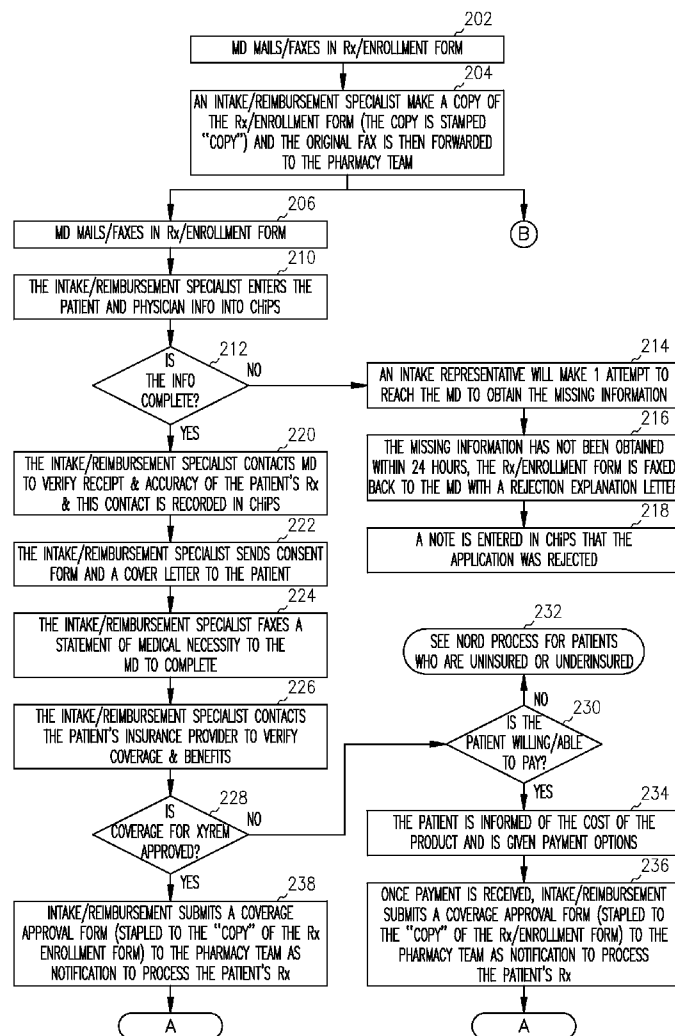


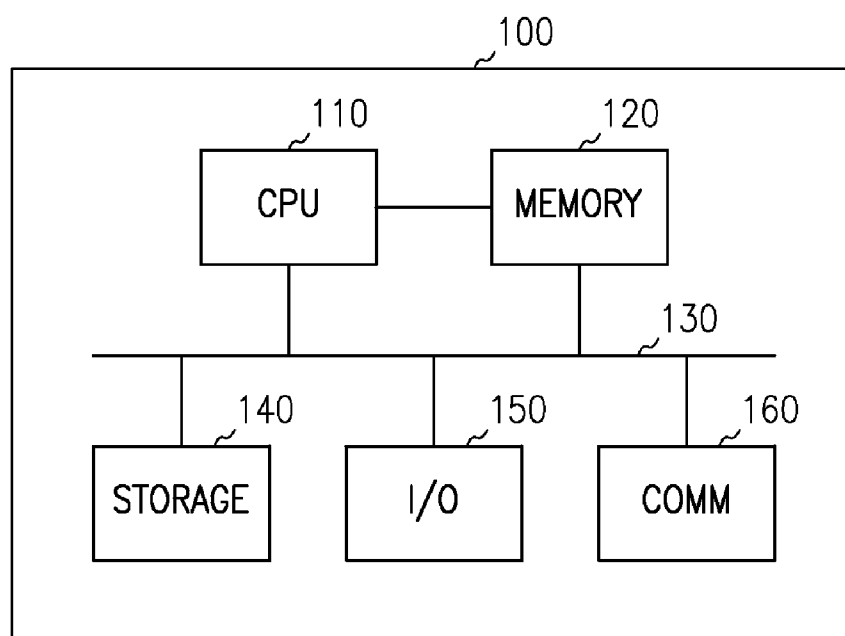


US 20110119085A1

(19) **United States**(12) **Patent Application Publication**  
**Reardan et al.**(10) **Pub. No.: US 2011/0119085 A1**(43) **Pub. Date: May 19, 2011**(54) **SENSITIVE DRUG DISTRIBUTION SYSTEM  
AND METHOD****Publication Classification**(75) Inventors: **Dayton T. Reardan**, Shorewood,  
MN (US); **Patti A. Engel**, Eagan,  
MN (US); **Bob Gagne**, St. Paul,  
MN (US)(51) **Int. Cl.**  
**G06Q 50/00** (2006.01)  
**G06Q 10/00** (2006.01)(52) **U.S. Cl. .... 705/2**(73) Assignees: **Orphan Medical, Inc.**, Palo Alto,  
CA (US); **Jazz Pharmaceuticals,  
Inc.**(21) Appl. No.: **13/013,680**(22) Filed: **Jan. 25, 2011****Related U.S. Application Data**(63) Continuation of application No. 12/704,097, filed on  
Feb. 11, 2010, now Pat. No. 7,895,059, which is a  
continuation of application No. 10/322,348, filed on  
Dec. 17, 2002, now Pat. No. 7,668,730.(57) **ABSTRACT**

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in the database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken against the physician. Multiple controls beyond those for normal drugs are imposed on the distribution depending on the sensitivity of the drug.



**FIG. 1**

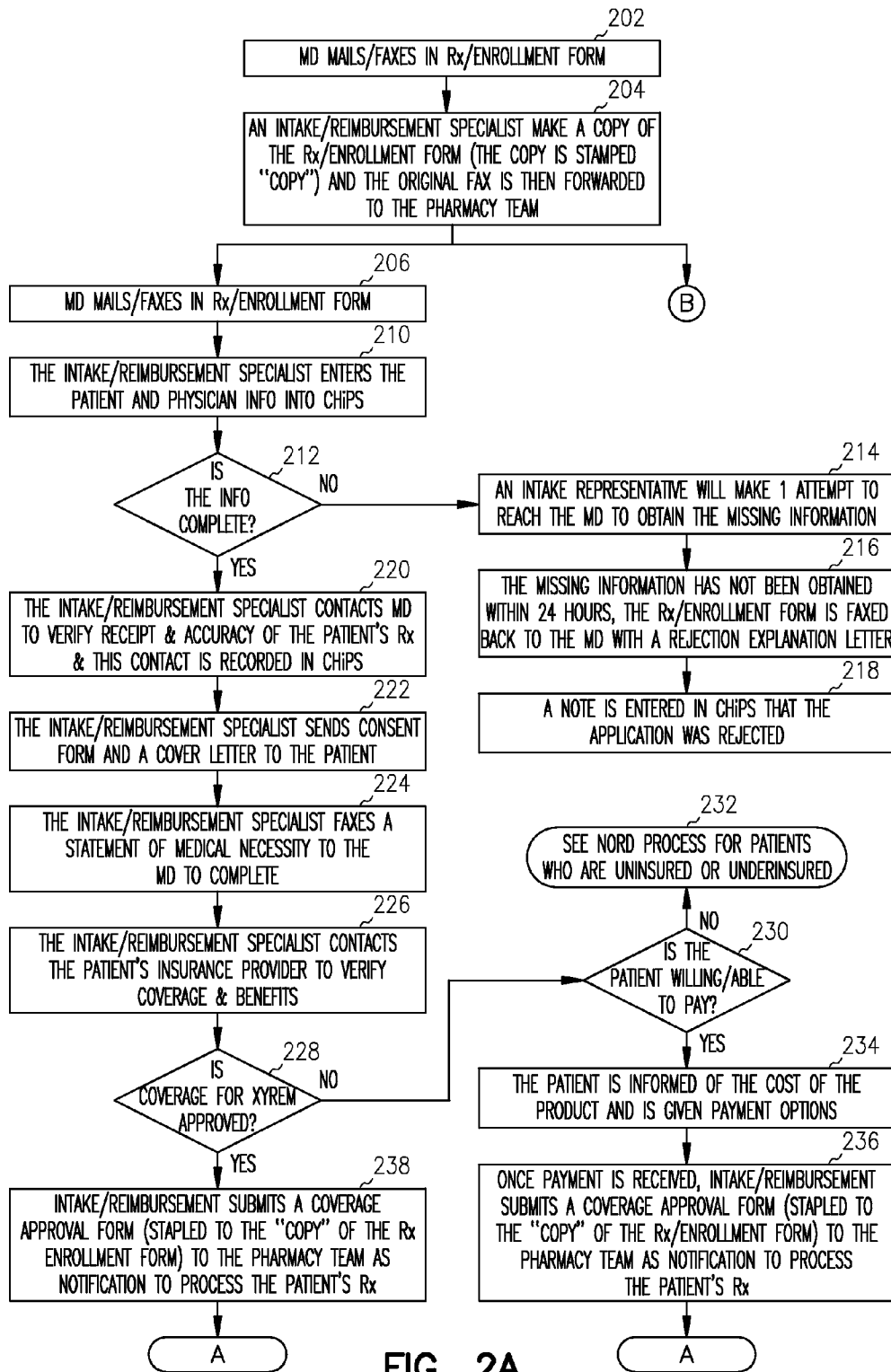


FIG. 2A

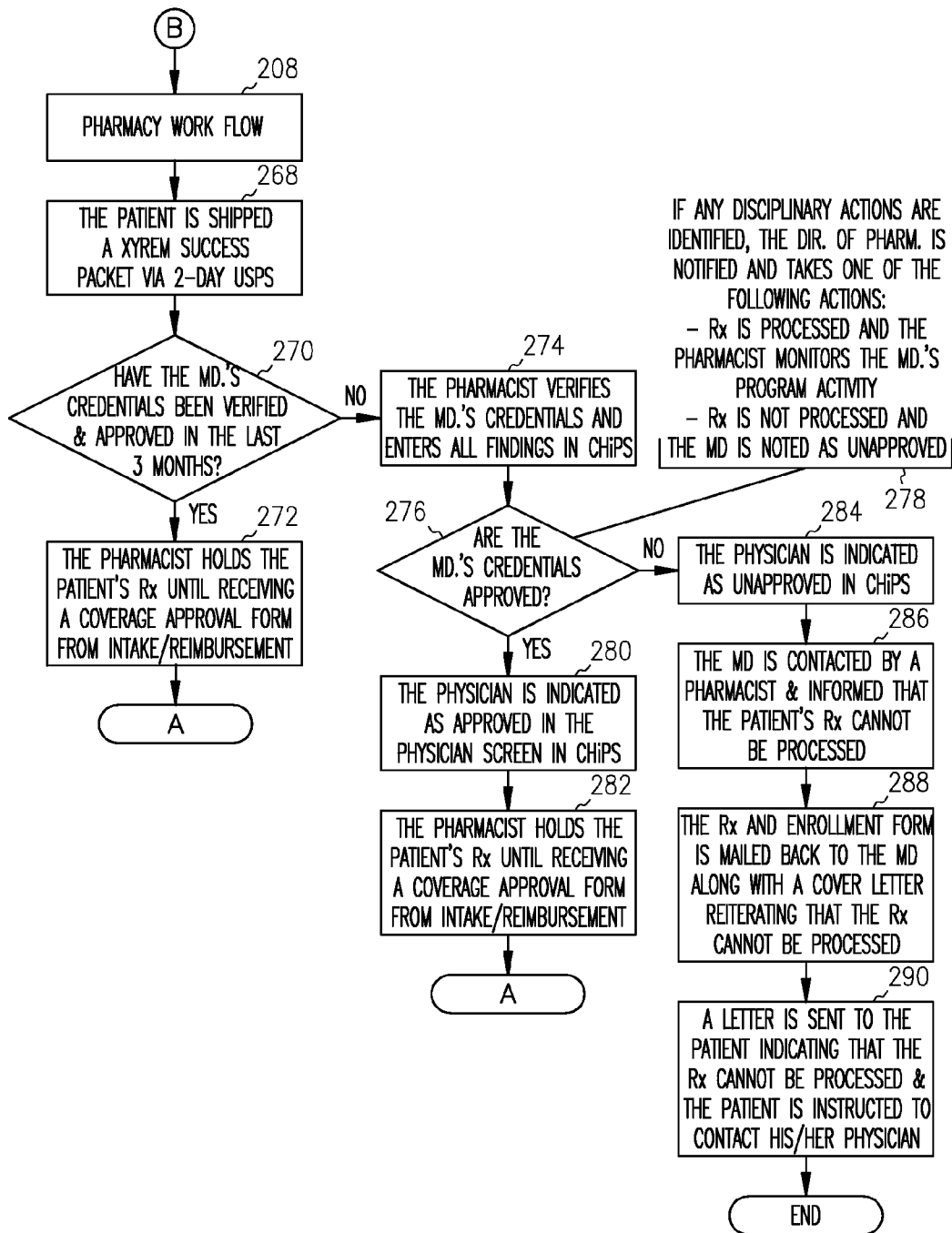


FIG. 2B

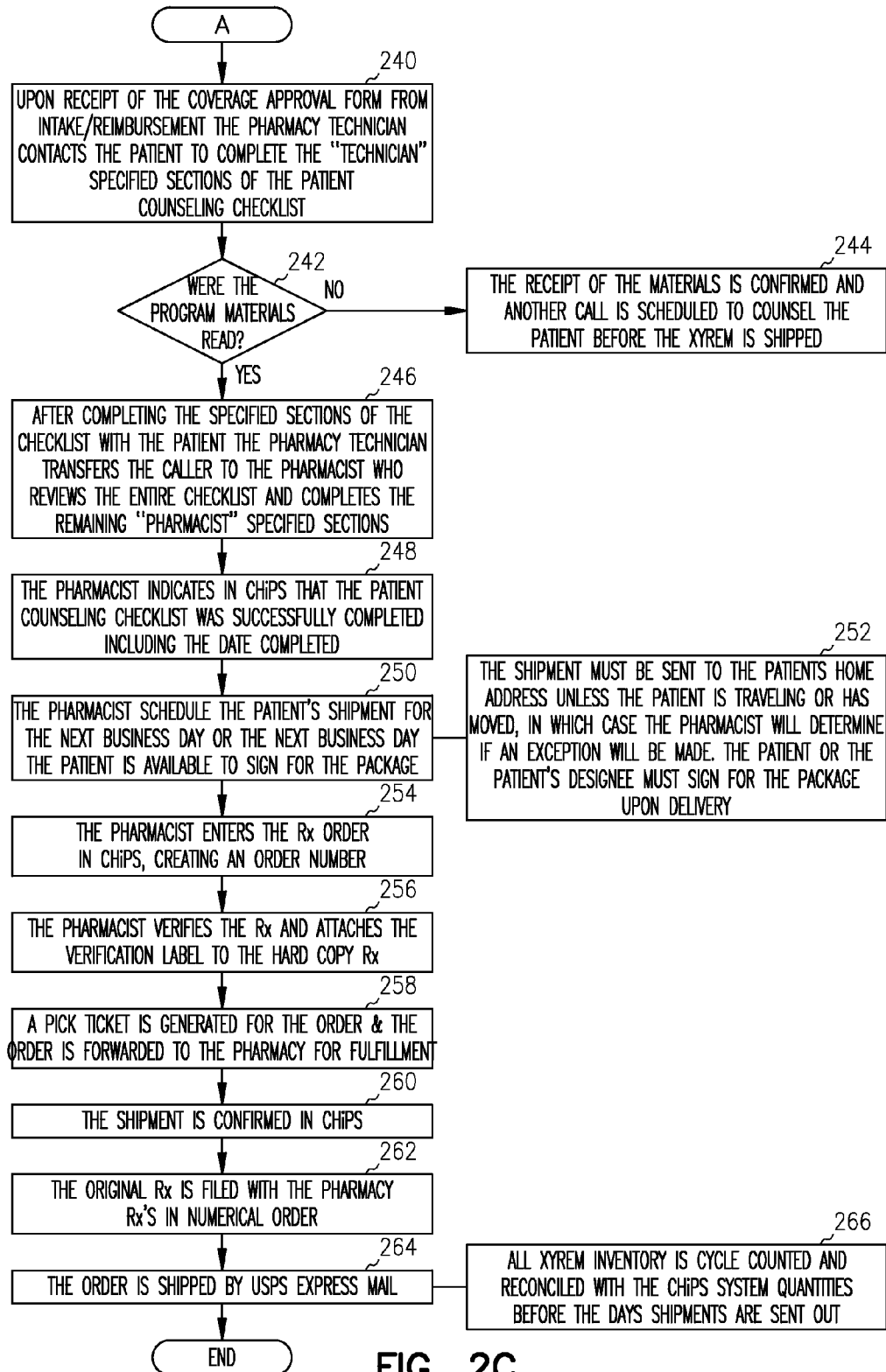


FIG. 2C

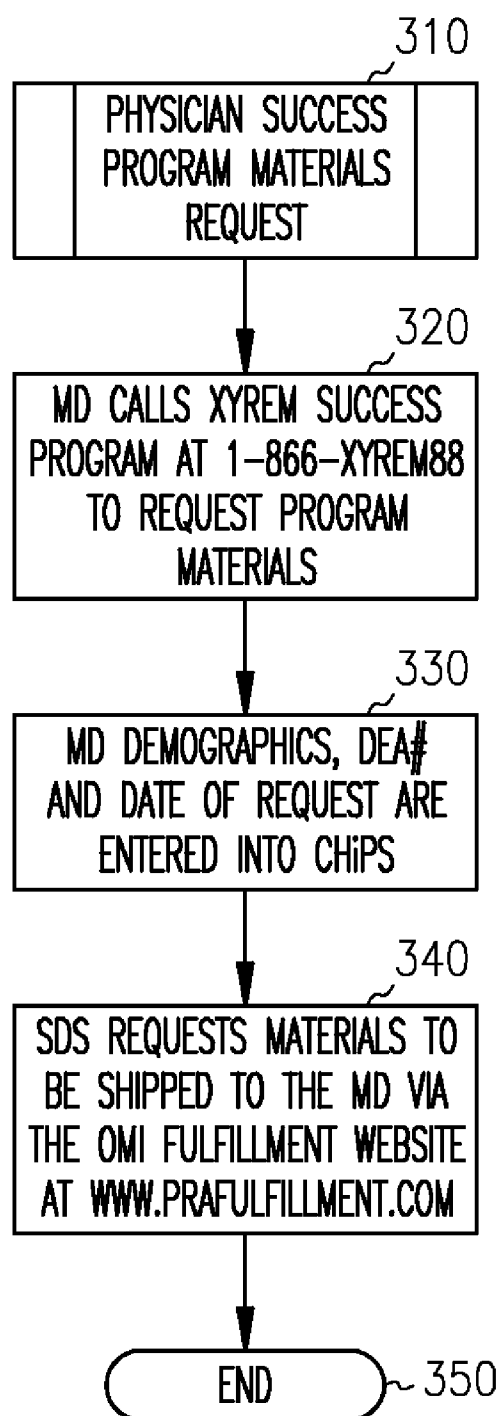


FIG. 3

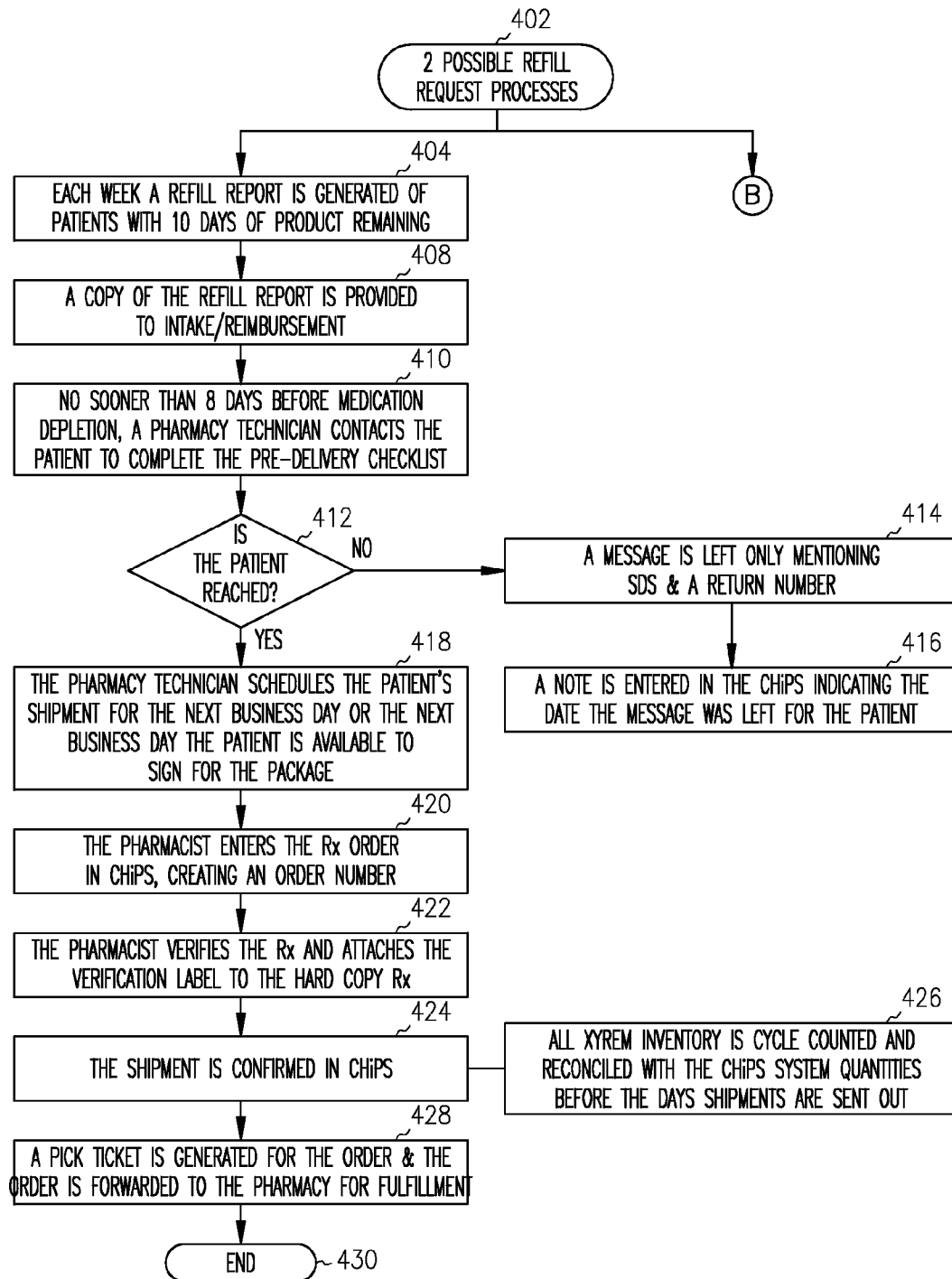


FIG. 4A

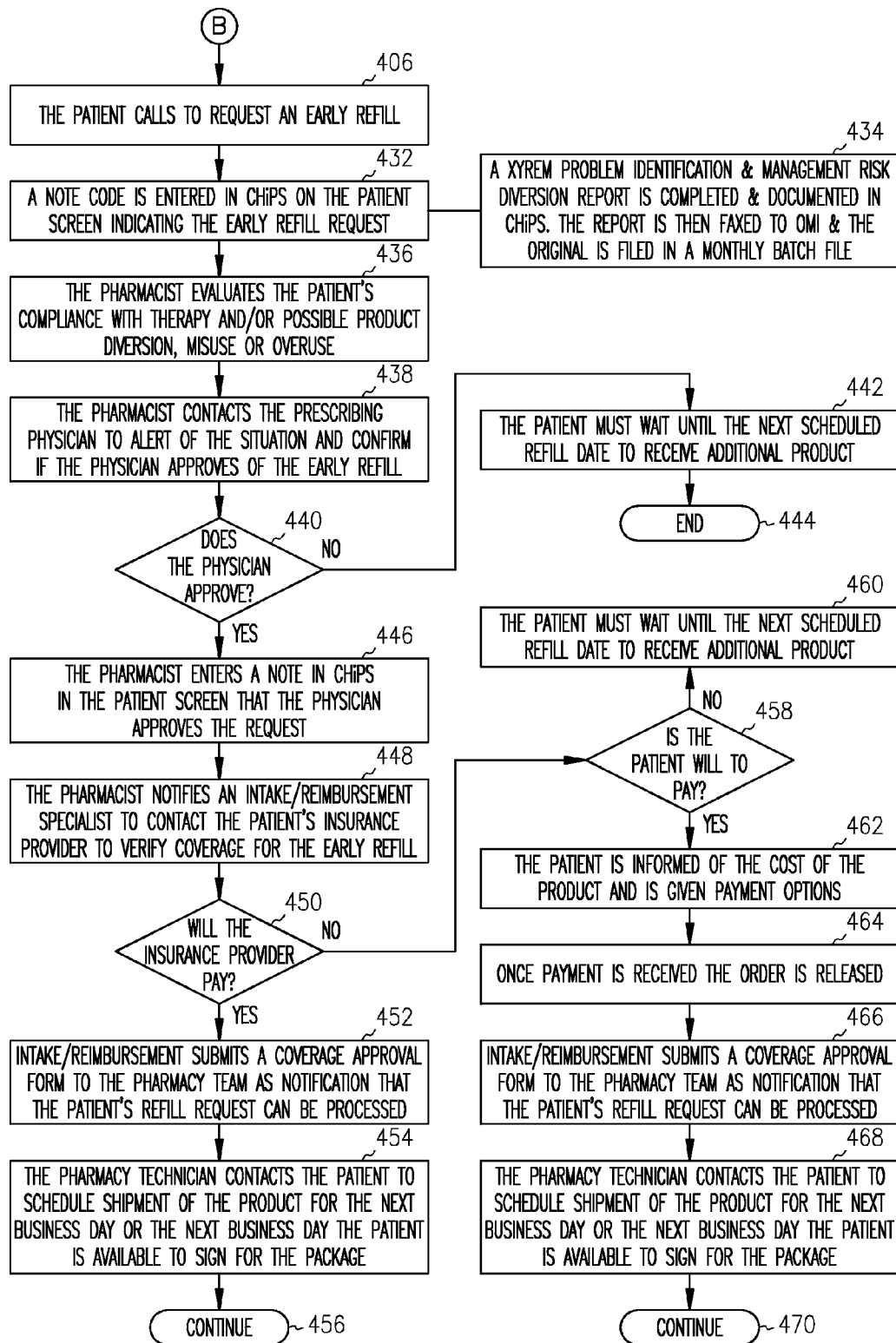


FIG. 4B



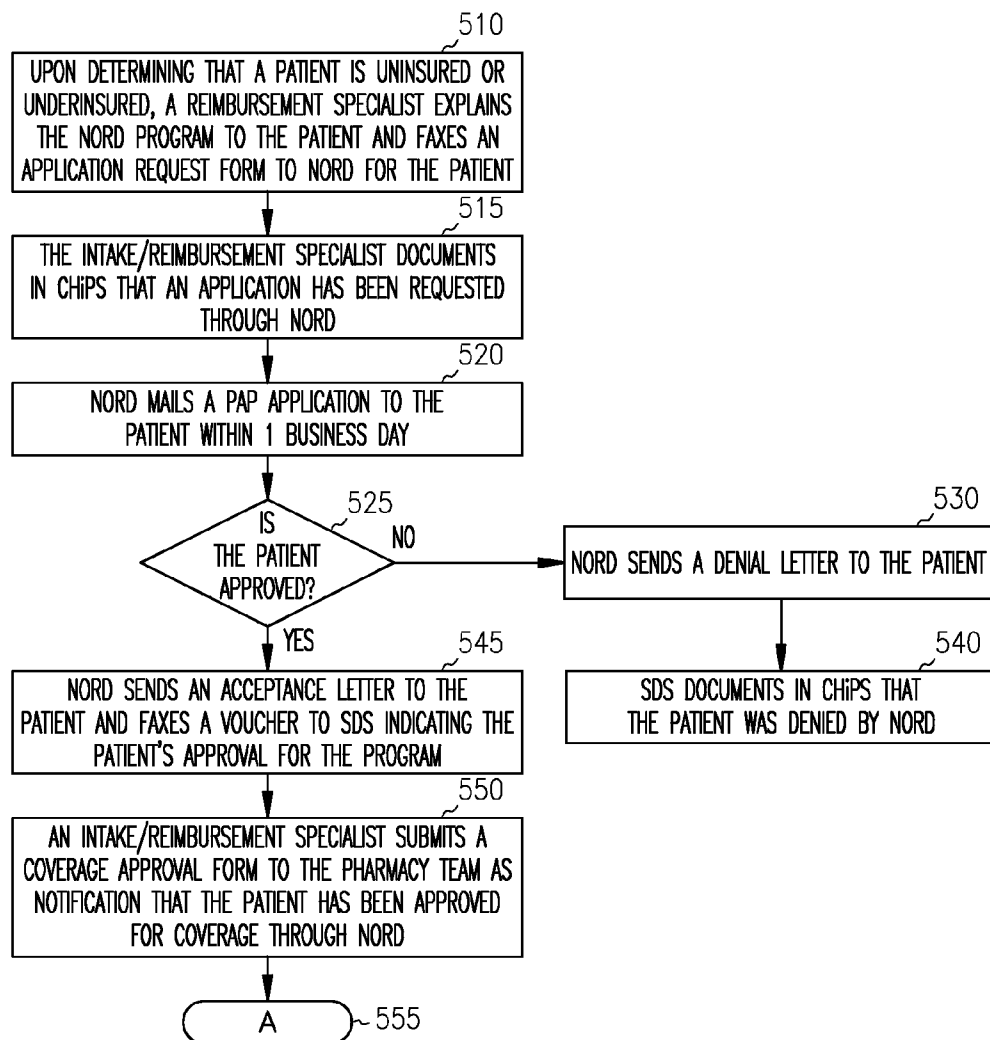


FIG. 5

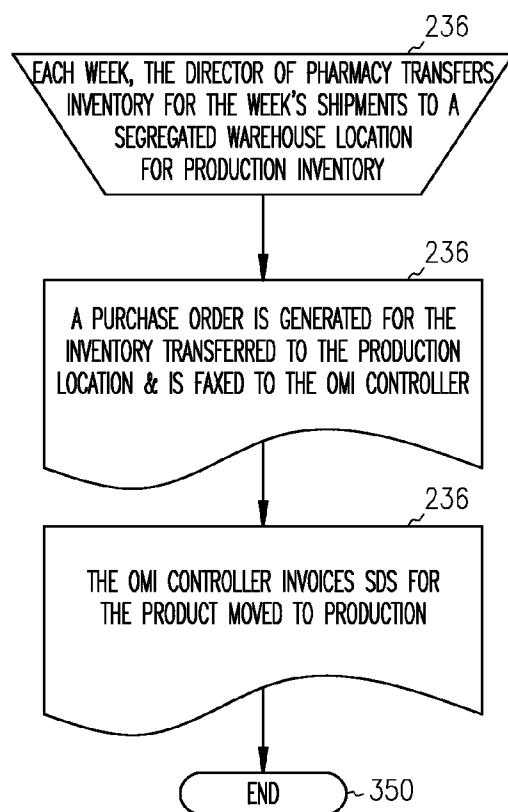


FIG. 6

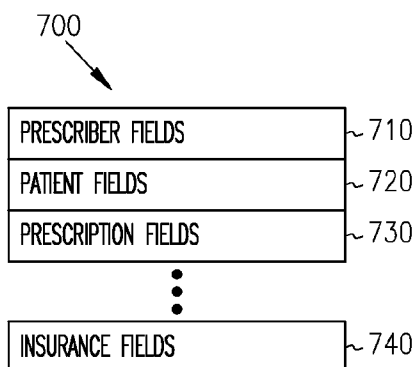


FIG. 7

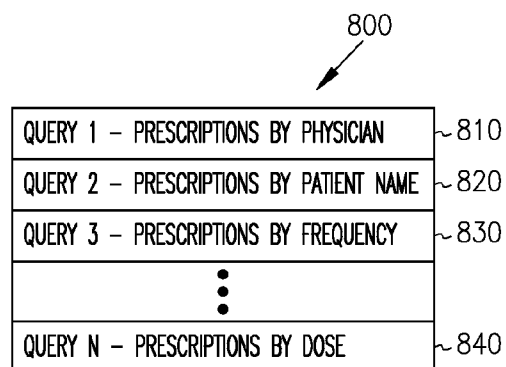


FIG. 8

900

PRESCRIPTION AND ENROLLMENT FORM

PRESCRIBER INFORMATION			
PRESCRIBER'S NAME: _____		OFFICE CONTACT: _____	
STREET ADDRESS: _____			
CITY: _____	STATE: _____	ZIP: _____	
PHONE: _____	FAX: _____		
LICENSE NUMBER: _____	DEA NUMBER: _____		
MD SPECIALTY: _____			

PRESCRIPTION FORM			
PATIENT NAME: _____	SS#: _____	DOB: _____	SEX M / F
ADDRESS: _____			
CITY: _____	STATE: _____	ZIP: _____	
Rx: XYREM ORAL SOLUTION (500 mg/mL) 180 ML. BOTTLE		QUANTITY: _____ MONTHS SUPPLY	
SIG: TAKE _____ GMS P.O. DILUTED IN 60 ML WATER AT H.S. AND THEN AGAIN 2 1/2 TO 4 HOURS LATER			
REFILLS (CIRCLE ONE): 0 1 2 (MAXIMUM OF 3 MONTH SUPPLY)			
		DATE:        /        /	
PRESCRIBER'S SIGNATURE			

PHYSICIAN DECLARATION—PLEASE CHECK EACH BOX		TO BE COMPLETED AT INITIAL PRESCRIPTION ONLY
<input type="checkbox"/> I HAVE READ THE MATERIALS IN THE XYREM PHYSICIAN SUCCESS PROGRAM		
<input type="checkbox"/> I VERIFY THAT THE PATIENT HAS BEEN EDUCATED WITH RESPECT TO XYREM PREPARATION, DOSING AND SCHEDULING.		
<input type="checkbox"/> I UNDERSTAND THAT XYREM IS APPROVED FOR THE TREATMENT OF CATAPLEXY IN PATIENTS WITH NARCOLEPSY, AND THAT SAFETY OR EFFICACY HAS NOT BEEN ESTABLISHED FOR ANY OTHER INDICATION.		
<input type="checkbox"/> I UNDERSTAND THAT THE SAFETY OF DOSES GREATER THAN 9gm/DAY HAS NOT BEEN ESTABLISHED		

PATIENT INFORMATION		
BEST TIME TO CONTACT PATIENT: <input type="checkbox"/> DAY <input type="checkbox"/> NIGHT		
DAY #: _____	EVENING #: _____	
INSURANCE COMPANY NAME: _____	PHONE #: _____	
INSURED'S NAME: _____	RELATIONSHIP TO PATIENT: _____	
IDENTIFICATION NUMBER: _____	POLICY/GROUP NUMBER: _____	
PRESCRIPTION CARD: <input type="checkbox"/> NO <input type="checkbox"/> YES    IF YES, CARRIER: _____	POLICY #: _____	GROUP: _____
PLEASE ATTACH COPIES OF PATIENT'S INSURANCE CARDS		

FAX COMPLETED FORM TO XYREM SUCCESS PROGRAM (TOLL-FREE) 1-866-470-1744  
FOR INFORMATION, CALL THE XYREM TEAM (TOLL FREE) AT 1-866-XYREM88 (1-866-997-3688)

**FIG. 9**

1000  
↙

# PATIENT ASSISTANCE APPLICATION REQUEST FORM

DATE:

TO: PATIENT ASSISTANCE ORGANIZATION  
FROM: SDS

FAX #: 203-798-2291

PLEASE SEND A XYREM PATIENT ASSISTANCE PROGRAM APPLICATION TO:

PATIENT NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

\_\_\_\_\_

TELEPHONE: ( ) \_\_\_\_\_

PATIENT DOSAGE: \_\_\_\_\_ (GRAMS) TWICE NIGHTLY FOR A TOTAL DOSAGE OF \_\_\_\_\_ (GRAMS)  
\_\_\_\_\_ BOTTLES (THREE MONTHS SUPPLY)

BACKGROUND INFORMATION:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

FIG. 10

SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM  
VOUCHER REQUEST FOR MEDICATION

1100  
↙

PATIENT INFORMATION

<FIRST NAME><LAST NAME>  
<ADDRESS 1>  
<ADDRESS 2>  
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

DOB: 01/01/1900

SSN: 123-45-6789

DRUG ALLOTMENT: 100%

LRD: 03/01/2001

CASE CODE: \*\*\*\*\*

PHYSICIAN INFORMATION

<PHYSICIAN NAME>  
<ADDRESS 1>  
<ADDRESS 2>  
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREEM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001
APPROVED _____	

***PHARMACY USE***
--------------------

NORD COPY

\*\*\*\*\*

(DETACH HERE)

PATIENT INFORMATION

<FIRST NAME><LAST NAME>  
<ADDRESS 1>  
<ADDRESS 2>  
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

DOB: 01/01/1900

SSN: 123-45-6789

DRUG ALLOTMENT: 100%

LRD: 03/01/2001

CASE CODE: \*\*\*\*\*

PHYSICIAN INFORMATION

<PHYSICIAN NAME>  
<ADDRESS 1>  
<ADDRESS 2>  
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001
APPROVED _____	

***PHARMACY USE***
--------------------

FIG. 11

1200  
↙

# SENSITIVE DRUG PHYSICIAN'S CERTIFICATE OF MEDICAL NEED

## PATIENT INFORMATION

DATE: \_\_\_\_\_

NAME: \_\_\_\_\_  
LAST FIRST M

DATE OF BIRTH: \_\_\_\_\_

DRUG BEING PRESCRIBED: XYREM

DIAGNOSIS/CONDITION FOR WHICH DRUG IS BEING PRESCRIBED: \_\_\_\_\_

ICD-9: \_\_\_\_\_

## PHYSICIAN INFORMATION

PHYSICIAN'S NAME (PLEASE PRINT): \_\_\_\_\_

PHYSICIAN'S SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

PLEASE FAX BACK TO SENSITIVE DRUG SUCCESS PROGRAM: (1-800-TOLL FREE NUMBER)

**FIG. 12**

## ACTIVITY REPORTS

	REPORT FREQUENCY		
	WEEKLY	MONTHLY	QUARTERLY
<b>SALES</b>			
Rx BY ZIP (NEW AND TOTAL)	X	X	X
Rx BY PHYSICIAN BY ZIP	X	X	
\$ BY ZIP	X	X	X
<b>REGULATORY</b>			
# OF PHYSICIAN REGISTRIES		X	
# OF DENIED PHYSICIAN REGISTRIES AND REASON		X	
# OF COMPLETED PATIENT REGISTRIES		X	
# OF PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORTS COMPLETED	X		
# OF CYCLE COUNTS PERFORMED & ACCURACY OF EACH		X	
<b>QUALITY ASSURANCE</b>			
# OF PRODUCT DEFECTS/COMPLAINTS REPORTED, TYPE AND LOT #		X	
<b>CALL CENTER</b>			
# OF CALLS RECEIVED		X	
# OF CALLS INITIATED		X	
# OF CALLS ANSWERED IN 30 SECONDS, ETC.		X	
PERCENTAGE OF CALLS ANSWERED IN 30 SECONDS		X	
# OF ABANDONED CALLS		X	
% OF ABANDONED CALLS		X	
AVERAGE CALL LENGTH		X	
<b>PHARMACY</b>			
# OF FAXED Rx/ENROLLMENT FORMS		X	
# OF MAILED Rx/ENROLLEMENT FORMS		X	
# OF Rxs SHIPPED WITHIN 1, 2, 3, 4 ETC. DAYS (FROM THE TIME INITIAL RECEIPT TO SHIPMENT OF Rx)		X	
# OF PATIENT SUCCESS PACKETS SHIPPED		X	

FIG. 13A

## ACTIVITY REPORTS

PHARMACY			X	
# OF PHYSICIAN SUCCESS PACKETS SHIPPED			X	
# OF COMPLETED SHIPMENTS			X	
# OF INCOMPLETE SHIPMENTS AND REASON			X	
# OF SHIPPING ERRORS			X	
# OF PAP SHIPMENTS			X	
# OF PAP APPLICATIONS			X	
# OF PAP APPROVALS			X	
# OF CANCELED ORDERS			X	
# OF USPS ERRORS			X	
INVENTORY			X	
# OF RETURNED PRODUCTS AND REASON			X	
# OF OUTDATED BOTTLES OF PRODUCT			X	
INVENTORY COUNTS OF CONSIGNMENT & PRODUCTION INVENTORY			X	
# OF UNITS RECEIVED			X	
LOTS RECEIVED			X	
REIMBURSEMENT			X	
# OF PENDED AND WHY			X	
# OF APPROVALS			X	
# OF DENIALS			X	
# OF REJECTIONS			X	
PAYOR TYPES			X	

FIG. 13B



## ACTIVITY REPORTS

PATIENT CARE			X	
# OF ADVERSE EVENTS REPORTED AND TYPE			X	
# OF ADVERSE EVENTS SENT TO OMI			X	
# OF DOSING PROBLEMS AND TYPE			X	
# OF NONCOMPLIANCE EPISODES AND REASON			X	
# OF PATIENT COUNSELED AND REASON			X	
# OF PATIENTS DISCONTINUED AND REASON			X	
PATIENT CARE			X	
# OF PATIENTS REFERRED TO PHYSICIAN AND REASON			X	
# OF ACTIVE PATIENTS			X	
# OF NEW PATIENTS			X	
# OF RESTART PATIENTS			X	
# OF DISCONTINUED PATIENTS AND REASON			X	
DRUG INFORMATION			X	
# OF DRUG INFORMATION REQUESTS AND TYPE			X	
# OF CALLS TRIAGED TO OMI			X	

FIG. 13C

## SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

### RELATED APPLICATION

**[0001]** This application is a Continuation of U.S. application Ser. No. 12/704,097, which is a Continuation of U.S. application Ser. No. 10/322,348, filed on Dec. 17, 2002 and issued on Feb. 23, 2010 as U.S. Pat. No. 7,668,730, which applications are incorporated by reference herein in their entirety.

### FIELD OF THE INVENTION

**[0002]** The present invention relates to distribution of drugs, and in particular to the distribution of sensitive drugs.

### BACKGROUND OF THE INVENTION

**[0003]** Sensitive drugs are controlled to minimize risk and ensure that they are not abused, or cause adverse reactions. Such sensitive drugs are approved for specific uses by the Food and Drug Administration, and must be prescribed by a licensed physician in order to be purchased by consumers. Some drugs, such as cocaine and other common street drugs are the object of abuse and illegal schemes to distribute for profit. Some schemes include Dr. shopping, diversion, and pharmacy thefts. A locked cabinet or safe is a requirement for distribution of some drugs.

**[0004]** Certain agents, such as gamma hydroxy buterate (GHB) are also abused, yet also are effective for therapeutic purposes such as treatment of daytime cataplexy in patients with narcolepsy. Some patients however, will obtain prescriptions from multiple doctors, and have them filled at different pharmacies. Still further, an unscrupulous physician may actually write multiple prescriptions for a patient, or multiple patients, who use cash to pay for the drugs. These patients will then sell the drug to dealers or others for profit.

**[0005]** There is a need for a distribution system and method that directly addresses these abuses. There is a further need for such a system and method that provides education and limits the potential for such abuse.

### SUMMARY OF THE INVENTION

**[0006]** A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database for a valid DEA license, and optionally state medical boards to determine whether any corrective or approved disciplinary actions relating to controlled substances have been brought against the physician. Multiple controls beyond those for traditional drugs are imposed on the distribution depending on the sensitivity of the drug.

**[0007]** Education is provided to both physician and patient. Prior to shipping the drug for the first time, the patient is contacted to ensure that product and abuse related educational materials have been received and/or read. The patient may provide the name of a designee to the central pharmacy who is authorized to accept shipment of the drug. Receipt of the initial drug shipment is confirmed by contacting the patient.

Either a phone call or other communication to the patient within a set time after delivery may be made to ensure receipt. Further, a courier service's tracking system is used to confirm delivery in further embodiments. If a shipment is lost, an investigation is launched to find it.

**[0008]** In one embodiment, the drug may be shipped by the central pharmacy to another pharmacy for patient pick-up. The second pharmacy's ability to protect against diversion before shipping the drug must be confirmed. This ability may be checked through NTIS and State Boards of Pharmacy.

**[0009]** Prescription refills are permitted in the number specified in the original prescription. In addition, if a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned. A lost, stolen, destroyed or spilled prescription/supply is documented and replaced to the extent necessary to honor the prescription, and will also cause a review or full investigation.

**[0010]** The exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information. Several queries and reports are run against the database to provide information which might reveal potential abuse of the sensitive drug, such as early refills.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0011]** FIG. 1 is a block diagram of a computer system for use in implementing the system and method of the present invention.

**[0012]** FIGS. 2A, 2B and 2C are a flowchart describing a method for sensitive drug distribution at least partially utilizing a computer system such as that shown in FIG. 1.

**[0013]** FIG. 3 is a flowchart of a physician success program at least partially implemented on a computer system such as that shown in FIG. 1.

**[0014]** FIGS. 4A and 4B are a flowchart describing a method for handling refill requests at least partially utilizing a computer system such as that shown in FIG. 1.

**[0015]** FIG. 5 is a flowchart of a process for requesting special reimbursement when a patient is uninsured or under-insured at least partially utilizing a computer system as that shown in FIG. 1.

**[0016]** FIG. 6 is a flowchart of a process for inventory control at least partially utilizing a computer system such as that shown in FIG. 1.

**[0017]** FIG. 7 is a block diagram of database fields.

**[0018]** FIG. 8 is a block diagram showing a list of queries against the database fields.

**[0019]** FIG. 9 is a copy of one example prescription and enrollment form.

**[0020]** FIG. 10 is a copy of one example of a NORD application request form for patient financial assistance.

**[0021]** FIG. 11 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10.

**[0022]** FIG. 12 is a copy of certificate of medical need.

**[0023]** FIGS. 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7.

### DETAILED DESCRIPTION OF THE INVENTION

**[0024]** In the following description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments

in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following description is, therefore, not to be taken in a limited sense, and the scope of the present invention is defined by the appended claims.

**[0025]** The functions or algorithms described herein are implemented in software or a combination of software and human implemented procedures in one embodiment. The software comprises computer executable instructions stored on computer readable media such as memory or other type of storage devices. The term “computer readable media” is also used to represent carrier waves on which the software is transmitted. Further, such functions correspond to modules, which are software, hardware, firmware of any combination thereof. Multiple functions are performed in one or more modules as desired, and the embodiments described are merely examples. The software is executed on a digital signal processor, ASIC, microprocessor, or other type of processor operating on a computer system, such as a personal computer, server or other computer system.

**[0026]** A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive. One example of such a drug is sodium oxybate, also known as gamma hydroxy butyrate (GHB  $C_4H_7NaO_3$ ) which is useful for treatment of cataplexy in patients with narcolepsy. GHB is marketed under the trademark of Xyrem® (sodium oxybate oral solution), which trademark can be used interchangeably with GHB herein. Sensitive drugs also include narcotics or other drugs which require controls on their distribution and use to monitor behaviors to prevent abuse and adverse side effects.

**[0027]** In one embodiment, Xyrem® is subject to a restricted distribution program. One aspect of the program is to educate physicians and patients about the risks and benefits of Xyrem, including support via ongoing contact with patients and a toll free helpline. Initial prescriptions are filled only after a prescriber and patient have received and read the educational materials. Further, patient and prescribing physician registries are maintained and monitored to ensure proper distribution.

**[0028]** In a further embodiment, bulk sodium oxybate is manufactured at a single site, as is the finished drug product. Following manufacture of the drug product, it is stored at a facility compliant with FDA Schedule III regulations, where a consignment inventory is maintained. The inventory is owned by a company, and is managed by a central pharmacy, which maintains the consignment inventory. Xyrem® is distributed and dispensed through a primary and exclusive central pharmacy, and is not stocked in retail pharmacy outlets. It is distributed by overnight carriers, or by US mail in one embodiment to potentially invoke mail fraud laws if attempts of abuse occur.

**[0029]** FIG. 1 is a simplified block diagram of a computer system 100, such as a personal computer for implementing at least a portion of the methods described herein. A central processing unit (CPU) 110 executes computer programs stored on a memory 120. Memory 120 in one embodiment comprises one or more levels of cache as desired to speed execution of the program and access to data on which the programs operate. The CPU is directly coupled to memory 120 in one embodiment. Both CPU 110 and memory 120 are

coupled to a bus 130. A storage 140, I/O 150 and communications 160 are also coupled to the bus 130. Storage 140 is usually a long term storage device, such as a disk drive, tape drive, DVD, CD or other type of storage device. In one embodiment, storage 140 is used to house a database for use with the present invention. I/O 150 comprises keyboards, sound devices, displays and other mechanisms by which a user interacts with the computer system 100. Communications 160 comprises a network, phone connection, local area network, wide area network or other mechanism for communicating with external devices. Such external devices comprise servers, other peer computers and other devices. In one embodiment, such external device comprises a database server that is used in place of the database on storage 140. Other computer system architectures capable of executing software and interacting with a database and users may also be used. Appropriate security measures such as encryption are used to ensure confidentiality. Further, data integrity and backup measures are also used to prevent data loss.

**[0030]** FIGS. 2A, 2B and 2C represent an initial prescription order entry process for a sensitive drug, such as Xyrem. At 202, a medical doctor (MD) sends a Rx/enrollment form via mail, fax, email or other means to an intake/reimbursement specialist at 204, who makes a copy of the RX/enrollment form that is stamped “copy”. The original fax is forwarded to a pharmacy team. The enrollment form contains prescriber information, prescription information, checkboxes for the prescriber indicating they have read materials, educated the patient, understand the use in treatment, and understand certain safety information, and also contains patient information.

**[0031]** The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription information includes name, social security number, date of birth, gender, contact information, drug identification, patient’s appropriate dosage, and number of refills allowed, along with a line for the prescriber’s signature. Patient insurance information is also provided.

**[0032]** There are two workflows involved at the pharmacy team, intake reimbursement 206 and pharmacy workflow 208, which may proceed in parallel or serially. The intake work flow 206 starts with an intake reimbursement specialist entering the patient and physician information into an application/database referred to as CHIPS, which is used to maintain a record of a client home infusion program (CHIP) for Xyrem®. A check is made to ensure the information is complete at 212. If not, at 214, an intake representative attempts to reach the MD or prescriber to obtain the missing information. If the missing information has not been obtained within a predetermined period of time, such as 24 hours at 216, the Rx/Enrollment form is sent back to the MD with a rejection explanation. A note is entered in CHIPS that the application was rejected.

**[0033]** If the information is complete at 212, the MD is contacted at 220 to verify receipt and accuracy of the patient’s Rx. This contact is recorded in CHIPS. The intake and reimbursement specialist then sends a consent form and a cover letter to the patient at 224. The insurance provider is contacted at 226 to verify coverage and benefits. At 228, a determination is made regarding coverage for the drug. If it is not available, it is determined at 230 whether the patient is willing and able to pay. If not, a process is performed for handling patients

who are uninsured or underinsured. In one embodiment, the process is referred to as a NORD process.

**[0034]** If the patient is willing and able to pay at **230**, the patient is informed of the cost of the product and is given payment options at **234**. At **236**, once payment is received, the intake reimbursement specialist submits a coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. If coverage is approved at **228**, the intake reimbursement specialist also submits the coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. Processing of the prescription is described below.

**[0035]** Upon receipt and initial processing of the prescription enrollment form and sending an original to the pharmacy work flow block **208**, the patient is shipped a Xyrem® success packet via mail. In one embodiment, the Xyrem® success packet contains educational material for a patient that advises of the proper use, care and handling of the drug and consequences of diversion at **268**. The medical doctor's credentials are checked to determine if the physician has a current DEA license to prescribe controlled substances and if he or she has had any actions related to misuse/misprescribing of controlled drugs against him or her, within a predetermined time, such as three months at **270**. If they have, a pharmacist holds the prescription until receiving a coverage approval form from the intake reimbursement specialist at **272**.

**[0036]** If the credentials have not been recently checked, the pharmacist verifies the credentials and enters all findings in the database at **274**. If the credentials are approved at **276**, the physician is indicated as approved in a physician screen populated by information from the database at **280**. The prescription is then held pending coverage approval at **282**.

**[0037]** If any disciplinary actions are identified, as referenced at block **278**, management of the pharmacy is notified and either approves processing of the prescription with continued monitoring of the physician, or processing of the prescription is not performed, and the physician is noted in the database as unapproved at **284**. The enrollment form is then mailed back to the physician with a cover letter reiterating that the prescription cannot be processed at **288**. The patient is also sent a letter at **290** indicating that the prescription cannot be processed and the patient is instructed to contact their physician.

**[0038]** Actual filling of the approved prescription begins with receipt of the coverage approval form as indicated at **240**. The patient is contacted by the pharmacy, such as by a technician to complete a technician section of a patient counseling checklist. If a pharmacist verifies that the program materials were not read at **242**, the receipt of the material is confirmed at **244** and another call is scheduled to counsel the patient before the drug is shipped.

**[0039]** If the program materials, were read at **242**, the checklist is completed at **246** and the technician transfers the patient to the pharmacist who reviews the entire checklist and completes remaining pharmacist specified sections. At **248**, the pharmacist indicates in the database that the patient counseling and checklist was successfully completed, indicating the date completed.

**[0040]** At **250**, the pharmacist schedules the patient's shipment for the next business day or the next business day that the patient or designee is able to sign for the package. Further, as indicated at **252**, the shipment must be sent to the patient's home address unless the patient is traveling or has moved. In

that event, the pharmacist may determine that an exception may be made. The patient or the patient's designee who is at least 18 years old, must sign for the package upon delivery.

**[0041]** At **254**, the pharmacist enters the prescription order in the database, creating an order number. The pharmacist then verifies at **256** the prescription and attaches a verification label to the hard copy prescription. At **258**, a pick ticket is generated for the order and the order is forwarded to the pharmacy for fulfillment. The shipment is confirmed in the database at **260**, and the order is shipped by USPS Express Mail. Use of the US mail invokes certain criminal penalties for unauthorized diversion. Optionally, other mail services may be used. Potential changes in the law may also bring criminal penalties into play. Following shipment, the patient is called by the central pharmacy to confirm that the prescription was received.

**[0042]** As noted at **266**, for the sensitive drug, Xyrem, all inventory is cycle counted and reconciled with the database system quantities before shipments for the day are sent. This provides a very precise control of the inventory.

**[0043]** A physician success program materials request process begins at **310** in FIG. 3. At **320**, the MD calls to the central pharmacy to request program materials. A special phone number is provided. MD demographics, DEA number, and data or request are entered into the database at **330**. At **340**, a request is made to ship the materials to the MD via a fulfillment website, or other mechanism. The request process ends at **350**.

**[0044]** A refill request process begins at **302** in FIGS. 4A and 4B. There are two different paths for refills. A first path beginning at **404** involves generating a report from the central database of patients with a predetermined number of days or product remaining. A second path beginning at **406** is followed when a patient calls to request an early refill.

**[0045]** In the first path, a copy of the report is provided to an intake reimbursement specialist at **408**. No sooner than 8 days before the medication depletion, a pharmacy technician contacts the patient at **410** to complete the pre-delivery checklist. At **412**, if the patient is not reached, a message is left mentioning the depletion, and a return number at **414**. A note is also entered into the database indicating the date the message was left at **416**.

**[0046]** If the patient is reached at **412**, the next shipment is scheduled at **418**, the prescription is entered into the database creating an order at **420**, the pharmacist verifies the prescription and attaches a verification label at **422** and the shipment is confirmed in the database at **424**. Note at **426** that the inventory is cycle counted and reconciled with the database quantities before the shipments for a day or other time period are sent. A pick ticket is generated for the order and the order is forwarded for fulfillment at **428**, with the first path ending at **430**.

**[0047]** The second path, beginning at **406** results in a note code being entered into the database on a patient screen indicating an early refill request at **432**. The pharmacist evaluates the patient's compliance with therapy or possible product diversion, misuse or over-use at **436**. In one embodiment, cash payers are also identified. The pharmacist then contacts the prescribing physician to alert them of the situation and confirm if the physician approves of the early refill at **438**. If the physician does not approve as indicated at **440**, the patient must wait until the next scheduled refill date to receive additional product as indicated at **442**, and the process ends at **444**.

[0048] If the physician approves at 440, the pharmacist enters a note in the database on a patient screen that the physician approves the request at 446. The pharmacist notifies an intake reimbursement specialist to contact the patient's insurance provider to verify coverage for the early refill at 448. If the insurance provider will pay as determined at 450, the specialist submits the coverage approval form as notification that the refill may be processed at 452. At 454, the pharmacy technician contacts the patient to schedule shipment of the product for the next business day, and the process of filling the order is continued at 456 by following the process beginning at 240.

[0049] If the insurance provider will not pay at 450, it is determined whether the patient is willing and/or able to pay at 458. If not, the patient must wait until the next scheduled refill date to receive additional product at 460. If it was determined at 458 that the patient was willing and able to pay, the patient is informed of the cost of the product and is given payment options at 462. Once payment is received as indicated at 464, the specialist submits a coverage approval form to the pharmacy team as notification that the refill request can be processed at 466. At 468, the pharmacy technician contacts the patient to schedule shipment. The process of filling the order is continued at 470 by following the process beginning at 240.

[0050] A process, referred to as a NORD process in one embodiment is used to determine whether donated, third party funds are available for paying for prescriptions where neither insurance will, nor the patient can pay. The process begins at 510 upon determining that a patient is uninsured or underinsured. A reimbursement specialist explains the NORD program to the patient and faxes an application request form to NORD for the patient. At 515, the intake reimbursement specialist documents in the database that an application has been received through NORD. At 520, NORD mails an application to the patient within one business day.

[0051] A determination is made at 525 by NORD whether the patient is approved. If not, at 530, NORD sends a denial letter to the patient, and it is documented in the database at 540 that the patient was denied by NORD. If the patient is approved, NORD sends an acceptance letter to the patient and faxes a voucher to the central pharmacy (SDS in one embodiment) to indicate the approval at 545. At 550, an intake reimbursement specialist submits a coverage approval form to the pharmacy team as notification that the patient has been approved for coverage. The process of filling the order is continued at 555 by following the process beginning at 240.

[0052] An inventory control process is illustrated in FIG. 6 beginning at 610. Each week, a responsible person at the central pharmacy, such as the director of the pharmacy transfers inventory for the week's shipments to a segregated warehouse location for production inventory. At 620, a purchase order is generated for the inventory transferred to the production location and is sent, such as by fax, to a controller, such as the controller of the company that obtained approval for distribution and use of the sensitive drug. At 630, the controller invoices the central pharmacy for the product moved to production. The process ends at 640.

[0053] The central database described above is a relational database running on the system of FIG. 1, or a server based system having a similar architecture coupled to workstations via a network, as represented by communications 160. The database is likely stored in storage 140, and contains multiple fields of information as indicated at 700 in FIG. 7. The organization and groupings of the fields are shown in one format

for convenience. It is recognized that many different organizations or schemas may be utilized. In one embodiment, the groups of fields comprise prescriber fields 710, patient fields 720, prescription fields 730 and insurance fields 740. For purposes of illustration, all the entries described with respect to the above processes are included in the fields. In further embodiments, no such groupings are made, and the data is organized in a different manner.

[0054] Several queries are illustrated at 800 in FIG. 8. There may be many other queries as required by individual state reporting requirements. A first query at 810 is used to identify prescriptions written by physician. The queries may be written in structured query language, natural query languages or in any other manner compatible with the database. A second query 820 is used to pull information from the database related to prescriptions by patient name. A third query 830 is used to determine prescriptions by frequency, and a  $n^{th}$  query finds prescriptions by dose at 840. Using query languages combined with the depth of data in the central database allows many other methods of investigating for potential abuse of the drugs. The central database ensures that all prescriptions, prescribers and patients are tracked and subject to such investigations. In further embodiments, the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug.

[0055] An example of one prescription and enrollment form is shown at 900 in FIG. 9. As previously indicated, several fields are included for prescriber information, prescription information and patient information.

[0056] FIG. 10 is a copy of one example NORD application request form 1000 used to request that an application be sent to a patient for financial assistance.

[0057] FIG. 11 is a copy of one example application 1100 for financial assistance as requested by form 1000. The form requires both patient and physician information. Social security number information is also requested. The form provides information for approving the financial assistance and for tracking assistance provided.

[0058] FIG. 12 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10. In addition to patient and physician information, prescription information and diagnosis information is also provided.

[0059] FIGS. 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7. The activities grouped by sales, regulatory, quality assurance, call center, pharmacy, inventory, reimbursement, patient care and drug information. Each report has an associated frequency or frequencies. The reports are obtained by running queries against the database, with the queries written in one of many query languages.

[0060] While the invention has been described with respect to a Schedule III drug, it is useful for other sensitive drugs that are DEA or Federally scheduled drugs in Schedule II-V, as well as still other sensitive drugs where multiple controls are desired for distribution and use.

1. A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is

distributed by a company that obtained approval for distribution of the prescription drug;

entering into the single database information identifying the narcoleptic patient and a prescriber, and entering into the single database information relating to the company's prescription drug;

entering information into the single database relating to abuse, misuse, or diversion of the company's prescription drug;

processing all prescriptions for the company's prescription drug using the single computer database to control the distribution of the company's prescription drug by tracking prescriptions and identifying patterns of abuse, misuse, or diversion;

providing the company's prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the company's prescription drug;

and selecting two or more controls from the group consisting of:

identifying the prescriber's name, license, and Drug Enforcement Agency (DEA) registration information;

verifying the prescription; obtaining patient information; verifying that a physician or other prescriber is eligible to prescribe the company's prescription drug by consulting the National Technical Information Services to determine whether the physician or other prescriber has an active DEA number and to check on whether any actions are pending against the physician or other prescriber; contacting the narcoleptic patient's insurance company; verifying patient registry information; providing educational information to the narcoleptic patient concerning the use of or risks associated with the company's prescription drug; verifying that the narcoleptic patient has received or read the educational materials concerning the company's prescription drug; verifying the home address of the narcoleptic patient; shipping the company's prescription drug via US Postal Service or other commercial shipping service; receiving the name of at least one 18-year-old designee to receive the company's prescription drug; confirming receipt of an initial shipment of the company's prescription drug to the narcoleptic patient; returning the company's prescription drug to a pharmacy after two attempts to deliver have failed; launching an investigation when a shipment is lost; shipping the company's prescription drug to a pharmacy for delivery to or pick-up by the narcoleptic patient; inquiring about the reason for requested early refills of the company's prescription drug; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription of the company's prescription drug to a one-month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse, misuse, or diversion patterns in the data;

authorizing the filling, using the single computer database, of a prescription for the company's prescription drug that has been subjected to the two or more controls and has been approved for shipment to the narcoleptic patient; and

noting, based on the analysis of potential abuse, misuse, or diversion of the company's prescription drug, that there is a potential for abuse, misuse, or diversion by the narcoleptic patient to whom the company's prescription drug is prescribed;

wherein the prescription drug that has the potential for misuse, abuse or diversion is a gamma hydroxy butyrate (GHB) drug product;

wherein said GHB drug product treats cataplexy in said narcoleptic patient.

2. A method of treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;

entering into the single computer database information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

entering into the single computer database information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;

entering and maintaining in the single computer database information that indicates that the narcoleptic patient or prescriber has abused, misused, or diverted the company's prescription drug; and

using the single computer database to authorize filling of the prescriptions for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient or prescriber, or if there is a record of such incidents, the single computer database indicates that such incidents have been investigated, and the single computer database indicates that such incidents do not involve abuse, misuse or diversion.

3. The method of claim 2, comprising delivering the prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug.

4. The method of claim 2, wherein an exclusive central pharmacy controls the single computer database.

5. The method of claim 2, comprising selectively blocking shipment of the prescription drug to a narcoleptic patient.

6. The method of claim 2, wherein an abuse pattern is associated with a narcoleptic patient, and shipment of the prescription drug is blocked based upon such association.

7. The method of claim 2, wherein the prescription drug comprises a gamma hydroxy butyrate (GHB) drug product.

8. The method of claim 7, wherein said GHB drug product treats cataplexy in said narcoleptic patient.

9. A method of treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for the prescription drug that has the potential for abuse, misuse or diversion;

entering into the single computer database information sufficient to identify the narcoleptic patient for whom the prescription drug is prescribed;

entering into the single computer database information sufficient to identify a physician or other prescriber of the prescription drug and information to show that the physician or other prescriber is authorized to prescribe the prescription drug;

entering and maintaining in the single computer database information that indicates that the narcoleptic patient or prescriber has abused, misused, or diverted the prescription drug;

using the single computer database to authorize filling of the prescriptions for the prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient or prescriber, or if there is a record of such incidents, the single computer database indicates that such incidents have been investigated, and the single computer database indicates that such incidents do not involve abuse, misuse or diversion; and

distributing the prescription drug by a company that obtained approval for distribution of the prescription drug.

10. The method of claim 9, comprising delivering the prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug.

11. The method of claim 9, wherein an exclusive central pharmacy controls the single computer database.

12. The method of claim 9, comprising selectively blocking shipment of the prescription drug to the narcoleptic patient.

13. The method of claim 9, wherein an abuse pattern is associated with the patient, and shipment of the prescription drug is blocked based upon such association.

14. The method of claim 9, wherein the prescription drug comprises a gamma hydroxy butyrate (GHB) drug product.

15. The method of claim 14, wherein said GHB drug product treats cataplexy in said narcoleptic patient.

16. A method of treatment of a narcoleptic patient with a gamma hydroxy butyrate (GHB) drug product while controlling potential misuse, abuse or diversion of said GHB drug product, comprising:

controlling with a computer processor the distribution of the GHB drug product, the GHB drug product sold or distributed by a company that obtained approval for distribution of the GHB drug product, the distribution implemented via an exclusive central pharmacy that maintains an exclusive central database that tracks all prescriptions of the company's GHB drug product and that analyzes for potential abuse situations;

receiving in the computer processor all prescription requests, for any and all narcoleptic patients being prescribed the company's GHB drug product, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the company's GHB drug product;

processing in the computer processor all prescriptions for the company's GHB drug product only by the exclusive central pharmacy using only the exclusive central database;

determining with the computer processor current and anticipated patterns of potential prescription abuse of the company's GHB drug product from periodic reports generated only by the exclusive central database, based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular narcoleptic patient, wherein the request data contain information identifying the narcoleptic patient, GHB as the drug prescribed, and credentials of the medical doctor; and

selecting with the computer processor multiple controls for distribution by the exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from the medical doctor to the exclusive central pharmacy; identifying the medical doctor's name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the medical doctor is eligible to prescribe the company's GHB drug product by consulting the National Technical Information Services to determine whether the medical doctor has an active DEA number and to check on whether any actions are pending against the medical doctor; providing comprehensive printed materials to the medical doctor; contacting the narcoleptic patient's insurance company; verifying patient registry information; providing comprehensive educational information to the narcoleptic patient; verifying the narcoleptic patient has reviewed the educational materials; verifying the home address of the narcoleptic patient; shipping the GHB drug product via US postal service or a commercial shipping service; receiving the name of an at least 18 year old designee to receive the GHB drug product; confirming receipt of an initial shipment of the GHB drug product to the narcoleptic patient; returning the GHB drug product to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the exclusive central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

17. The method of claim 16, comprising consulting a separate database to verify that the medical doctor is eligible to prescribe the GHB drug product.

18. The method of claim 16, comprising delivering the GHB drug product to the narcoleptic patient in order to treat the narcoleptic patient with the GHB drug product.

19. The method of claim 16, wherein the exclusive central pharmacy controls the exclusive computer database.

20. The method of claim 16, comprising selectively blocking shipment of the GHB drug product to the narcoleptic patient.

21. The method of claim 16, wherein an abuse pattern is associated with the narcoleptic patient, and shipment of the GHB drug product is blocked based upon such association.

22. A method of treatment of a narcoleptic patient with a prescription drug while controlling potential misuse, abuse or diversion of said prescription drug, comprising:

receiving in a computer processor all prescription requests, for any and all narcoleptic patients being prescribed the prescription drug, wherein the prescription drug is distributed by a company that obtained approval for distribution of the prescription drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the company's prescription drug, the prescription requests containing information identifying narcoleptic patients, the prescription drug, and various credentials of the any and all medical doctors;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, wherein the exclusive central pharmacy and the exclusive central database are unique in that they are the only pharmacy and database in existence for the company's prescription drug, and such that all prescriptions for the company's prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the company's prescription drug;

confirming with a narcoleptic patient that educational material has been read prior to shipping the company's prescription drug;

checking the exclusive computer database for potential abuse of the company's prescription drug, wherein the uniqueness of the exclusive central pharmacy and the exclusive central database facilitates a determination of the potential abuse of the company's prescription drug;

providing the company's prescription drug to the narcoleptic patient only if no potential abuse is found by the narcoleptic patient to whom the company's prescription drug is prescribed and the doctor prescribing the company's prescription drug;

confirming receipt by the narcoleptic patient of the company's prescription drug; and

generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns.

**23.** The method of claim **22**, wherein one or more of the exclusive central pharmacy and the exclusive central database are distributed over multiple computers, and wherein a query operates over all data in all the distributed databases relating to the prescriptions, the doctors, and the narcoleptic patients.

**24.** The method of claim **22**, wherein the providing the company's prescription drug to the narcoleptic patient comprises the exclusive central pharmacy authorizing the company's prescription drug to be dispensed to the narcoleptic patient by another pharmacy.

**25.** The method of claim **22**, comprising delivering the company's prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the company's prescription drug.

**26.** The method of claim **22**, wherein the exclusive central pharmacy controls the exclusive computer database.

**27.** The method of claim **22**, comprising selectively blocking shipment of the company's prescription drug to the narcoleptic patient.

**28.** The method of claim **22**, wherein an abuse pattern is associated with the narcoleptic patient, and shipment of the company's prescription drug is blocked based upon such association.

**29.** The computerized method of claim **22**, wherein the company's prescription drug comprises a gamma hydroxy butyrate (GHB) drug product.

**30.** A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for a prescription drug with the potential for abuse, misuse or diversion sold or distributed under a single trademark;

entering into the single database, information identifying the narcoleptic patient, the prescriber; and the trademarked prescription drug;

entering information into the single database relating to or indicating abuse, misuse, or diversion of said prescription drug;

processing all prescriptions for said prescription drug using the single computer database to control the distribution of said prescription drug by tracking prescriptions and identifying patterns of abuse, misuse, or diversion;

providing said prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug;

and selecting two or more controls from the group comprising:

identifying a prescriber's name, license, and Drug Enforcement Agency (DEA) registration information; verifying the prescription; obtaining patient information; verifying that the physician or other prescriber is eligible to prescribe said prescription drug by consulting the National Technical Information Services to determine whether the physician or other prescriber has an active DEA number and to check on whether any actions are pending against the physician or other prescriber; contacting the narcoleptic patient's insurance company if any; verifying patient registry information; providing education information to the narcoleptic patient concerning the use of or risks associated with said prescription drug; verifying that the narcoleptic patient has received or read the educational materials concerning said prescription drug; verifying the home address of the narcoleptic patient; shipping said prescription drug via US Postal Service or other commercial shipping service; receiving the name of at least one 18-year-old designee to receive said prescription drug; confirming receipt of an initial shipment of said prescription drug to the narcoleptic patient; returning said prescription drug to a pharmacy after two attempts to deliver have failed; launching an investigation when a shipment is lost; shipping said prescription drug to a pharmacy for delivery to or pick-up by the narcoleptic patient; requiring manufacture of said prescription drug at a single location; inquiring about the reason for requested early refills of said prescription drug; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription of said prescription drug to a one-month supply; requiring rewriting of the prescription periodically; making the database available to the DEA for checking for abuse, misuse, or diversion patterns in the data; authorizing the filling, using the single computer database, of a prescription for said prescription drug that has been subjected to two or more controls and has been approved for shipment to the narcoleptic patient; noting based on one or more of the analysis of potential abuse, misuse, or diversion of the prescription drug, that there is a potential for abuse, misuse, or diversion by a narcoleptic patient to whom the prescription drug is prescribed;

wherein the prescription drug that has the potential for misuse, abuse or diversion is a gamma hydroxy butyrate (GHB) drug product;

wherein said GHB drug product treats cataplexy in said narcoleptic patient.



**31.** A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for a prescription drug that has the potential for abuse, misuse or diversion which has been manufactured at a single manufacturing site;

entering into the single database, information identifying the narcoleptic patient, the prescriber; and the trademarked prescription drug;

entering information into the single database relating to or indicating abuse, misuse, or diversion of said prescription drug;

processing all prescriptions for said prescription drug using the single computer database to control the distribution of said prescription drug by tracking prescriptions and identifying patterns of abuse, misuse, or diversion;

providing said prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug;

and selecting two or more controls from the group comprising:

identifying a prescriber's name, license, and Drug Enforcement Agency (DEA) registration information; verifying the prescription; obtaining patient information; verifying that the physician or other prescriber is eligible to prescribe said prescription drug by consulting the National Technical Information Services to determine whether the physician or other prescriber has an active DEA number and to check on whether any actions are pending against the physician or other prescriber; contacting the narcoleptic patient's insurance company if any; verifying patient registry information; providing education information to the narcoleptic patient concerning the use of or risks associated with said prescription drug; verifying that the narcoleptic patient has received or read the educational materials concerning said prescription drug; verifying the home address of the narcoleptic patient; shipping said prescription drug via US Postal Service or other commercial shipping service; receiving the name of at least one 18-year-old designee to receive said prescription drug; confirming receipt of an initial shipment of said prescription drug to the narcoleptic patient; returning said prescription drug to a pharmacy after two attempts to deliver have failed; launching an investigation when a shipment is lost; shipping said prescription drug to a pharmacy for delivery to or pick-up by the narcoleptic patient; requiring manufacture of said prescription drug at a single location; inquiring about the reason for requested early refills of said prescription drug; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription of said prescription drug to a one-month supply; requiring rewriting of the prescription periodically; making the database available to the DEA for checking for abuse, misuse, or diversion patterns in the data; authorizing the filling, using the single computer database, of a prescription for said prescription drug that has been subjected to two or more controls and has been approved for shipment to the narcoleptic patient; noting based on one or more of the analysis of potential abuse, misuse, or diversion of the prescription drug, that there is a potential for abuse, misuse, or diversion by a narcoleptic patient to whom the prescription drug is prescribed.

**32.** A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising: receiving into a single computer data-

base all prescriptions for a prescription drug with the potential for abuse, misuse or diversion sold or distributed under a single trademark;

entering into the single database information sufficient to identify the narcoleptic patient for whom said prescription drug was prescribed;

entering into the single database information sufficient to identify the physician or other prescriber of said prescription drug and information to show that the physician or other prescriber was authorized to prescribe said prescription drug;

entering and maintaining in the single database information which may suggest that the narcoleptic patient or prescriber has abused, misused, or diverted said prescription drug;

using the single computer database to authorize filling of the prescriptions for said prescription drug only if there is no record of incidents that may suggest abuse, misuse, or diversion by the narcoleptic patient or prescriber or if any such incidents have been investigated and found not to involve abuse, misuse or diversion.

**33.** A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for a prescription drug that has been manufactured at a single manufacturing site with the potential for abuse, misuse or diversion;

entering into the single database information sufficient to identify the narcoleptic patient for whom said prescription drug was prescribed, entering into the single database information sufficient to identify the physician or other prescriber of said prescription drug and information to show that the physician or other prescriber was authorized to prescribe said prescription drug;

entering and maintaining in the single database information which may suggest that the narcoleptic patient or prescriber has abused, misused, or diverted said prescription drug;

using the single computer database to authorize filling of the prescription for said prescription drug only if there is no record of incidents that may suggest abuse, misuse, or diversion by the narcoleptic patient or prescriber or if any such incidents have been investigated and found not to involve abuse, misuse or diversion; providing said prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug;

wherein the prescription drug that has the potential for misuse, abuse or diversion is a gamma hydroxybutyrate (GHB) drug product;

wherein said GHB drug product treats cataplexy in said narcoleptic patient.

**34.** A method of treatment of a narcoleptic patient with a prescription drug that has the potential for misuse, abuse or diversion, comprising:

receiving into a single computer database all prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug inventory is owned by a company and is managed thorough said single computer database;

entering into the single database information identifying the narcoleptic patient and a prescriber, and entering into the single database information relating to the company's prescription drug;

entering information into the single database relating to abuse, misuse, or diversion of the company's prescription drug;

- processing all prescriptions for the company's prescription drug using the single computer database to control the distribution of the company's prescription drug by tracking prescriptions and identifying patterns of abuse, misuse, or diversion;
- providing the company's prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the company's prescription drug;
- and selecting two or more controls from the group consisting of:
- identifying the prescriber's name, license, and Drug Enforcement Agency (DEA) registration information; verifying the prescription; obtaining patient information; verifying that a physician or other prescriber is eligible to prescribe the company's prescription drug by consulting the National Technical Information Services to determine whether the physician or other prescriber has an active DEA number and to check on whether any actions are pending against the physician or other prescriber; contacting the narcoleptic patient's insurance company; verifying patient registry information; providing educational information to the narcoleptic patient concerning the use of or risks associated with the company's prescription drug; verifying that the narcoleptic patient has received or read the educational materials concerning the company's prescription drug; verifying the home address of the narcoleptic patient; shipping the company's prescription drug via US Postal Service or other commercial shipping service; receiving the name of at least one 18-year-old designee to receive the company's prescription drug; confirming receipt of an initial shipment of the company's prescription drug to the narcoleptic patient; returning the company's prescription drug to a pharmacy after two attempts to deliver have failed; launching an investigation when a shipment is lost; shipping the company's prescription drug to a pharmacy for delivery to or pick-up by the narcoleptic patient; inquiring about the reason for requested early refills of the company's prescription drug; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription of the company's prescription drug to a one-month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse, misuse, or diversion patterns in the data;
- authorizing the filling, using the single computer database, of a prescription for the company's prescription drug that has been subjected to the two or more controls and has been approved for shipment to the narcoleptic patient; and
- noting, based on the analysis of potential abuse, misuse, or diversion of the company's prescription drug, that there is a potential for abuse, misuse, or diversion by the narcoleptic patient to whom the company's prescription drug is prescribed
- wherein the prescription drug that has the potential for misuse, abuse or diversion is a gamma hydroxybutyrate (GHB) drug product;
- wherein said GHB drug product treats cataplexy in said narcoleptic patient.
- 35.** A method of treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:
- receiving into a single computer database all prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug inventory is owned by a company and is managed thorough said single computer database;
- entering into the single computer database information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;
- entering into the single computer database information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;
- entering and maintaining in the single computer database information that indicates that the narcoleptic patient or prescriber has abused, misused, or diverted the company's prescription drug; and
- using the single computer database to authorize filling of the prescriptions for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient or prescriber, or if there is a record of such incidents, the single computer database indicates that such incidents have been investigated, and the single computer database indicates that such incidents do not involve abuse, misuse or diversion.
- 36.** The method of claim **33**, comprising delivering the prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the prescription drug.
- 37.** The method of claim **35**, wherein an exclusive central pharmacy controls the single computer database.
- 38.** The method of claim **35**, comprising selectively blocking shipment of the prescription drug to a narcoleptic patient.
- 39.** The method of claim **35**, wherein an abuse pattern is associated with a narcoleptic patient, and shipment of the prescription drug is blocked based upon such association.
- 40.** The method of claim **35**, wherein the prescription drug comprises a gamma hydroxy butyrate (GHB) drug product.
- 41.** The method of claim **40**, wherein said GHB drug product treats cataplexy in said narcoleptic patient.
- 42.** A method of treatment of a narcoleptic patient with a gamma hydroxy butyrate (GHB) drug product while controlling potential misuse, abuse or diversion of said GHB drug product, comprising:
- controlling with a computer processor the distribution of the GHB drug product, wherein the GHB drug product inventory is owned by a company and the distribution is implemented via an exclusive central pharmacy that maintains an exclusive central database that tracks all prescriptions of the company's GHB drug product and that analyzes for potential abuse situations;
- receiving in the computer processor all prescription requests, for any and all narcoleptic patients being prescribed the company's GHB drug product, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the company's GHB drug product;
- processing in the computer processor all prescriptions for the company's GHB drug product only by the exclusive central pharmacy using only the exclusive central database;
- determining with the computer processor current and anticipated patterns of potential prescription abuse of the company's GHB drug product from periodic reports

generated only by the exclusive central database, based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular narcoleptic patient, wherein the request data contain information identifying the narcoleptic patient, GHB as the drug prescribed, and credentials of the medical doctor; and

selecting with the computer processor multiple controls for distribution by the exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from the medical doctor to the exclusive central pharmacy; identifying the medical doctor's name, license, and DEA (Drug Enforcement Agency) registration information;

verifying the prescription; obtaining patient information; verifying the medical doctor is eligible to prescribe the company's GHB drug product by consulting the National Technical Information Services to determine whether the medical doctor has an active DEA number and to check on whether any actions are pending against the medical doctor; providing comprehensive printed materials to the medical doctor; contacting the narcoleptic patient's insurance company; verifying patient registry information; providing comprehensive educational information to the narcoleptic patient; verifying the narcoleptic patient has reviewed the educational materials; verifying the home address of the narcoleptic patient; shipping the GHB drug product via US postal service or a commercial shipping service; receiving the name of an at least 18 year old designee to receive the GHB drug product; confirming receipt of an initial shipment of the GHB drug product to the narcoleptic patient; returning the GHB drug product to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the exclusive central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

43. The method of claim 42, comprising consulting a separate database to verify that the medical doctor is eligible to prescribe the GHB drug product.

44. The method of claim 42, comprising delivering the GHB drug product to the narcoleptic patient in order to treat cataplexy in the narcoleptic patient with the GHB drug product.

45. The method of claim 42, wherein the exclusive central pharmacy controls the exclusive computer database.

46. The method of claim 42, comprising selectively blocking shipment of the GHB drug product to the narcoleptic patient.

47. The method of claim 42, wherein an abuse pattern is associated with the narcoleptic patient, and shipment of the GHB drug product is blocked based upon such association.

48. A method of treatment of a narcoleptic patient with a prescription drug while controlling potential misuse, abuse or diversion of said prescription drug, comprising:

receiving in a computer processor all prescription requests, for any and all narcoleptic patients being prescribed the prescription drug, wherein the prescription drug inventory is owned by a company, only at the exclusive central

pharmacy from any and all medical doctors allowed to prescribe the company's prescription drug, the prescription requests containing information identifying narcoleptic patients, the prescription drug, and various credentials of the any and all medical doctors;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, wherein the exclusive central pharmacy and the exclusive central database are unique in that they are the only pharmacy and database in existence for the company's prescription drug, and such that all prescriptions for the company's prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the company's prescription drug;

confirming with a narcoleptic patient that educational material has been read prior to shipping the company's prescription drug;

checking the exclusive computer database for potential abuse of the company's prescription drug, wherein the uniqueness of the exclusive central pharmacy and the exclusive central database facilitates a determination of the potential abuse of the company's prescription drug;

providing the company's prescription drug to the narcoleptic patient only if no potential abuse is found by the narcoleptic patient to whom the company's prescription drug is prescribed and the doctor prescribing the company's prescription drug;

confirming receipt by the narcoleptic patient of the company's prescription drug; and

generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns.

49. The method of claim 48, wherein one or more of the exclusive central pharmacy and the exclusive central database are distributed over multiple computers, and wherein a query operates over all data in all the distributed databases relating to the prescriptions, the doctors, and the narcoleptic patients.

50. The method of claim 48, wherein the providing the company's prescription drug to the narcoleptic patient comprises the exclusive central pharmacy authorizing the company's prescription drug to be dispensed to the narcoleptic patient by another pharmacy.

51. The method of claim 48, comprising delivering the company's prescription drug to the narcoleptic patient in order to treat the narcoleptic patient with the company's prescription drug.

52. The method of claim 48, wherein the exclusive central pharmacy controls the exclusive computer database.

53. The method of claim 46, comprising selectively blocking shipment of the company's prescription drug to the narcoleptic patient.

54. The method of claim 48, wherein an abuse pattern is associated with the narcoleptic patient, and shipment of the company's prescription drug is blocked based upon such association.

55. The method of claim 48, wherein the company's prescription drug comprises a gamma hydroxy butyrate (GHB) drug product.

56. The method of claim 53, wherein said GHB drug product treats cataplexy in said narcoleptic patient.