UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, *ex rel.*
JENNIFER BUTH, f/k/a JENNIFER DENK,

Plaintiffs,

v. Civil Action, File No. 09-CV-720

PHARMERICA CORPORATION,

Defendant.

UNITED STATES OF AMERICA,
STATE OF FLORIDA, and
COMMONWEALTH OF MASSACHUSETTS,
ex rel. ERIC BEEDERS and LESA MARTINO,

Plaintiffs,

v. Civil Action, File No. 11-CV-706

PHARMERICA CORPORATION as successor
in interest to Integrity Pharmacy Services, LLC,

Defendant.

COMPLAINT OF THE UNITED STATES

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1. The United States hereby brings this action against defendant long-term care pharmacy PharMerica Corporation ("PharMerica") to recover civil penalties under the

Controlled Substances Act, 21 U.S.C. § 801 (the "CSA"), *et seq.*, for dispensing Schedule II controlled substances without a valid prescription from a practitioner.

2. The United States also brings this action under the False Claims Act ("FCA"), 31 U.S.C. 3729 *et seq.*, and the common law, for causing the submission of false claims to Medicare for Schedule II drugs that were dispensed without a valid prescription. The United States seeks to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law theory of unjust enrichment.

3. PharMerica is a long-term care pharmacy that dispenses drugs to residents of nursing homes and other long-term care facilities. Between January 2007 and December 2009, PharMerica serviced approximately 300,000 beds for residents of long-term care facilities and filled approximately 40 million prescriptions annually. Approximately 45% of PharMerica's revenue during this period came from prescription drugs paid for by the Medicare Part D program.

4. Many of the prescriptions filled by PharMerica between January 2007 and December 2009 were for controlled substances listed in Schedule II under the CSA. Schedule II drugs, such as oxycodone and morphine, can cause significant harm if used improperly and have a high potential for abuse.

5. PharMerica filled prescriptions for residents of long-term care facilities based only on requests from the long-term care facility, rather than dispensing Schedule II drugs upon a valid prescription from a practitioner. The manner in which PharMerica circumvented the requirements of the CSA took many different forms. In some cases, PharMerica filled prescriptions based solely on order forms it received from staff at long-term care facilities even

though these forms did not originate from a treating practitioner and did not contain a practitioner's signature. In some cases, PharMerica filled prescriptions for Schedule II drugs based solely on a resident's previous hospital discharge order provided by the long-term care facility staff. In some cases, PharMerica dispensed Schedule II drugs after receiving replenishment stickers that PharMerica had previously provided to the long-term care facility. In all of these cases and others, PharMerica dispensed Schedule II controlled substances to Medicare beneficiaries and others without a valid prescription from a practitioner.

6. PharMerica's actions violated both the spirit and the letter of the CSA by enabling nursing home staff to order narcotics, and pharmacists to dispense these narcotics, without confirmation that a practitioner had exercised his/her medical judgment about whether these controlled substances were issued for a legitimate medical purpose and appropriate in form, strength and quantity for the resident. PharMerica violated the CSA each time it dispensed or distributed a Schedule II controlled substance without a valid prescription as required under the statute. Each instance was a violation of 21 U.S.C. § 842(a)(1) and is subject to a civil penalty of up to $25,000 for each violation.

7. After dispensing Schedule II drugs without a valid prescription, PharMerica then caused claims for these drugs to be submitted to the Medicare program. PharMerica did so notwithstanding that it knew or recklessly disregarded the fact that: (i) Schedule II controlled substances could not be legally dispensed without a valid prescription; (ii) many of PharMerica's pharmacies were dispensing Schedule II controlled substances without a valid prescription; and (iii) drugs dispensed without a valid prescription are not payable under Medicare Part D. As a direct, proximate and foreseeable result of PharMerica's dispensing of Schedule II drugs without

a valid prescription, PharMerica knowingly caused false claims to be submitted to the Medicare program and made or caused false statements to be made that were material to such claims.

I. JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1345 and 1355, as well as the civil provisions of the CSA, 21 U.S.C. § 842(c)(1). The Court has supplemental jurisdiction to entertain the common law cause of action under 28 U.S.C. § 1367(a).

9. The Court may exercise personal jurisdiction over PharMerica, and venue is appropriate in this Court pursuant to 31 U.S.C. § 3732(a), because PharMerica transacts business in the Eastern District of Wisconsin and caused false claims to be submitted in this District.

II. THE PARTIES

10. Plaintiff United States of America ("United States"), acting through the Department of Justice and delegated to the Drug Enforcement Administration ("DEA"), regulates the distribution of controlled substances under the authority of the CSA, 21 U.S.C. §§ 801, *et seq*. Additionally, the United States, acting through the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), administers the Medicare Part D Program.

11. Relator Jennifer Buth, formerly known as Jennifer Denk, is a resident of Wisconsin. Ms. Buth is a pharmacist licensed in the State of Wisconsin and was employed by Defendant PharMerica as a Pharmacy Operations Manager in PharMerica's facility in Pewaukee, Wisconsin.

12. Relator Eric Beeders is a resident of Florida. Mr. Beeders was employed by PharMerica's predecessor-in-interest company, Integrity Pharmacy Services, as a pharmacist in its facility in Largo, Florida.

13. Relator Lesa Martino is a resident of Florida. Ms. Martino was employed by PharMerica's predecessor-in-interest company, Integrity Pharmacy Services, as a pharmacist in its facility in Largo, Florida.

14. Defendant PharMerica Corporation is a Delaware corporation whose principal business is providing pharmacy services to residents in long-term care facilities. PharMerica's principal place of business is at 1901 Campus Place, Louisville, Kentucky 40299. PharMerica operates approximately 95 pharmacies in the United States and conducts extensive business in, among other places, Wisconsin, Florida, California and Colorado. Each pharmacy operated and controlled by Defendant PharMerica is individually registered with the DEA pursuant to 21 U.S.C. §§ 822 and 823.

15. At all times relevant to this complaint, Defendant operated a pharmacy that conducted business at N29 W2371 Woodgate Ct., Pewaukee, Wisconsin (DEA #BP9444136).

16. At all times relevant to this complaint, Defendant operated a pharmacy that conducted business at 735 W. Highway 434, Suite B., Longwood, Florida (DEA #BP5703788).

17. At all times relevant to this complaint, Defendant operated a pharmacy that conducted business at 557 Burbank St., #Q, Broomfield, Colorado (DEA #BP5723449).

18. At all times relevant to this complaint, Defendant operated a pharmacy that conducted business at 45 E. Dana St., Suite B, Mountain View, California (DEA #FK0624571).

19. Any and all acts alleged herein to have been committed by PharMerica were committed by officers, directors, employees, representatives or agents who at all times acted on behalf of PharMerica and within the course and scope of their employment.

20. Integrity Pharmacy Services, LLC was an institutional pharmacy based in Largo, Florida which operated pharmacies in Florida, Pennsylvania and the Commonwealth of Massachusetts. Its principal business was providing pharmacy services to residents of long-term care facilities.

21. Effective December 31, 2009, PharMerica, through a wholly-owned subsidiary, acquired all of the interests in Integrity Pharmacy Services, LLC for $38.0 million in cash plus $3.3 million to pay off outstanding promissory notes. PharMerica completed its acquisition of Integrity Pharmacy Services on or about January 4, 2009.

22. Defendant PharMerica is the successor-in-interest to Integrity Pharmacy Services, LLC and has assumed its rights, duties and liabilities.

III. THE CONTROLLED SUBSTANCES ACT

23. The CSA regulates entities that dispense controlled substances by establishing controls over all stages of the chain of distribution of controlled substances in the United States, including practitioners and pharmacies, through a closed and monitored system which makes it unlawful to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA. 21 U.S.C. § 801 *et seq.* The Attorney General is authorized to promulgate regulations for "the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821.

24. Under the CSA, "controlled substances are strictly regulated to ensure a sufficient supply for legitimate medical . . . purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under the proper circumstances." 75 Fed. Reg. 61,613 – 61,617 (Oct. 6, 2010) (DEA Policy Statement, "Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies").

25. Controlled substances are organized into schedules according to the characteristics of each substance: drugs included in Schedule I have the greatest potential for abuse and do not have legitimate medical uses, whereas drugs included in Schedule V have legitimate medical uses and have the least potential for abuse. 21 U.S.C. § 812. Schedule II controlled substances have a high potential for abuse but also have a currently accepted medical use in medical treatment in the United States, but with significant restrictions because of their potential for abuse. 21 U.S.C. § 812(b)(2).

26. Entities that dispense controlled substances are required to have a valid DEA registration number and are referred to by DEA regulations as a "registrant." 21 C.F.R. §§ 1301.11(a) and 1300.01.

27. Under the CSA, a practitioner is a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist or a pharmacy. 21 C.F.R. § 1300.01(b)(7).

28. The CSA prohibits any manufacturer, distributor, or dispenser, including a pharmacy, from distributing or dispensing a controlled substance without a valid prescription. 21 U.S.C. § 829(a) and (b). For Schedule II controlled substances, the CSA requires that the prescription be in writing except that a practitioner may give an oral prescription in an emergency situation. 21 U.S.C. § 829(a).

29. All prescriptions for controlled substances shall:

(a) be dated as of, and signed on, the day when issued;

(b) bear the full name and address of the patient;

(c) bear the drug name, strength, dosage form, quantity prescribed and directions for use; and,

(d) bear the name, address and registration number of the practitioner.

21 C.F.R. § 1306.05.

30. For Schedule II controlled substances, the dispensing pharmacy must have an original written prescription signed by the practitioner or, in an emergency situation, an oral prescription from the practitioner prior to dispensing the drug. 21 C.F.R. § 1306.11(a) and (d). For purposes of nursing home residents, a valid prescription that is transmitted via facsimile to the pharmacy serves as the original written prescription. 21 C.F.R. § 1306.11(f).

31. Under the CSA, no prescription for a Schedule II controlled substance may be refilled. 21 U.S.C. § 829(a). A new prescription is required.

32. In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving an oral authorization of a prescribing practitioner, provided that:

a. The oral prescription must be from the prescribing individual practitioner;

b. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during only the emergency period;

c. The pharmacist shall immediately reduce the prescription to a writing that meets the requirements of 21 C.F.R. § 1306.05, except for the signature of the prescribing individual practitioner; and

d. The pharmacy must receive a written prescription from the prescribing individual practitioner within seven (7) days of the oral prescription.

21 C.F.R. § 1306.11(d).

33. An emergency situation means those situations in which the practitioner determines that immediate administration of a controlled substance is necessary for proper treatment and there are no appropriate alternative treatments available. 21 C.F.R. § 290.10.

34. Each element of a valid prescription must be specified by the prescribing practitioner and cannot be delegated to an employee or other agent of the practitioner. 75 Fed. Reg. 61,613, 61,614 (Oct. 6, 2010).

35. Prescriptions for Schedule II controlled substances are valid only for 60 days. 21 C.F.R. § 1306.13(b).

36. If a pharmacy dispenses a controlled substance without a valid prescription, it is liable for a civil penalty of up to $25,000 for each violation. 21 U.S.C. §§ 842(a)(1) and 842(c)(1).

IV. THE UNIFORM CONTROLLED SUBSTANCES ACT

37. The Uniform Controlled Substances Act ("Uniform CSA") was originally drafted by the United States Department of Justice in 1969 and promulgated by the National Conference

of Commissioners on Uniform State Laws in 1970. One of the stated goals in promulgating the Uniform CSA was to foster parallel law between the states and the federal government. The Uniform Act was updated in 1990, and again in 1994, to incorporate relevant changes made in the federal CSA.

38. Nearly every state in the United States, along with the District of Columbia, Guam, the Virgin Islands, and Puerto Rico, has adopted either the 1970, 1990 or 1994 Version of the Uniform Act. Because the Uniform CSA was modeled after the federal drug laws, the provisions in the federal CSA are very similar to the provisions that exist in state law.

39. Every state and territory in the United States has adopted the federal practice of organizing controlled substances into schedules according to the characteristics of each substance. Consistent with the Uniform CSA, every state and territory in the United States has enacted laws which provide that Schedule II controlled substances cannot be legally dispensed absent a valid prescription from a licensed practitioner.

40. Although the definition of a valid prescription varies slightly across jurisdictions, every state and territory in the United States prohibits the dispensing of a Schedule II controlled substance in non-emergency situations without a written hard-copy or electronic prescription issued by a licensed practitioner.

41. For example, Wisconsin law provides that "no controlled substance included in schedule II may be dispensed without the written hard copy or electronic prescription of a practitioner." Wis. Stat. § 961.38. "All prescription orders shall specify . . . the name and quantity of the drug product or device prescribed . . . and . . . the signature of the practitioner." Wis. Stat. § 450.11.

42. Similarly, Florida law provides that "[a] prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner," and further provides that written prescriptions must be "dated and signed by the prescribing practitioner on the day when issued," and "must include the name of the controlled substance prescribed and the strength, quantity, and directions for use thereof." Fla. Stat. § 893.04(1).

43. Similarly, California law provides that "[e]ach prescription for a controlled substance classified in Schedule II, III, IV, or V . . . shall meet the following requirements: (1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number . . . and the name, quantity, strength, and directions for use of the controlled substance prescribed." Cal. Health & Safety Code § 11164.

44. In those circumstances that qualify as an emergency under state and/or federal law, states and territories in the United States permit an exception for the dispensing of Schedule II controlled substances without a written prescription but nonetheless prohibit pharmacies from dispensing Schedule II controlled substances absent the oral authorization of a prescribing practitioner that is promptly reduced to writing by the pharmacist. *See, e.g.* Wis. Stat. § 961.38(2); Fla. Stat. § 893.04(1); Cal. Health & Safety Code § 11167; C.R.S. § 18-18-414(b).

V. THE FALSE CLAIMS ACT

45. The False Claims Act provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)-(2), as amended by 31 U.S.C. §§ 3729(a)(1)(A)-(B).

46. To show that an entity acted "knowingly" under the False Claims Act, the United States must prove that the entity, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. The United States does not have to prove that the entity had the specific intent to defraud the United States. 31 U.S.C. § 3729(b), as amended by 31 U.S.C. § 3729(b)(1).

VI. PAYMENT OF CLAIMS UNDER THE MEDICARE PART D PROGRAM

47. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a). Prior to passage of the Act, with a few limited exceptions, Medicare did not cover outpatient prescription drugs. The new Medicare prescription drug benefits program became effective January 1, 2006. 42 U.S.C. § 1395w-101(a)(2).

48. Unlike coverage in Medicare Parts A and B, Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan "Sponsors" to administer prescription drug plans.

49. Part D benefits are delivered by a Part D Plan Sponsor, which is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-inclusive Care for the Elderly ("PACE")

organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

A. Part D Plan Sponsors Submit Prescription Drug Events for Drugs Covered under Medicare Part D

50. When a pharmacy such as PharMerica dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary.

51. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

52. The PDE includes 37 separate fields of data, including information on the service provider of the drug (fields 10 and 11), the prescriber of the drug (fields 13 and 14), the quantity dispensed and days supply of the drug (fields 18 and 19), and whether or not the drug is covered under the Medicare Part D benefit (field 22).

53. Payments to a Part D Plan Sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors for qualified prescription drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

54. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. CMS relies on the information in all 37 data fields of a PDE record to process

payments and to validate claims. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" at 5-6 (April 27, 2006).

55. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. The data contained in PDEs are data related to the payment of claims.

56. In addition, CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

B. CMS Makes Three Types of Payments to Part D Plan Sponsors

57. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

58. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

59. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R.

§ 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies ("LICS") and are documented and reconciled using PDE data submitted to CMS.

60. The reinsurance subsidy is paid to the Part D Plan Sponsor to cover the Government's share of drug costs above an enrollee's catastrophic threshold.

61. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for correcting submitted PDE data it determines erroneous. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" at 4 (April 27, 2006).

62. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs to calculate final payments and risk sharing amounts. CMS determines the Sponsor's actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records.

C. Part D Plan Sponsors and Their Contractors Certify Compliance with all Applicable Federal Laws, Regulations and CMS Instructions.

63. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors (including pharmacies) are required to comply with all applicable federal laws, regulations, as well as CMS instructions.

64. By statute, all contracts between a Part D Plan Sponsor and the Department of Health and Human Services must include a provision whereby the Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

65. Medicare Part D Plan Sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1).

66. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

67. PharMerica, as a subcontractor provider for Part D Plan Sponsors, is required to comply with all applicable federal laws, regulations, and CMS instructions, which include the CSA, the Social Security Act, and regulations that define the requirements of a valid prescription. 42 C.F.R. § 423.505(i)(4)(vi).

68. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to the payment. This provision, entitled "Certification of data that determine payments," provides in relevant part, as follows:

> (1) General Rule. As a condition for receiving a monthly payment . . . the Part D Plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
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> …
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> (3) Part D Sponsor Certification of Claims Data: The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are

> accurate, complete and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1) & (3).

69. All approved Part D Plan Sponsors who received payment under Medicare Part D in benefit years 2007, 2008 and 2009, submitted the required attestations for data submitted that related to payment. 42 C.F.R. § 423.505(k).

70. The "Certification of data that determine payments" provision of the applicable regulation further provides: "[i]f the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

71. Compliance with the requirement that PDE data is "true, accurate, and complete" is a condition of payment under the Medicare Part D program.

72. PDEs submitted to Medicare for Schedule II drugs dispensed without a valid prescription do not contain accurate, complete and truthful information about all data related to payment.

VII. THE SOCIAL SECURITY ACT PROHIBITS PAYMENT FOR CONTROLLED SUBSTANCES DISPENSED WITHOUT A VALID PRESCRIPTION

73. It is a precondition for payment under Medicare Part D that prescription drugs provided to Medicare beneficiaries be dispensed upon a valid prescription under the law.

74. Under Medicare Part D, CMS will only pay for drugs that meet the definition of "covered Part D drug."

75. A "covered Part D drug" is a drug that "may be dispensed only upon a prescription." 42 U.S.C. § 1395w-102(e). A prescription drug is not a "covered Part D drug" unless it is dispensed upon a valid prescription.

76. A Part D sponsor may only provide benefits for Part D prescription drugs if those drugs are dispensed upon a valid prescription in accordance with law. A valid prescription is one that complies with all applicable state law requirements constituting a valid prescription.

VIII. PHARMERICA DISPENSED SCHEDULE II CONTROLLED SUBSTANCES WITHOUT VALID PRESCRIPTIONS

77. PharMerica contracts with long-term care facilities (such as nursing homes) to provide the residents of those facilities with medications, including Schedule II controlled substances.

78. PharMerica conducts its business of providing medications to long-term care facilities through local, "closed door" pharmacies, meaning that those pharmacies only provide services to contracted long-term care facilities and do not provide any retail pharmacy services.

A. PharMerica's Practice of Dispensing Schedule II Drugs

79. At all times relevant to the complaint, the PharMerica pharmacies engaged in the following practices when dispensing Schedule II controlled substances to residents of long-term care facilities in non-emergency situations:

a. When a resident needed either a new Schedule II drug or needed additional Schedule II drugs that the resident had already been taking, an employee of the long-term care facility either called the pharmacy or, most often, sent a facsimile request. The requests most often took the form of "Prescription Fax Request" sheets, "EZ Refill" forms, or monthly physician orders from the

resident's chart at the facility, and came from long-term care facility staff, and not the treating physician. The requests rarely, if ever, contained the elements of a valid prescription, such as the practitioner's signature and the quantity of the medication requested.

b. Upon receipt of a request for a Schedule II drug from the long-term care facility, PharMerica dispensed the drugs to the facility and the PharMerica pharmacist simultaneously created a template and sent it to the resident's physician for signature. At this stage, the pharmacist had to exercise his/her own judgment regarding key elements of the prescription, such as the quantity prescribed.

c. In many of these cases, the templates created by the PharMerica pharmacist were not returned. In those cases where the PharMerica generated template was signed and returned by the physician, it was typically returned after the drug was dispensed to the long-term care facility.

80. Such practices are not permitted under the CSA or its state analogs, and the Schedule II controlled substances dispensed under these circumstances were not dispensed upon a valid prescription under applicable law.

B. PharMerica's Practices were Widespread and Existed Nationwide.

81. The practices described above were employed at PharMerica pharmacies across the country, including at PharMerica's facility located at N29 W2371 Woodgate Ct., Pewaukee, Wisconsin ("PharMerica-Pewaukee"). Between at least 2007 and 2009, employees at PharMerica-Pewaukee received faxed documents from long-term care facilities requesting

Schedule II drugs. Many of these requests did not indicate the quantity of the drug to be dispensed and did not contain a practitioner's signature. Employees at PharMerica-Pewaukee assigned quantities to the orders (usually a 60-day supply) and processed the requests. Even though these were not emergency situations, PharMerica-Pewaukee partially filled the orders by dispensing 3-day so-called "emergency" supplies of Schedule II drugs, and simultaneously generated templates to send to a practitioner for a signature. PharMerica-Pewaukee continued to dispense additional Schedule II drugs out of the 60-day supply regardless of whether the practitioner had returned the template with a signature. Unsigned templates typically remained in an accordion folder in the office and employees occasionally re-faxed the unsigned templates to the practitioner for a signature. Eventually, unsigned templates were removed from the accordion file and placed into boxes in an unmarked storeroom called the "Harry Potter" room. By 2009, the so-called Harry Potter room at PharMerica-Pewaukee contained multiple boxes full of unsigned templates for Schedule II drugs.

82. Similar practices were also followed at the PharMerica pharmacy located at 45 E. Dana St., in Mountain View, California ("PharMerica-Mountain View"). Between at least 2007 and 2009, PharMerica employees at PharMerica-Mountain View received requests for Schedule II drugs from staff and nurses at long-term care facilities. Even though these were not emergency situations, PharMerica-Mountain View dispensed 3-day so-called "emergency" supplies of Schedule II drugs and generated templates to be sent to a practitioner. Many of these templates were not returned, and by 2009, PharMerica-Mountain View had over 200 outstanding unsigned templates for drugs that had been illegally dispensed to residents of long-term care facilities.

83. Similar practices were also followed at the PharMerica pharmacy located at 735 W. Highway 434, in Longwood, Florida ("PharMerica-Longwood"). Between at least 2007 and 2009, PharMerica employees at PharMerica-Longwood received telephone or fax admission orders for Schedule II drugs from staff and nurses and long-term care facilities. Many of the documents that facilities used to initiate a Schedule II dispensation did not list the quantity of the drug, and so employees at PharMerica-Longwood assigned quantities to the orders. Even though these were not emergency situations, PharMerica-Longwood dispensed 3-day so-called "emergency" supplies of the Schedule II drugs and sent them to the facility along with a card of refill stickers. PharMerica-Longwood then generated templates for a 3-day "emergency" supply and for a 60-day maintenance supply of the Schedule II drug and sent those templates in order to obtain the signature of a practitioner.

84. By engaging in these practices at these PharMerica pharmacies and others, PharMerica dispensed thousands of Schedule II controlled substances without a valid prescription and in violation of the Controlled Substances Act.

85. Over a combined period of eight months (May 2008, and from September 2008 through March 2009), PharMerica-Pewaukee dispensed Schedule II controlled substances at least 4285 times without a valid prescription and in violation of the Controlled Substances Act.

86. In February 2009, PharMerica-Mountain View dispensed Schedule II controlled substances at least 282 times without a valid prescription and in violation of the Controlled Substances Act.

87. In November 2008, the PharMerica pharmacy in Longwood, Florida, dispensed Schedule II controlled substances at least 43 times without a valid prescription and in violation of the Controlled Substances Act.

88. In November 2008, the PharMerica pharmacy in Broomfield, Colorado, dispensed Schedule II at least 22 times without a valid prescription and in violation of the Controlled Substances Act.

IX. THE SUBMISSION OF FALSE CLAIMS TO THE MEDICARE PROGRAM

89. During the relevant time period, PharMerica dispensed thousands of Schedule II controlled substances to Medicare beneficiaries in long-term care facilities without a valid prescription.

90. PharMerica knowingly made, or caused to be made, false or fraudulent PDEs that, among other things: (i) inaccurately or incompletely designated these drugs as covered Part D drugs, (ii) inaccurately or incompletely represented that these drugs were dispensed upon a valid prescription, and (iii) inaccurately or incompletely identified the prescriber of the drug and the prescriber's instructions.

91. PharMerica knowingly caused Part D Plan Sponsors to submit false or fraudulent claims to Medicare for Schedule II drugs that had been dispensed without a valid prescription.

92. PharMerica knowingly caused Part D Plan Sponsors to submit false certifications to Medicare that were material to the payment of claims.

93. Between January 1, 2007 and December 31, 2009, PharMerica caused false or fraudulent claims to be submitted on at least 250 occasions where Schedule II drugs were dispensed by PharMerica without a valid prescription. These false claims include PDEs for

Schedule II drugs dispensed from 61 PharMerica pharmacies across 28 states. Because these 250 false or fraudulent PDEs for drugs paid by the Medicare program and the following three examples include beneficiary-specific information protected by the Health Insurance Portability and Accountability Act, this list will be provided separately to PharMerica and the patients identified below are referred to by their initials.

A. First Example of a False Claim Caused to be Submitted by PharMerica (Patient MLW)

94. On January 12, 2008, a long-term care facility faxed a "medical reorder sheet" to a PharMerica pharmacy in Meridian, Idaho, that included a request for fentanyl patches, a Schedule II drug, for Patient MLW. This faxed documentation was not a valid prescription because, among other reasons, it was not initiated or signed by a practitioner.

95. The PharMerica pharmacy in Meridian dispensed 5 fentanyl patches for Patient MLW on January 12, 2008. The fentanyl patches were not dispensed in an emergency situation and there was no record of an oral communication from a licensed prescriber. These drugs were dispensed without a written prescription in violation of the CSA.

96. The only prescription that PharMerica had on file for fentanyl for Patient MLW was dated May 16, 2006, and therefore had long since expired and could not be the basis of a legal prescription under 21 C.F.R. § 1306.13(b).

97. PharMerica submitted a request for payment to Patient MLW's Part D plan, Humana Insurance Company ("Humana") and received payment for 5 fentanyl patches dispensed to Patient MLW.

98. Humana submitted PDE data to CMS for the 5 fentanyl patches that were dispensed to Patient MLW, and CMS made payments to Humana in reliance on the submission of this PDE data.

99. The fentanyl patches dispensed to Patient MLW were ineligible for payment under Medicare Part D as covered Part D drugs because they were not dispensed upon a valid prescription and were not dispensed in a manner consistent with federal and state law.

100. The PDE data that Humana sent to CMS for the fentanyl patches dispensed to Patient MLW was false, inaccurate and incomplete.

101. PharMerica caused Humana to submit a false claim to CMS, and in turn caused CMS to make payments to Humana for the 5 fentanyl patches dispensed to Patient MLW. As a result of this conduct, the Government suffered damages in the amount of $74.33.

B. Second Example of a False Claim Caused to be Submitted by PharMerica (Patient MRB)

102. On October 13, 2009, a long-term care facility faxed a "medication reorder sheet" to the PharMerica pharmacy in Monrovia, California, that included a request for duragesic patches, a schedule II drug, for Patient MRB. This faxed documentation was not a valid prescription because, among other reasons, it was not initiated or signed by a practitioner.

103. The PharMerica pharmacy in Monrovia dispensed 10 duragesic patches to the long-term care facility for Patient MRB on October 15, 2009. The duragesic patches were not dispensed in an emergency situation and there was no record of an oral communication from a licensed prescriber. These drugs were dispensed without a valid prescription in violation of the CSA.

104. PharMerica submitted a request for payment to Patient MRB's Part D plan, Unicare Life and Health Insurance Company ("Unicare"), and received payment for the 10 duragesic patches dispensed to Patient MRB.

105. Unicare submitted PDE data to CMS for the 10 duragesic patches that were dispensed to Patient MRB, and CMS made payments to Unicare in reliance on the submission of this PDE data.

106. The duragesic patches dispensed to Patient MRB were ineligible for payment under Medicare Part D as covered Part D drugs because they were not dispensed upon a valid prescription and were not dispensed in a manner consistent with federal and state law.

107. The PDE data that Unicare sent to CMS for the duragesic patches dispensed to Patient MRB was false, inaccurate and incomplete.

108. PharMerica caused Unicare to submit a false claim to CMS, and in turn caused CMS to make payments to Humana for the 10 duragesic patches dispensed to Patient MRB. As a result of this conduct, the Government suffered damages in the amount of $150.14.

C. Third Example of a False Claim Caused to be Submitted by PharMerica (Patient LMW)

109. On or about April 8, 2008, a long-term care facility faxed a request to the PharMerica pharmacy in Greensboro, North Carolina, that included a request for duragesic patches, a Schedule II drug, for Patient LMW. This faxed documentation was not a valid prescription because, among other reasons, it was not initiated or signed by a practitioner.

110. The PharMerica pharmacy in Greensboro dispensed 5 duragesic patches to the long-term care facility for Patient LMW on May 19, 2008. The duragesic patches were not

dispensed in an emergency situation and there was no record of an oral communication from a licensed prescriber.

111. PharMerica submitted a request for payment to Patient LMW's Part D plan, Silverscript Insurance Company ("Silverscript"), and received payment for the 5 duragesic patches dispensed to Patient LMW.

112. Silverscript submitted PDE data to CMS for the 5 duragesic patches that were dispensed to Patient LMW, and CMS made payments to Silverscript in reliance on the submission of valid PDE data.

113. The duragesic patches dispensed to Patient LMW were ineligible for payment under Medicare Part D as covered Part D drugs because they were not dispensed upon a valid prescription and were not dispensed in a manner consistent with federal and state law.

114. The PDE data that Silverscript sent to CMS for the duragesic patches dispensed to Patient LMW was false, inaccurate and incomplete.

115. PharMerica caused Silverscript to submit a false claim to CMS, and in turn caused CMS to make payments to Silverscript for the 5 duragesic patches dispensed to Patient LMW. As a result of this conduct, the Government suffered damages in the amount of $48.79.

X. PHARMERICA'S PRACTICES REGARDING NARCOTIC BOXES VIOLATED THE CSA

116. At all times relevant to the compliant, PharMerica also dispensed Schedule II drugs to residents of long-term care facilities through "narcotic boxes" or so-called "emergency kits" that were located in the long-term care facilities. The narcotic boxes contained small quantities of several drugs, including Schedule II drugs, that are intended to be used by the long-

term care facility only in the situation where a resident encounters an emergency, as defined by 21 C.F.R. § 290.10, and there is not sufficient time to get a prescription filled by the pharmacy.

117. In order to properly dispense Schedule II controlled substances from a narcotic box, the CSA's requirements for an emergency prescription must be met. To wit, there must be an emergency (as defined by 21 C.F.R. § 290.10) and the practitioner is required to either (1) submit a written prescription to the pharmacy or (2) give the pharmacy an oral prescription prior to the drug being dispensed and then provide the pharmacy with a written prescription within seven (7) days of dispensing the medication.

118. PharMerica provided staff at long-term care facilities with access to narcotic boxes for emergency situations but did not ensure that the prescriber had an oral communication with a PharMerica pharmacist prior to dispensing the Schedule II drug.

119. Once the drug was dispensed from a narcotics box, PharMerica routinely failed to obtain written prescriptions from the prescriber within 7 days as required under the CSA.

120. There were at least 1,660 instances where PharMerica dispensed Schedule II drugs from narcotic boxes without a valid a prescription.

121. The PharMerica pharmacy in Pewaukee, Wisconsin, caused Schedule II controlled substances to be dispensed without a valid prescription at least 1,549 times from narcotic boxes in long-term care facilities between October 2008 and July 2009.

122. The PharMerica pharmacy in Longwood, Florida, caused Schedule II controlled substances to be dispensed without a prescription at least 90 times from narcotic boxes in long term care facilities in November 2008.

123. The PharMerica pharmacy in Broomfield, Colorado, caused Schedule II controlled substances to be dispensed without a prescription at least 21 times from narcotic boxes in long term care facilities in November 2008.

XI. PHARMERICA'S KNOWLEDGE OF THE CSA AND THE MEDICARE RULES, AND ITS VIOLATION OF THOSE RULES

124. Since at least February 2000, PharMerica has been on notice that its practices for dispensing Schedule II narcotics failed to comply with the CSA and were prohibited by law. In February 2000, diversion investigators from the DEA audited the PharMerica pharmacy located in Indianapolis, Indiana. The audit included a review of PharMerica's practices concerning prescriptions for controlled substances, including Schedule II drugs. Among other things, the audit revealed that PharMerica did not use valid prescriptions to authorize the dispensation of controlled substances. Rather, the pharmacy relied on "medication orders" provided by long-term care facilities. Those medication orders did not contain the prescriber's DEA registration number, the prescriber's address, or the quantity of the drug. The DEA advised PharMerica that its practices for dispensing controlled substances were not in compliance with the CSA.

125. PharMerica pharmacies later implemented a procedure whereby PharMerica employees created a template for the practitioner's signature. Once the pharmacy received a medication request from employees at a long-term care facility, it dispensed the drug to the facility and simultaneously generated a template to be faxed to the practitioner for a signature. This procedure, which is discussed in greater detail above, did not bring PharMerica into compliance with the CSA because PharMerica continued to dispense Schedule II drugs absent a valid prescription from a practitioner.

126. In 2004, PharMerica's Regulatory Affairs Department revised the company's Controlled Substance Policy. In a cover memo that went to the general managers of the pharmacies and to the pharmacists-in-charge, the Director of Regulatory Affairs highlighted the significant changes to the policy. One of the significant changes that she noted was that each pharmacy "must have a valid signed Schedule II prescription PRIOR to dispensing." Specifically, the policy issued by PharMerica (entitled "Dispensing of Controlled Substances," Policy Number TX 11.11) on February 1, 2004, stated in relevant part: "All Schedule II controlled substances may be dispensed after the pharmacist has received a WRITTEN prescription SIGNED and dated (day when issued) by the Prescriber/practitioner."

127. Although PharMerica's February 1, 2004, policy appeared to require a practitioner's signature before a Schedule II drug could be dispensed, the policy also stated that controlled substances could be dispensed immediately if the situation were considered to be an "emergency." It further stated that PharMerica employees needed only to obtain "a single manually signed prescription to cover both the emergency supply and the continuation of the prescription."

128. PharMerica pharmacists routinely dispensed Schedule II drugs on an "emergency" basis so that they could avoid the requirement of waiting for a written prescription prior to dispensing a Schedule II drug and instead try to obtain a signature after the dispensation. For example, PharMerica-Pewaukee issued Schedule II drugs under the pretext of an emergency even though no emergency situation existed.

129. PharMerica's Compliance and Regulatory Affairs Department audited PharMerica's pharmacies for compliance with all laws and regulations, including the CSA's

requirements regarding prescriptions for Schedule II controlled substances. For example, PharMerica's pharmacy in Warren, Michigan, was audited between April 2 and April 4, 2007. Among other things, the auditor noted that:

a. "A review of outstanding Emergency Schedule II prescriptions noted more than #1300 unsigned prescriptions at the time of the audit (oldest from 08/05)."

b. "There is not a process in place to ensure a minimum of three documented attempts are made within the first 30 days to obtain a hard copy Schedule II prescription."

130. In 2007, the PharMerica Compliance and Regulatory Affairs auditor who performed the Warren, Michigan, audit prepared a PowerPoint presentation titled "Identifying Improper Emergency CII Prescriptions." Among other things, the presentation describes PharMerica's practice of using the emergency prescribing rules so that it could easily dispense controlled substances without a prescription. The presentation included a slide that said "[n]o prescription equals false claim." The presentation also stated that only one PharMerica pharmacy reviewed was following the correct procedure.

131. The auditor discussed his concerns regarding PharMerica's dispensing practices during a training meeting with other PharMerica auditors and managers. The auditor's concerns about the practice of sending out Schedule II medications without physician authorization were validated by, among others, the Director of Regulatory Affairs, but these concerns were ultimately not addressed at the corporate level.

132. In May 2008, the PharMerica Compliance Department asked each pharmacy to complete a "regulatory Self Analysis." Multiple pharmacies indicated that they had a significant number of unsigned so-called emergency Schedule II prescriptions, including:

a. Phoenix, Arizona: 297 unsigned prescriptions;

b. Mountain View, California: 200 unsigned prescriptions;

c. Largo, Florida: 325 unsigned prescriptions;

d. Warren, Michigan: 989 unsigned prescriptions; and

e. Pewaukee, Wisconsin: 171 unsigned prescriptions.

133. During the relevant time period, PharMerica knew or recklessly disregarded the facts that: (i) Medicare Part D is administered by Part D Plan Sponsors, (ii) CMS chooses Part D Plan Sponsors to administer the Part D program based on the Sponsor's proposed formularies, premiums and plan design, (iii) CMS makes payments to Part D Plan Sponsors for the cost of providing covered Part D drugs, including premium and cost sharing subsidies on behalf of subsidy-eligible individuals, and (iv) drugs dispensed without a valid prescription are not payable under Medicare Part D.

134. In late 2008, PharMerica hosted a series of teleconferences so it could share its knowledge of the Medicare Part D program with its largest long-term care facility clients. One installment of this series was a teleconference on November 6, 2008 entitled "Introduction to Medicare Part D: Back to the Basics."

135. It was reasonably foreseeable that PharMerica's practice of dispensing Schedule II controlled substances without valid prescriptions to residents of long-term care facilities would

cause false PDEs and false certifications to be submitted to Part D Plan Sponsors and false claims to be paid by Medicare Part D.

Count One
(Controlled Substances Act)

136. The United States realleges and incorporates by reference each allegation in the preceding paragraphs as if fully set forth herein.

137. The PharMerica pharmacies located in Pewaukee, Wisconsin; Longwood, Florida; Broomfield, Colorado; and Mountain View, California failed to comply with the requirements of the CSA by dispensing Schedule II controlled substances without a prescription in violation of 21 U.S.C. §§ 829(a), 842(a)(1) and 21 C.F.R. § 1306.11(a).

138. Each of the above dispensations is in violation of 21 U.S.C. § 842(a)(1), and the defendant is subject to a civil penalty of not more than $25,000 for each violation. 21 U.S.C. § 842(c)(1)(A).

Count Two
(Controlled Substances Act)

139. The United States realleges and incorporates by reference each allegation in the preceding paragraphs as if fully set forth herein.

140. The PharMerica pharmacies located in Pewaukee, Wisconsin; Longwood, Florida; and Broomfield, Colorado failed to comply with the requirements of the CSA by causing controlled substances to be dispensed from narcotic boxes provided to long-term care facilities without a prescription, either written or oral, in violation of 21 U.S.C. §§ 829(a), 842(a)(1) and 21 C.F.R. § 1306.11(a), and 21 C.F.R. § 290.10.

141. Each of the above dispensations is in violation of 21 U.S.C. § 842(a)(1), and the defendant is subject to a civil penalty of not more than $25,000 for each violation. 21 U.S.C. § 842(c)(1)(A).

Count Three
(False Claims Act, 31 U.S.C. § 3729(a)(1)(A), formerly 31 U.S.C. § 3729(a)(1))

142. Plaintiff United States repeats and realleges each allegation in each of the proceeding paragraphs as if fully set forth herein.

143. PharMerica submitted requests for payment to Part D Plan Sponsors for Schedule II controlled substances that were dispensed without obtaining a valid prescription. As a result, PharMerica knowingly caused Part D Plan Sponsors to submit false or fraudulent claims for payment to CMS for Schedule II drugs that were ineligible for payment under the Part D program.

144. By virtue of the acts described above, PharMerica knowingly presented or caused to be presented to an officer or employee of the United States false or fraudulent Medicare claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended by 31 U.S.C. § 3729(a)(1)(A).

145. By reason of the foregoing, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Four
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B), formerly 31 U.S.C. § 3729(a)(2))

146. Plaintiff United States repeats and realleges each allegation in each of the proceeding paragraphs as if fully set forth herein.

147. PharMerica knowingly submitted false information to Part D Plan Sponsors regarding Schedule II controlled substances dispensed to Medicare beneficiaries.

148. PharMerica also knowingly caused Part D Plan Sponsors to submit false certifications that were material to the payment of claims.

149. By virtue of the acts described above, PharMerica knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent Medicare claims, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(2), as amended by 31 U.S.C. § 3729(a)(1)(B).

150. By reason of the foregoing, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Five
(Unjust Enrichment)

151. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

152. The United States claims the recovery of all monies by which PharMerica has been unjustly enriched, including profits earned by PharMerica because of dispensing Schedule II controlled substances without valid prescriptions.

153. By retaining monies received for dispensing Schedule II controlled substances that were paid for by the Medicare Part D program, PharMerica retained money that was the property of Medicare and to which it was not entitled.

154. As a consequence of the acts set forth above, PharMerica was unjustly enriched at the expense of the United States in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States.

Prayer For Relief

WHEREFORE, the United States demands and prays that judgment be entered in favor of the United States as follows:

1. On Counts One and Two for civil monetary penalties for violations of the Controlled Substances Act.

2. On Counts Three and Four under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with such further relief as may be just and proper.

3. On Count Five for unjust enrichment, for the damages sustained and/or amounts by which PharMerica retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.

Demand for Jury Trial

The United States demands a jury trial on each of the issues so triable in this case.

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