing in which CMS chose not to participate, on September 5, 2017, Judge Shurtliff issued a decision denying Mr. Sargent's claim. (ALJ Appeal No. 1-6274941714). Judge Shurtliff acknowledged that Mr. Sargent had previously received a fully favorable decision from another ALJ on the same items. Further, Judge Shurtliff stated that she did "not doubt the benefit that [Mr. Sargent] derives from use of the CGM. Nor do we question the testimony that [Mr. Sargent] needs these items."

117. Nevertheless, Judge Shurtliff denied the claim on the grounds that it was excluded by LCD L33822 as not "therapeutic" based on CMS-1682-R, which issued after the supplies were provided. Thereafter, Mr. Sargent appealed to the MAC on October 30, 2017. As detailed above, the MAC was required to issue a decision within 90 days.

118. On October 15, 2018 (*i.e.*, nearly a year later), the MAC issued a decision denying Mr. Sargent's appeal. The MAC concluded that a CGM is not "primarily and customarily used to serve a medical purpose." In so doing, the MAC dismissed the final decisions in *Whitcomb*, *Bloom*, *Finigan*, and *Lewis* on the grounds that the agency's view should be deferred to under *Chevron* and that the MAC just otherwise disagreed with those courts.

119. Further, the MAC held that the several district court decisions, numerous ALJ decisions, and the prior ALJ decision in favor of Mr. Sargent himself all finding that a CGM is covered DME, did not collaterally estop the MAC from arriving at a different conclusion.

B. MAC Appeal M-18-6040

120. On April 12, 2017, Mr. Sargent received a 90 day supply of sensors for use with his Medtronic MiniMed CGM system. The total cost for these sensors was $1,419.

121. Mr. Sargent's claim for coverage of these sensors was rejected on April 21, 2017, on the grounds that the items were "statutorily excluded" and that "Medicare does not pay for this item or service." Thereafter, Mr. Sargent sought redetermination.

122. On August 15, 2017, Mr. Sargent's appeal was denied on the grounds that the sensors were excluded because they were not "therapeutic" as defined by CMS-1682-R. Thereafter, Mr. Sargent sought reconsideration.

123. On March 2, 2018, Mr. Sargent's appeal was denied on the grounds that a CGM is "not a covered Medicare benefit." Thereafter, Mr. Sargent filed an appeal that was assigned to ALJ James Han.

124. After a hearing in which CMS chose not to participate, on June 15, 2018, Judge Han issued a decision approving Mr. Sargent's claim. Judge Han found that the CGM sensors met the definition of durable medical equipment and CMS-1682-R as "therapeutic." (ALJ Appeal No. 1-7414111088). Thereafter, the MAC reviewed Judge Han's decision under so called "own motion review."

125. On October 15, 2018, the MAC issued a decision reversing the ALJ essentially in the same grounds as M-18-239. Thus, the MAC held that a CGM is not "primarily and customarily used to serve a medical purpose" unless it completely replaces finger sticks and is, therefore, "therapeutic."

VIII. CLASS ALLEGATIONS

126. Plaintiff repeats and re-alleges every allegation above as if set forth herein in full.

A. The Class

127. Plaintiff brings this action on his own behalf and, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of the following class (the "Class"):

All persons who submitted claims for coverage of CGM equipment or supplies whose claims were denied (and not later reversed on appeal) since December 13, 2012.

Subclasses:

All persons who submitted claims for coverage of Medtronic CGM equipment or supplies whose claims were denied (and not later reversed on appeal) since December 13, 2012.

All persons who submitted claims for coverage of Dexcom CGM equipment or supplies whose claims were denied (and not later reversed on appeal) since December 13, 2012.

128. Excluded from the Class are: (a) Defendant and his employees, officers, and agents; and (b) any trial judge who may preside over the case and members of such Judge's staff and immediate families.

B. Nume rosity: FED.R.CIV.P. 23(a)(1)

129. The Members of the Class are so numerous that joinder of all Members is impracticable. On information and belief, at least thousands of persons have had their claims for CGM coverage denied. Disposition of the claims of the proposed Class in a class action will provide substantial benefits to both the parties and the Court.

130. In 2015, approximately 23 million people in the United States suffered from diagnosed diabetes - with 9.9 million aged 65 or older.[11]

[11] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 2.

131. In 2016, the CDC estimated that 5.8% of those with diagnosed diabetes suffered from Type I diabetes.[12] For the 2015 diabetic population, using uniform distribution, this results in 1.3 million Type I cases total – with 575,000 in the 65 or older group.

132. Approximately 40% of Type I patients suffer from hypoglycemic unawareness.[13] Again, using the 2015 diabetic population and uniform distribution, this results in 520,000 Type I cases with hypoglycemic unawareness – with 230,000 in the 65 or older group.

133. There are few statistics on patients suffering from "brittle diabetes." One study in Britain estimated the prevalence at 0.29% of the Type I population.[14] Again, using the 2015 diabetic population and uniform distribution, this results in nearly 3,800 Type I cases with brittle diabetes – with more then 1,600 in the 65 or older group.

134. Persons suffering from Type II diabetes may also have hyperglycemic/hypoglycemic unawareness and/or "brittle diabetes" and their numbers would add to the potential pool of Class Members.

135. Medicare coding schemes make it difficult to determine how many claims for CGM coverage have actually been submitted and/or denied. In response to a FOIA request from counsel, one of the four regional contractors (Noridian) reported that over an approximately two (2) year window in 2015-17, more than 53,000 claims were submitted using five (5) different billing codes. Of these, approximately 1,600 claims – less than 3% - were allowed.

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[12] *See* Centers for Disease Control, "Prevalence of Diagnosed Diabetes in Adults by Diabetes Type – United States, 2016", Morbidity and Mortality Weekly Report, March 30, 2018 / 67(12);359–361.

[13] *See* Martin-Timon and Gomez, "Mechanisms of Hypoglycemic Unawareness and Implications in Diabetic Patients", World Journal of Diabetes, July 10, 2015; 6(7): 912-926.

[14] *See* Gill, Lucas, Kent, "Prevalence and Characteristics of Brittle Diabetes in Britain", QJM 1996 Nov; 89(11): 839-43.

136. Thus, while the exact number of Class Members and claims is unknown at this time, it is expected to be in the thousands and could range into the hundreds of thousands.

C. Commonality: FED.R.CIV.P. 23(a)(2)

137. The rights of each member of the proposed Class were violated in a similar fashion based upon Defendant's wrongful actions and/or inaction.

138. The following questions of law and fact are common to each proposed Class Member and predominate over questions that may affect individual Class Members:

Whether Defendant's denials of CGM claims for coverage as not durable medical equipment (DME) are not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and/or contrary to the applicable statutes and regulations?

D. Typicality: FED.R.CIV.P. 23(a)(3)

139. The claims of Ms. Lewis and Mr. Sargent are typical of the claims of the Class and do not conflict with the interests of any other members of the Class, in that Ms. Lewis and Mr. Sargent and the other members of the Class were subjected to the same uniform practices of the Defendant.

E. Adequacy: FED.R.CIV.P. 23(a)(4)

140. Ms. Lewis and Mr. Sargent will fairly and adequately represent the interest of the Class. Ms. Lewis and Mr. Sargent are committed to the vigorous prosecution of the Class' claims and have retained attorneys who are qualified to pursue this litigation and are experienced in CGM litigation against the Secretary.

141. Defendant has acted or refused to act on grounds generally applicable to the proposed Class, thereby making appropriate equitable relief with respect to the Class.

F. The pre-requisites to maintaining a class action for injunctive relief apparent: FED.R.CIV.P. 23(b)(3)

142. The prerequisites for maintaining a class action for injunctive relief exist:

143. By its nature, an action against the Secretary demanding coverage is an action for injunctive relief, enjoining the Secretary to follow the governing law and regulations by providing coverage for CGMs consistent with the same.

144. The Secretary's actions/denials on the grounds that CGMs are not durable medical equipment is generally applicable to the Class as a whole and Ms. Lewis and Mr. Sargent seek, *inter alia*, equitable remedies with respect to the Class as a whole.

G. Common questions predominate and the class action device is superior, making certification appropriate: FED.R.CIV.P. 23(b)(3)

145. The common questions of law and fact enumerated above predominate over questions affecting only individual members of the Class and a class action is the superior method for fair and efficient adjudication of the controversy. The likelihood that individual members of the Class will have the necessary resources to prosecute separate action is remote due to the time and expense necessary to conduct such complex litigation in relation to each person's individual potential recovery. The prosecution of this action as a class action will conserve the resources of the judicial system and ensure consistent judgment for the Secretary as well as for Medicare beneficiaries. Plaintiff's counsel foresee little difficulty in the management of this case as a class action.

IX. CAUSES OF ACTION

COUNT I
Violation of 42 U.S.C. §405(g)
(contrary to law)

146. Plaintiff hereby incorporates paragraphs 1-145 herein.

147. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

148. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

149. Paragraphs 1-148 are incorporated by reference as if fully set forth herein.

150. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

151. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

152. Paragraphs 1-151 are incorporated by reference as if fully set forth herein.

153. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

154. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or
limitations or short of statutory right)

155. Paragraphs 1-154 are incorporated by reference as if fully set forth herein.

156. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

157. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that a CGM and its related supplies covered durable

medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

158. Paragraphs 1-157 are incorporated by reference as if fully set forth herein.

159. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

160. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law (e.g., notice and comment required for modification of LCDs) and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

161. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

162. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

163. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that a CGM and its

related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VII
28 U.S.C § 2201
(declaratory judgment)

164. Paragraphs 1-163 are incorporated by reference as if fully set forth herein.

165. An actual, present and justiciable case or controversy exists between Plaintiffs and the Secretary as to whether CGMs (including particularly the Medtronic MiniMed and the Dexcom devices) are covered durable medical equipment under the statutes and regulations.

166. Plaintiffs seek a declaration from this Court that CGMs generally (whether they completely replace finger sticks or not) and, in particular, the Medtronic MiniMed and Dexcom devices are covered durable medical equipment under the statutes and regulations.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) finding that CGMs (whether they completely replace finger prick/test strips or not) are: 1) DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202; 2) medically reasonable and necessary for the class; and 3) not otherwise excluded from coverage;

(3) directing Defendants to provide coverage for CGMs for the class member' claims;

(4) declaring that the Medtronic MiniMed and Dexcom CGMs are durable medical equipment; and

(5) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not DME is not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Provide such further and other relief this Court deems appropriate.

Dated: December 13, 2018

Respectfully submitted,

/s/Jeffrey Blumenfeld
D.C. Bar No. 181768
LOWENSTEIN SANDLER LLP
2200 Pennsylvania Avenue, NW
Washington, DC 20037
Telephone: (202) 753-3800
Facsimile: (202) 753-3838
jblumenfeld@lowenstein.com

Attorneys for Plaintiffs

Of Counsel, Pro Hac Vice Admission Subject to Motion:

PARRISH LAW OFFICES
James C. Pistorino
788 Washington Road
Pittsburgh, PA 15228
Telephone: (412) 561-6250
Facsimile: (412) 561-6253
james@dparrishlaw.com

Attorneys for Plaintiffs