SEALED

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. DAVID FRANKLIN, Plaintiff	COMPLAINT
v.	FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730
PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY, Defendant	PLAINTIFF DEMANDS A JURY TRIAL

96-11651PBS

I.
PARTIES

1. David Franklin is a resident of the Commonwealth of Massachusetts and a former employee of Parke-Davis Division of Warner Lambert Company. David Franklin is the original source of the facts and information hereinafter set forth concerning the activities of the defendant. The facts averred herein are based entirely upon his personal observation and documents in his possession.

2. Parke-Davis Division of Warner-Lambert Company (hereinafter "Parke-Davis") is a corporation with its principal place of business in Morris Plains, New Jersey. Parke-Davis is principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug Administration.

II.
JURISDICTION

3. Jurisdiction is based on 31 U.S.C. § 3730.

SEALED

4. At all times material hereto Parke-Davis regularly conducted substantial business within the Commonwealth of Massachusetts, maintained permanent employees and offices, and made and is making significant sales within Massachusetts, and is thus subject to personal jurisdiction in the Commonwealth of Massachusetts pursuant to Massachusetts General Laws C. 223A § 3.

III.
FACTS

5. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source.

6. In 1994 Parke-Davis obtained approval from the U.S. Food and Drug Administration (hereinafter the "FDA") to market the prescription drug gabapentin. Parke-Davis had acquired the patent rights to gabapentin from another company. Those patent rights will expire in the near future, even though FDA approval of the use of the drug was only recently obtained. The FDA approved gabapentin for use as an adjunct to standard antiepileptic drugs in adults, in dosages of 900 to 1800 mg/d. Parke-Davis thereafter began marketing the drug under the brand name "neurontin". The FDA has not approved the use of gabapentin for any other purpose or in any other dosage. The FDA approved use of gabapentin represents a relatively narrow market, since it includes only persons suffering from seizures who are not fully responsive to the usual medications and who require additional medication.

7. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

8. After achieving FDA approval of gabapentin, Parke-Davis formed a scheme to increase the sales of gabapentin while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of gabapentin. The scheme consisted of an elaborate and clandestine promotion of off-label uses of gabapentin, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency, and in particular for the off-label uses of pain control, mono-therapy for seizures using extremely high doses, control of bi-polar disease, attention deficit disorder, and other diseases and conditions.

9. This scheme was carried out by employing, among other things:

a. illegal kickbacks to physicians who prescribed large amounts of gabapentin for "off-label" purposes to patients whose prescriptions were paid for by medicare or medicaid;

b. the formation of a nationwide network of employees falsely referred to as "medical liaisons" whose actual assigned duties consisted entirely of conventional direct sales activities and which did not include any legitimate scientific activity;

c. the illegal direct solicitation of physicians for off-label uses;

d. the making of false statements to physicians and pharmacists concerning the efficacy and safety of gabapentin for off-label uses;

e. the making of such false statements directly to the Veterans Administration concerning the safety and efficacy of gabapentin for off label uses;

f. the charging of full price for drugs actually being used in experimental trials and thus subject to federal price restriction;

g. the systematic avoidance of filing requirements with the FDA;

h. the deliberate avoidance of the FDA's classification of gabapentin as to its therapeutic equivalency and thus the avoidance of medicare and medicaid price limitations based on therapeutic equivalency;

i. the use of active concealment to avoid the FDA's enforcement mechanisms and the resultant mandatory interruption of medicare and medicaid payments for gabapentin prescriptions;

j. the use of active concealment to avoid the "formulary" policies of various state agencies administering medicare and medicaid programs and which are intended to refuse payment for uses of drugs which are not medically recognized as statutorily defined;

k. the payment or offering of gratuities to Parke-Davis employees in order to procure their silence;

l. the active training of Parke-Davis employees in methods of avoiding detection of their activities by the FDA.

10. Parke-Davis' sales of gabapentin are projected to exceed $150 million annually by the end of 1996. Approximately 50% of these sales are accounted for by off-label use of gabapentin. This rapid growth in off-label use of gabapentin is a direct result of Parke-Davis' illegal marketing activities. Of all of the off-label use of gabapentin, more than 50% is accounted for by patients whose prescriptions are paid for, directly or indirectly, by the United States, in the form of reimbursements thru medicare and medicaid, and purchases by the Veterans Administration. The United States is currently paying between $30 and $40 million per year for off-label uses of gabapentin not authorized by the FDA.

11. The off-label uses of gabapentin which are actively being promoted by Parke-Davis are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these off-label uses are

beyond the scope of uses designated by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

12. There is no valid scientific evidence to support the contention that gabapentin is safe and effective for pain, for mono-therapy for seizures, for bi-polar disorder, for attention deficit disorder, for reflex-sympathetic dystrophy, for post-herpetic neuropathy, or for diabetic neuropathy. There is no valid scientific evidence concerning the therapeutic equivalence of gabapentin in any of these diseases. Parke-Davis is currently conducting actual legitimate trials investigating the use of gabapentin for relief of certain types of pain; however, these trials are not complete, and the actual results of these trials have not been made available to any of Parke-Davis' medical liaison employees.

COUNT I
DIRECT SALES TO VETERANS ADMINISTRATION

13. Parke-Davis had sold, and is selling, significant quantities of gabapentin to the Veterans Administration for off-label uses.

14. Parke-Davis is conducting, and has conducted, illegal direct promotion of off-label uses of gabapentin directly to the Veterans Administration. Parke-Davis has a special sales division assigned to the Veterans Administration. That division has, on a nationwide basis, illegally and directly promoted off-label uses of gabapentin to Veterans Administration physicians and pharmacists.

These illegal promotional activities have resulted in greatly increased use of gabapentin by the Veterans Administration. Parke-Davis' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United States and the deliberate active concealment of those violations. Parke-Davis' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729.

15. Parke-Davis' medical liaison and sales personnel have promoted the off-label use of gabapentin by the Veterans Administration by making false and unfounded claims to Veterans Administration physicians and pharmacists concerning the safety and efficacy of gabapentin for off-label uses. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth. Parke-Davis' use of false statements concerning the safety and efficacy of gabapentin used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT II
DELIBERATE AVOIDANCE OF FDA REGULATIONS/
MEDICARE AND MEDICAID FINANCED SALES

16. A significant percentage of patients who use or have used gabapentin for off-label purposes are persons whose prescriptions are paid for in whole or in part by state administered medical assistance programs which receive 90% reimbursement from the federal government, to wit, medicare and medicaid.

17. The medicare and medicaid programs of the federal government include detailed provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full federal participation ("FFP"), price controls on prescription drugs, and drug manufacturer rebate agreements. These laws and regulations include, inter alia, as set forth as 42 U.S.C. § 1395Y(c), that no federal payment shall be made in the case of a prescription drug for which the FDA has issued a notice of hearing regarding the effectiveness of the drug. Thus, the taking of a regulatory action by the FDA against the sale and promotion of a drug will, in circumstances, immediately interrupt the flow of federal funds for reimbursements of prescriptions written for the drug.

18. Direct promotion of off-label usage of a drug constitutes "labeling" as defined by the food and drug laws of the United States. It is reasonably certain, and Parke-Davis is aware, that if the FDA became aware of its extensive program of illegal promotion of off-label uses of gabapentin, the FDA would take administrative action against Parke-Davis, including, among other things, a notice of hearing regarding the effectiveness of gabapentin for the promoted off-label uses. Such a notice would, by federal statute, instantly interrupt the flow of federal funds for reimbursement for off-label prescriptions.

19. Parke-Davis has, as alleged, actively concealed its off-label promotion of gabapentin from the FDA. Said active concealment is motivated by the desire to, and has had the effect

of, preserving the flow of federal funds to reimburse gabapentin prescriptions. Said active concealment constitutes a pattern of fraudulent conduct through which federal payments are derived, and constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT III
AVOIDING FEDERAL PRICE CONTROLS/
EXPERIMENTAL USE OF DRUG

20. Federal law, in particular 21 C.F.R. § 312.7, imposes price controls on investigational new drugs used in clinical trials. The regulations state that charging for an investigational new drug is not permitted without FDA approval.

21. Parke-Davis has launched a nationwide illegal program of experimentation with gabapentin. Although Parke-Davis has actually commenced certain legitimate clinical trials of gabapentin to control pain in limited circumstances, Parke-Davis has simultaneously encouraged and caused many physicians to experiment with gabapentin for off-label uses. These experimental programs are informal, generally unscientific, and not reported to the FDA. Parke-Davis has encouraged these experimental programs with offers to physicians of cash incentives, medical liaison "assistance" in drafting publications, and other benefits. These informal experiments have been conducted for the dual purpose of increasing sales of gabapentin while at the same time developing data for possible use with the FDA. These informal experiments were conducted by means of prescriptions to patients whose prescriptions have been paid for, in a substantial number of cases, by medicare and medicaid at regular prices.

22. Parke-Davis's deliberate avoidance of federal price controls on the experimental investigational use of drugs has caused financial harm to the federal government by inducing the federal government to pay for drug prescriptions for which payment is prohibited by federal law. Parke-Davis' deliberate avoidance of federal price controls on experimental use of drugs constitutes a pattern of fraudulent conduct which induced payments by the federal government, and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT IV
VIOLATING STATE FORMULARIES/
MEDICARE AND MEDICAID

23. Under the statutes and regulations establishing the medicare and medicaid programs, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their medicare programs. Federal law, in particular 42 U.S.C. § 1396r-8, requires a state formulary to include medically accepted uses of prescription drugs by reference to the publications set forth, in ¶ 11, supra.

24. Many state medicare agencies intend not to reimburse for prescription drugs for uses not set forth in the publications referred to in ¶ 11, supra, in that the states do not intend to spend money on prescriptions not recognized as medically necessary in sources specified by federal law. However, many states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical

ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications. This lack of technical ability represents a loop-hole in the scheme of the medicare and medicaid programs.

25. Parke-Davis has recognized and aggressively exploited this loop-hole by means of a direct, illegal, nationwide program of promotion of off-label use of gabapentin by physicians. Parke-Davis has conducted this program of promotion knowing that prescriptions for gabapentin are generally reimbursed by the state medicare programs even though individual prescriptions for gabapentin fall outside of state formularies because they are not medically accepted.

26. Parke-Davis' aggressive, illegal scheme of off-label promotion has induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the federal government, to pay out sums to claimants they did not intend to benefit. Parke-Davis' conduct constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT V
ILLEGAL KICKBACKS

27. Federal laws and regulations governing the medicare and medicaid programs prohibit kick-backs to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

28. As part of its nationwide program of off-label promotion of gabapentin, Parke-Davis has established a system of kick-backs to physicians who are prescribers of large amounts of gabapentin. These kick-backs are administered by the Parke-Davis sales department, and frequently disguised as consultantships although unrelated to any scientific or educational activity. The kick-backs have taken the form of cash payments, travel benefits, entertainment, Olympics tickets, and other benefits. Parke-Davis has established formal internal guidelines for the award of these benefits to physicians which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing gabapentin for off-label uses.

29. These kick-backs are strictly illegal and have had the effect of greatly increasing the amount of gabapentin prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by medicare. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT VI
FALSE STATEMENTS TO PHYSICIANS

30. As part of its illegal off-market promotion of gabapentin, Parke-Davis has instructed and caused its sales personnel and its medical liaison employees to make false

statements to physicians, and to provide physicians with written materials containing false statements, concerning the safety and efficacy of gabapentin for off-label uses. These statements were made with the intent of, and had the effect of, inducing physicians to increase their off-label prescription of gabapentin. This increased off-label prescription of gabapentin caused harm to the federal government by increasing the number of medicare claims for gabapentin prescriptions.

31. The false statements made by Parke-Davis employees to physicians have included representations that scientific evidence exists that gabapentin is an effective remedy for pain, bi-polar disorder, attention deficit disorder, reflex sympathetic dystrophy, post herpetic neuralgia, and mono-therapy for seizures. The false statements also include representations that gabapentin is known to be safeand effective in dosages of up to 4800 mg/d. in all populations. The false statements include representations that clinical trials are ongoing or planned with respect to each of the above off-label uses. Each of these statements is unsupported by any legitimate scientific evidence.

32. Parke-Davis' false statements made to physicians were a pattern of fraud designed to induce payments by the federal government, and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT VII
AVOIDING PRICE CONTROLS
BASED ON THERAPEUTIC EQUIVALENCY

33. The federal laws establishing the medicare and medicaid programs contain drug price controls based on therapeutic

equivalencies, as established by the FDA in an official publication (42 U.S.C. § 1396r-8). Parke-Davis' illegal program of off-label promotion and avoidance of proper FDA procedures for approval of a new drug use has resulted in the lack of any classification of gabapentin for therapeutic equivalency as to its off-label uses, such as pain control and control of bi-polar disorder. In fact, gabapentin is relatively ineffective for pain control, bi-polar disorder, or mono-therapy for seizures. As a result, gabapentin has not been subject to federal medicare price limits based on therapeutic equivalency.

34. The federal government has been harmed by this avoidance of a rating of gabapentin for therapeutic equivalency because other less expensive drugs are capable of conferring the same benefit as gabapentin for various off-label uses. If gabapentin were properly rated for therapeutic equivalency, the states and the federal government would be able to achieve the same benefits for less money.

35. Parke-Davis's illegal scheme of off-label promotion is a deliberate avoidance of federal price controls based on therapeutic equivalency, and constitutes inducement of federal payments through a pattern of fraudulent conduct and constitutes a False Claim within the meaning of 31. U.S.C. § 3729.

COUNT VIII
FRUSTRATION OF FEDERAL POLICY

36. All of the conduct referred to above, to wit, off-label promotion of gabapentin in violation of FDA rules, payment of

illegal kick-backs to physicians, deliberate avoidance of federal price controls of experimental drugs and drugs with therapeutic equivalents, inducement of physicians and the Veterans Administration to prescribe or purchase gabapentin by use of false statements, and avoidance of state formulary restrictions, are substantial and deliberate frustrations of clear federal law, regulation, and policy concerning the promotion and sale of prescription drugs.

37. Parke-Davis has sold more than $50 million of gabapentin knowing that such sales were directly or indirectly paid for by the federal government, and knowing that such sales and the promotions leading to them represented a direct frustration and violation of federal law, regulation and policy, and knowing that the federal government was paying out sums on behalf of beneficiaries it did not intend to benefit, to wit, veterans and medicare and medicaid patients who were prescribed experimental or off-label uses of gabapentin as a result of Parke-Davis' illegal promotions and schemes. Parke-Davis' overall pattern of conduct aimed at avoiding federal law while inducing the payment of federal funds was pattern of fraud to induce federal payments and constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT IX
ILLEGAL PROMOTION OF ACCUPRIL

38. Another prescription drug manufactured by Parke-Davis is accupril. Although Parke-Davis has sought, and recently obtained approval from the FDA for additional uses of accupril, Parke-Davis

has, over the past year, used the same illegal means and methods of promoting the off-label use of accupril which it has used, as alleged above, to promote gabapentin. A substantial portion of all accupril prescriptions are paid for, indirectly, by the federal government under the medicare and medicaid programs. Parke-Davis' use of illegal and prohibited methods of promoting accupril has caused direct financial harm to the federal government by substantially increasing the amount of money spent on reimbursements of accupril prescriptions. Such illegal promotion constitutes a pattern of fraudulent activity to induce claims against the federal government, and is a False Claim within the meaning of 31 U.S.C. § 3729.

WHEREFORE, the plaintiff demands judgment on behalf of the United States, together with all costs, fees, awards, and interest allowed by 31 U.S.C. § 3730.

PLAINTIFF DEMANDS A JURY TRIAL

Respectfully Submitted

Dated:

8-13-96

Thomas G. Hoffman, Esquire
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Thomas M. Greene, Esquire
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(Rev. 07/86)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

FILED
IN CLERK'S OFFICE
AUG 13 1996
U.S. DISTRICT COURT

I (a) PLAINTIFFS

UNITED STATES OF AMERICA, ex rel. DAVID FRANKLIN

DEFENDANTS

2 PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____ (EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____ (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Thomas G. Hoffman, Esquire
Greene & Hoffman, P.C.
Sixty State Street
Boston, MA 02109 (617) 722-0227

ATTORNEYS (IF KNOWN)

96-11651PBS

II. BASIS OF JURISDICTION (PLACE AN x IN ONE BOX ONLY)

- XX 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (For Diversity Cases Only)

(PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business in This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

This is a Qui Tam action filed under 31 U.S.C. Sec. 3730 (b) (2) seeking to recover damages suffered by the United States due to false claims made and caused to be made by the Defendant.

V. NATURE OF SUIT (PLACE AN x IN ONE BOX ONLY)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury—Med Malpractice
- ☐ 365 Personal Injury—Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 Habeas Corpus
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Food & Drug
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC (405(g))
- ☐ 863 DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- XX 890 Other Statutory Actions

VI. ORIGIN (PLACE AN x IN ONE BOX ONLY)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23

DEMAND $

Check YES only if demanded in complaint:

JURY DEMAND: ☒ YES ☐ NO

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 8-13-96

SIGNATURE OF ATTORNEY OF RECORD

UNITED STATES DISTRICT COURT

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FILED
IN CLERK'S OFFICE
AUG 13 12 13 PM '96
U.S.

1. TITLE OF CASE (NAME OF FIRST PARTY ON EACH SIDE ONLY) United States of America, ex rel. David Franklin v. Parke-Davis, Division of Warner-Lambert Company

2. CATEGORY IN WHICH THE CASE BELONGS BASED UPON THE NUMBERED NATURE OF SUIT CODE LISTED ON THE CIVIL COVER SHEET. (SEE LOCAL RULE 40.1(A)(1)).

___	I.	160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.
X	II.	195, 368, 400, 440, 441-444, 540, 550, 625, 710, 720, 730, 740, 790, 791, 820, 830, 840, 850, 890, 892-894, 895, 950.
___	III.	110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.
___	IV.	220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.
___	V.	150, 152, 153.

96- PBS

AUG 13 10 50 AM '96
U.S. DISTRICT COURT
CLERK'S OFFICE

3. TITLE AND NUMBER, IF ANY, OF RELATED CASES. (SEE LOCAL RULE 40.1(E)).
N/A

4. HAS A PRIOR ACTION BETWEEN THE SAME PARTIES AND BASED ON THE SAME CLAIM EVER BEEN FILED IN THIS COURT?
No

5. DOES THE COMPLAINT IN THIS CASE QUESTION THE CONSTITUTIONALITY OF AN ACT OF CONGRESS AFFECTING THE PUBLIC INTEREST? No
IF SO, IS THE U.S.A. OR AN OFFICER, AGENT OR EMPLOYEE OF THE U.S. A PARTY? (SEE 28 USC 2403) _____

6. IS THIS CASE REQUIRED TO BE HEARD AND DETERMINED BY A DISTRICT COURT OF THREE JUDGES PURSUANT TO TITLE 28 USC 2284? No

7. DO ALL PARTIES IN THIS ACTION RESIDE IN THE CENTRAL SECTION OF THE DISTRICT OF MASSACHUSETTS (WORCESTER COUNTY) - (SEE LOCAL RULE 40.1(C)). YES No OR IN THE WESTERN SECTION (BERKSHIRE, FRANKLIN, HAMPDEN OR HAMPSHIRE COUNTIES)? - (SEE LOCAL RULE 40.1(D)). YES No

8. DO ALL OF THE PARTIES RESIDING IN MASSACHUSETTS RESIDE IN THE CENTRAL AND/OR WESTERN SECTIONS OF THE DISTRICT? YES No (a) IF YES, IN WHICH SECTION DOES THE PLAINTIFF RESIDE? _____

9. IN WHICH SECTION DO THE ONLY PARTIES RESIDING IN MASSACHUSETTS RESIDE? Eastern

10. IF ANY OF THE PARTIES ARE THE UNITED STATES, COMMONWEALTH OF MASSACHUSETTS, OR ANY GOVERNMENTAL AGENCY OF THE U.S.A. OR THE COMMONWEALTH, DO ALL OTHER PARTIES RESIDE IN THE CENTRAL SECTION No _____ OR WESTERN SECTION No

(PLEASE TYPE OR PRINT)
ATTORNEY'S NAME Thomas G. Hoffman, Esquire
ADDRESS Greene & Hoffman, P.C., 60 State St., Boston, MA 02109
TELEPHONE NO. (617) 722-0227

(Category.frm - 09/92)