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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ROXANE LABORATORIES, INC., WEST-WARD PHARMACEUTICALS CORP., EUROHEALTH (USA), INC., and HIKMA PHARMACEUTICALS PLC,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals"), by its undersigned attorneys, for its Complaint against defendants Roxane Laboratories, Inc. ("Roxane Labs."), West-Ward Pharmaceuticals Corp. ("West-Ward"), Eurohealth (USA), Inc. ("Eurohealth"), and Hikma Pharmaceuticals PLC ("Hikma") (collectively, "Roxane") alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Roxane's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz Pharmaceuticals' XYREM® drug

product prior to the expiration of United States Patent No. 8,731,963 ("the '963 patent" or "the patent-in-suit") owned by Jazz Pharmaceuticals.

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. On information and belief, Defendant Roxane Labs. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

4. On information and belief, Defendant West-Ward is a corporation organized and existing under the laws of Delaware, having a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

5. On information and belief, Defendant Eurohealth is a corporation organized and existing under the laws of Delaware, having a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

6. On information and belief, Defendant Hikma is a company organized and existing under the laws of Jordan, having a principal place of business in Bayader Wadi Seer, P.O. Box 182400, Amman 1118, Jordan.

7. On information and belief, Roxane Labs. is a wholly owned subsidiary of Hikma.

8. On information and belief, West-Ward is a wholly owned subsidiary of Eurohealth.

9. On information and belief, Eurohealth is a wholly owned subsidiary of Hikma.

10. On information and belief, defendants Roxane Labs., West-Ward, Eurohealth, and Hikma manufacture and/or distribute generic drugs for sale and use throughout the United States,

including in this Judicial District. On information and belief, defendants Roxane Labs., West-Ward, Eurohealth, and Hikma also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

11. On information and belief, the acts of Roxane Labs. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, West-Ward, Eurohealth, and Hikma.

Jurisdiction and Venue

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Roxane Labs. by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Roxane Labs. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Roxane Labs. has customers in the State of New Jersey. On information and belief, Roxane Labs. is registered to do business in the State of New Jersey and maintains a registered agent for service of process in New Jersey. On information and belief, Roxane Labs. regularly transacts business within this Judicial District. Further, on information and belief, Roxane Labs. develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. Roxane Labs. has litigated patent cases in this Judicial District in the past without contesting personal jurisdiction and, in at least some of those actions, Roxane Labs. has asserted counterclaims.

14. On information and belief, if approved by the FDA, Roxane Labs. will market the ANDA product referenced herein in this Judicial District, either on its own or through its agent, West-Ward.

15. This Court has personal jurisdiction over West-Ward by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, West-Ward has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, West-Ward has customers in the State of New Jersey. On information and belief, West-Ward is registered to do business in the State of New Jersey and maintains a registered agent for service of process in New Jersey. On information and belief, West-Ward regularly transacts business within this Judicial District, including through its principal place of business in Eatontown, New Jersey. Further, on information and belief, West-Ward develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. West-Ward has litigated patent cases in this Judicial District in the past without contesting personal jurisdiction, and, in at least some of those actions, West-Ward has asserted counterclaims.

16. On information and belief, if approved by the FDA, West-Ward will market the ANDA product referenced herein in this Judicial District, either on its own or through its agent, Roxane Labs.

17. This Court has personal jurisdiction over Eurohealth by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Eurohealth has purposefully availed itself of this forum by, among other things, making,

shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Eurohealth has customers in the State of New Jersey. On information and belief, Eurohealth regularly transacts business within this Judicial District, including through its principal place of business in Eatontown, New Jersey. Further, on information and belief, Eurohealth develops numerous generic drugs for sale and use throughout the United States, either on its own or through its agent, West-Ward, including in this Judicial District.

18. On information and belief, if approved by the FDA, Eurohealth will market the ANDA product referenced herein in this Judicial District, either on its own or through its agents, Roxane Labs. and/or West-Ward.

19. This Court has personal jurisdiction over Hikma by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Hikma has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Hikma has customers in the State of New Jersey. On information and belief, Hikma regularly transacts business within this Judicial District. Further, on information and belief, Hikma develops numerous generic drugs for sale and use throughout the United States, either on its own or through its agent, West-Ward, including in this Judicial District. Hikma has litigated patent cases in this Judicial District in the past without contesting personal jurisdiction and, in at least some of those actions, Hikma has asserted counterclaims.

20. On information and belief, if approved by the FDA, Hikma will market the ANDA product referenced herein in this Judicial District, either on its own or through its agents, Roxane Labs. and/or West-Ward.

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

22. On May 20, 2014, the USPTO duly and lawfully issued the '963 patent, entitled "Sensitive Drug Distribution System and Method" to assignee Jazz Pharmaceuticals, Inc. A copy of the '963 patent is attached hereto as Exhibit A.

The XYREM® Drug Product

23. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the patent-in-suit cover, *inter alia*, a drug distribution system and method of distributing sodium oxybate utilizing a central pharmacy database to track all prescriptions. Jazz Pharmaceuticals owns the patent-in-suit.

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '963 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

Acts Giving Rise to This Suit

25. Pursuant to Section 505 of the FFDCA, Roxane filed ANDA No. 202090 ("Roxane's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of 500 mg/mL sodium oxybate oral solution ("Roxane's Proposed Product"), before the patent-in-suit expires.

26. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Roxane has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Roxane's Paragraph IV Certification"), alleging that the claims of the '963 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

27. No earlier than January 9, 2015, Jazz Pharmaceuticals received written notice of Roxane's Paragraph IV Certification ("Roxane's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Roxane's Notice Letter alleged that the claims of the '963 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA. Roxane's Notice Letter also informed Jazz Pharmaceuticals that Roxane seeks approval to market Roxane's Proposed Product before the patent-in-suit expires.

Count for Infringement of the '963 Patent

28. Jazz Pharmaceuticals repeats and realleges the allegations of paragraphs 1-27 as though fully set forth herein.

29. Roxane's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '963 patent, constitutes infringement of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '963 patent.

31. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will infringe the claims of the '963 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Roxane's Proposed Product in the United States.

32. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will induce infringement of the claims of the '963 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Roxane's Proposed Product in the United States. On information and belief, upon FDA approval of Roxane's ANDA, Roxane will intentionally encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will contributorily infringe the claims of the '963 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Roxane's Proposed Product in the United States. On information and belief, Roxane has had and continues to have knowledge that Roxane's Proposed Product is especially adapted for a use that infringes the '963 patent and that there is no substantial non-infringing use for Roxane's Proposed Product.

34. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Roxane's infringement of the '963 patent is not enjoined.

35. Jazz Pharmaceuticals does not have an adequate remedy at law.

36. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Jazz Pharmaceuticals respectfully requests the following relief:

(A) A Judgment be entered that Roxane has infringed the patent-in-suit by submitting ANDA No. 202090;

(B) A Judgment be entered that Roxane has infringed, and that Roxane's making, using, selling, offering to sell, or importing Roxane's Proposed Product will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 202090 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Roxane and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Roxane's Proposed Product until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Roxane, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, offer for sale, sale, or importation into the United States of Roxane's Proposed Product will directly infringe, induce and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Roxane has committed any acts with respect to the compositions and methods claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Jazz Pharmaceuticals be awarded damages for such acts;

(H) If Roxane engages in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Roxane's Proposed Product prior to the expiration of the

patent-in-suit, a Judgment awarding damages to Jazz Pharmaceuticals resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: August 12, 2016

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360 (ES)(JAD), and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-7580 (ES)(JAD), are related to the matter in controversy because the matter in controversy involves defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: August 12, 2016

By: s/ Charles M. Lizza

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EXHIBIT A

US008731963B1

(12) **United States Patent**
Reardan et al.

(10) **Patent No.: US 8,731,963 B1**
(45) **Date of Patent: *May 20, 2014**

(54) **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**

(75) Inventors: **Dayton T. Reardan**, Shorewood, MN (US); **Patti A. Engel**, Eagan, MN (US); **Bob Gagne**, St. Paul, MN (US)

(73) Assignee: **Jazz Pharmaceuticals, Inc.**, Palo Alto, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/592,202**

(22) Filed: **Aug. 22, 2012**

Related U.S. Application Data

(63) Continuation of application No. 13/013,680, filed on Jan. 25, 2011, now abandoned, which is a 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.

(51) **Int. Cl.**
G06Q 10/00 (2012.01)

(52) **U.S. Cl.**
USPC **705/2**; 705/3; 707/803

(58) **Field of Classification Search**
USPC 707/803; 705/2, 3
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,556,342	A	1/1971	Guarr	
4,847,764	A	7/1989	Halvorson	
4,976,351	A	12/1990	Mangini et al.	
5,737,539	A	4/1998	Edelson et al.	
5,845,255	A	12/1998	Mayaud	
5,924,074	A	7/1999	Evans	
5,963,919	A *	10/1999	Brinkley et al.	705/28
6,021,392	A	2/2000	Lester et al.	
6,045,501	A	4/2000	Elsayed et al.	
6,055,507	A	4/2000	Cunningham	
6,112,182	A	8/2000	Akers et al.	
6,315,720	B1	11/2001	Williams et al.	
6,347,329	B1	2/2002	Evans	
6,564,121	B1	5/2003	Wallace et al.	
6,687,676	B1	2/2004	Denny	

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0527027 A1	2/1993

OTHER PUBLICATIONS

"Advisory Committee Video on Xyrem, Oral Solution", (May 29, 2001), 9 minutes, 8 seconds.

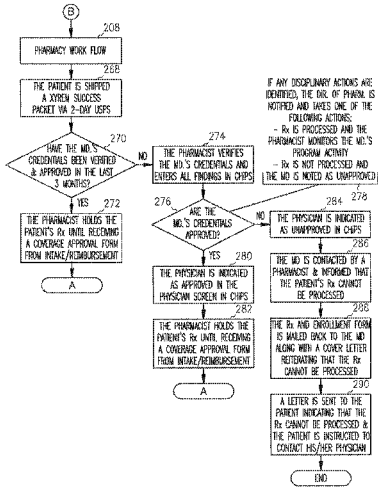
(Continued)

Primary Examiner — Lena Najarian
(74) *Attorney, Agent, or Firm* — Schwegman Lundberg & Woessner, P.A.

(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.

28 Claims, 16 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

6,755,784	B2	6/2004	Williams et al.	
6,952,681	B2	10/2005	McQuade et al.	
7,058,584	B2	6/2006	Kosinski et al.	
7,668,730	B2	2/2010	Reardan et al.	
7,765,106	B2	7/2010	Reardan et al.	
7,765,107	B2	7/2010	Reardan et al.	
7,797,171	B2	9/2010	Reardan et al.	
7,895,059	B2	2/2011	Reardan et al.	
8,457,988	B1	6/2013	Reardan et al.	
8,589,182	B1	11/2013	Reardan et al.	
2001/0001144	A1	5/2001	Kapp	
2001/0042050	A1	11/2001	Fletcher et al.	
2001/0047281	A1	11/2001	Keresman, III et al.	
2002/0010661	A1	1/2002	Waddington et al.	
2002/0032581	A1	3/2002	Reitberg	
2002/0032582	A1	3/2002	Feeney, Jr. et al.	
2002/0042725	A1	4/2002	Mayaud	
2002/0042762	A1	4/2002	McQuade et al.	
2002/0052762	A1	5/2002	Kobylevsky et al.	
2002/0161607	A1	10/2002	Subich	
2002/0177232	A1	11/2002	Melker et al.	
2003/0033168	A1	2/2003	Califano et al.	
2003/0046110	A1	3/2003	Gogolak	
2003/0050731	A1*	3/2003	Rosenblum	700/232
2003/0050802	A1	3/2003	Jay et al.	
2003/0074225	A1	4/2003	Borsand et al.	
2003/0093295	A1	5/2003	Lilly et al.	
2003/0110060	A1	6/2003	Clementi	
2003/0127508	A1	7/2003	Jones	
2003/0144876	A1	7/2003	Kosinski et al.	
2003/0160698	A1	8/2003	Andreasson et al.	
2003/0197366	A1	10/2003	Kusterbeck	
2003/0229519	A1	12/2003	Eidex et al.	
2003/0233256	A1	12/2003	Cardenas et al.	
2004/0008123	A1	1/2004	Carrender et al.	
2004/0019567	A1	1/2004	Herceg et al.	
2004/0019794	A1	1/2004	Moradi et al.	
2004/0078237	A1	4/2004	Kaafarani et al.	
2004/0107117	A1	6/2004	Denny	
2004/0117126	A1	6/2004	Fetterman et al.	
2004/0122712	A1	6/2004	Hill, Sr. et al.	
2004/0122713	A1	6/2004	Hill, Sr. et al.	
2004/0162740	A1	8/2004	Ericsson et al.	
2004/0176985	A1	9/2004	Lilly et al.	
2005/0090425	A1	4/2005	Reardan et al.	
2005/0216309	A1	9/2005	Reardan et al.	
2005/0222874	A1	10/2005	Reardan et al.	
2010/0138237	A1	6/2010	Reardan et al.	
2011/0119085	A1	5/2011	Reardan et al.	
2012/0209623	A1	8/2012	Reardan et al.	

OTHER PUBLICATIONS

"An Interview with Orphan Medical about Xyrem", http://www.talkaboutsleep.com/sleepdisorders/archives/Narcolepsy_xyrem_interview.htm, (Feb. 12, 2001), 3 pgs.
"U.S. Appl. No. 10/322,348, Advisory Action mailed Feb. 5, 2007", 3 pgs.
"U.S. Appl. No. 10/322,348, Appeal Brief filed May 21, 2007", 32 pgs.
"U.S. Appl. No. 10/322,348, Examiner Interview Summary mailed Oct. 21, 2009", 3 pgs.
"U.S. Appl. No. 10/322,348, Final Office Action mailed Oct. 18, 2006", 14 pgs.
"U.S. Appl. No. 10/322,348, Final Office Action mailed Dec. 29, 2005", 11 pgs.
"U.S. Appl. No. 10/322,348, Non Final Office Action mailed Jun. 17, 2005", 26 pgs.
"U.S. Appl. No. 10/322,348, Non Final Office Action mailed Jun. 19, 2006", 18 pgs.
"U.S. Appl. No. 10/322,348, Non Final Office Action mailed Jun. 29, 2005", 12 pgs.
"U.S. Appl. No. 10/322,348, Notice of Allowance mailed Dec. 31, 2009", 16 pgs.
"U.S. Appl. No. 10/322,348, Preliminary Amendment mailed Sep. 30, 2004", 11 pgs.
"U.S. Appl. No. 10/322,348, Reply Brief filed Dec. 3, 2007", 4 pgs.
"U.S. Appl. No. 10/322,348, Response filed Jan. 17, 2007 to Final Office Action mailed Oct. 18, 2006", 17 pgs.
"U.S. Appl. No. 10/322,348, Response filed Mar. 29, 2006 to Final Office Action mailed Dec. 29, 2005", 11 pgs.
"U.S. Appl. No. 10/322,348, Response filed Aug. 8, 2006 to Non Final Office Action mailed Jun. 19, 2006", 10 pgs.
"U.S. Appl. No. 10/322,348, Response filed Sep. 29, 2005 to Non Final Office Action mailed Jun. 29, 2005", 19 pgs.
"U.S. Appl. No. 10/731,915, Non Final Office Action mailed Sug. 12, 2005", 22 pgs.
"U.S. Appl. No. 10/731,915, Non Final Office Action mailed Oct. 5, 2004", 21 pgs.
"U.S. Appl. No. 10/731,915, Non Final Office Action Response mailed Feb. 2, 2005", 17 pgs.
"U.S. Appl. No. 10/979,665, Non-Final Office Action mailed Nov. 17, 2009", 19 pgs.
"U.S. Appl. No. 10/979,665, Notice of Allowance mailed Apr. 30, 2010", 8 pgs.
"U.S. Appl. No. 10/979,665, Preliminary Amendment filed Jun. 22, 2006", 7 pgs.
"U.S. Appl. No. 10/979,665, Preliminary Amendment mailed Nov. 2, 2004", 3 pgs.
"U.S. Appl. No. 10/979,665, Response filed Mar. 11, 2010 to Non Final Office Action mailed Nov. 17, 2009", 13 pgs.
"U.S. Appl. No. 10/979,665, Response filed Jul. 14, 2009 to Restriction Requirement mailed Jun. 25, 2009", 8 pgs.
"U.S. Appl. No. 10/979,665, Restriction Requirement mailed Jun. 25, 2009", 7 pgs.
"U.S. Appl. No. 11/097,651, Examiner Interview Summary mailed May 27, 2010", 3 pgs.
"U.S. Appl. No. 11/097,651, Final Office Action mailed Nov. 12, 2009", 14 pgs.
"U.S. Appl. No. 11/097,651, Non-Final Office Action mailed Mar. 3, 2010", 19 pgs.
"U.S. Appl. No. 11/097,651, Non-Final Office Action mailed May 27, 2009", 21 pgs.
"U.S. Appl. No. 11/097,651, Notice of Allowance mailed Jul. 23, 2010", 9 pgs.
"U.S. Appl. No. 11/097,651, Preliminary Amendment mailed Apr. 1, 2005", 6 pgs.
"U.S. Appl. No. 11/097,651, Response filed Feb. 9, 2010 to Final Office Action mailed Nov. 12, 2009", 11 pgs.
"U.S. Appl. No. 11/097,651, Response filed Jun. 3, 2010 to Non Final Office Action mailed Mar. 3, 2010", 12 pgs.
"U.S. Appl. No. 11/097,651, Response filed Sep. 17, 2009 to Non Final Office Action mailed May 29, 2009", 10 pgs.
"U.S. Appl. No. 11/097,985, Non Final Office Action mailed Sep. 14, 2009", 22 pgs.
"U.S. Appl. No. 11/097,985, Notice of Allowance mailed Mar. 10, 2010", 11 pgs.
"U.S. Appl. No. 11/097,985, Preliminary Amendment mailed Apr. 1, 2005", 7 pgs.
"U.S. Appl. No. 11/097,985, Response filed Nov. 3, 2009 to Non Final Office Action mailed Sep. 14, 2009", 15 pgs.
"U.S. Appl. No. 11/097,985, Supplemental Notice of Allowability mailed Jun. 29, 2010", 3 pgs.
"U.S. Appl. No. 12/704,097, Non-Final Office Action mailed Sep. 24, 2010", 5 pgs.
"U.S. Appl. No. 12/704,097, Notice of Allowance mailed Dec. 21, 2010", 8 pgs.
"U.S. Appl. No. 12/704,097, Response filed Nov. 4, 2010 to Non Final Office Action mailed Sep. 24, 2010", 12 pgs.
"U.S. Appl. No. 13/013,680, Response filed Jun. 12, 2012 to Restriction Requirement mailed Dec. 14, 2011", 9 pgs.
"U.S. Appl. No. 13/013,680, Restriction Requirement mailed Dec. 14, 2011", 7 pgs.
"U.S. Appl. No. 13/013,680, Preliminary Amendment filed Jun. 13, 2012", 4 pgs.

(56) **References Cited**

OTHER PUBLICATIONS

"Civil Docket", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 2:10-CV-06108-ES-CLW), (Nov. 22, 2010), 15 pgs.
"Complaint for Patent Infringement", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 10-6108 (ES) (CLW)), (Nov. 22, 2010), 14 pgs.
"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001), 12 pages.
"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (Jun. 2001), 14 Pages.
"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (Nov. 2001), 15 pages.
"Jazz Pharmaceuticals, Inc.'s Opening Markman Brief", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* United States District Court, District of New Jersey Civil Action No. 10-6108 (ES) (CLW), (Dec. 5, 2011), 34 pgs.
"Jazz Pharmaceuticals, Inc.'s Responsive Markman Brief", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 10-6108 (ES) (CLW)), (Feb. 21, 2012), 41 pgs.
"Joint Claim Construction and Prehearing Statement", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 10-6108 (ES) (CLW)), (Oct. 21, 2011), 31 pgs.
"Letter dated Oct. 14, 2010 from Randall S. Wilson (Roxane Labs) to Bruce C. Cozadd (Jazz Pharmaceuticals)", Re: Patent Notice Pursuant to Section 505(b)(3)(B) [21 USC Sec. 355(b)(3)(B)], (Oct. 14, 2010), 11 pgs.
"Letter from Theodora McCormick to Magistrate Judge Cathy L. Weldor", (w/ Exhibits), (Feb. 27, 2012), 60 pgs.
"Letter from Theodora McCormick to Magistrate Judge Cathy L. Weldor", (w/ Exhibits), (Mar. 19, 2012), 104 pgs.
"Letter from Theodora McCormick to Magistrate Judge Cathy L. Weldor", (Mar. 29, 2012), 4 pgs.
"NASCSA National Conference", Orphan Medical, Inc., (Nov. 2000), 8 pgs.
"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland, (Jun. 6, 2001), 7 pages.
"Preliminary Amendment pursuant to 37 CFR Sec. 1.115", U.S. Appl. No. 11/104,013, filed Apr. 12, 2005, 3 pgs.
"Reply to Counterclaims", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 10-6108 (SDW) (MCA), (Feb. 7, 2011), 37 pgs.
"Reply to Counterclaims", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 11-660 (SDW) (MCA) Lead Action CV-10-6108), (Apr. 18, 2011), 6 pgs.
"Roxane Laboratories, Inc.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 10-6108 (ES) (CLW), (Dec. 29, 2010), 21 pgs.
"Roxane Laboratories, Inc.'s Initial Invalidity and Noninfringement Contentions Pursuant to Local Patent Rule 3.6", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 2:10-cv-06108 (SDW) (MCA)), (Apr. 14, 2011), 317 pgs.
"Roxane Laboratories, Inc.'s Opening Markman Brief in Support of Its Claim Constructions", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 2.10-cv-06108 (ES) (CLW)), (Dec. 5, 2011), 37 pgs.
"Roxane Laboratories, Inc.'s Responsive Markman Brief in Support of Its Claim Constructions", *Jazz Pharmaceuticals, Inc.* v. *Roxane Laboratories, Inc.,* (United States District Court, District of New Jersey Civil Action No. 2:10-cv-06108 (ES) (CLW)), (Feb. 21, 2012), 27 pgs.
"System for Thalidomide Education and Prescribing Safety (S.T.E. P.S.) Starter Kit", Celgene Corporation, (2001), 103 pgs.
Ukens, C., "Specialty Pharmacy", Drug Topics, 144, (Jun. 5, 2000), 40-47.
"U.S. Appl. No. 13/595,757, Non Final Office Action mailed Jan. 17, 2013", 6 pgs.
"Markman Opinion, filed Sep. 14, 2012, in the case of *Jazz Pharmaceuticals, Inc.,* Plaintiff, v. *Roxane Laboratories, Inc.,* Defendant (United States District Court for the District of New Jersey, Civil 10-6108 ES)", 43 pgs.
"Roxane Laboratories, Inc.'s Answer and Affirmative Defenses to Plaintiff's Complaint", (Jan. 4, 2013), 8 pgs.
"Roxane Laboratories, Inc.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint", (Mar. 9, 2011), 13 pgs.
"Roxane Laboratories, Inc.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint", (Jun. 1, 2011), 12 pgs.
"Roxane Laboratories, Inc.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint", (Nov. 9, 2012), 18 pgs.
"Briefing Booklet for the Peripheral and Central Nervous System Drugs Advisory Committee Meeting", Orphan Medical, Inc., (Jun. 6, 2001), 353 pgs.
"Civil Cover Sheet", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey, (Jan. 18, 2013), 2 pgs.
"Complaint for Patent Infringement", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey, (Jan. 18, 2013), 17 pgs.
"Controlled Substances Act", Drugs of Abuse, U.S. Department of Justice, Drug Enforcement Administration, (1997), 9 pgs.
"Detailed Factual and Legal Basis of Non-Infringement and/or Invalidity", Amneal Pharmaceuticals, LLC, (Dec. 12, 2012), 3 pgs.
"Detailed Factual and Legal Basis of Non-Infringement and/or Invalidity", Amneal Pharmaceuticals, LLC, (Dec. 7, 2012), 6 pgs.
"Exhibits A-D", *Jazz Pharmaceuticals* v *Amneal Pharmaceuticals, LLC*, (Jan. 18, 2013), 151 pgs.
"Exhibits D-G", *Jazz Pharmaceuticals* v *Amneal Pharmaceuticals, LLC*, (Jan. 18, 2013), 123 pgs.
"Fed. R. Civ. P. Rule 7.1 Disclosure Statement", (Jan. 18, 2013), 2 pgs.
"Making Good in Your Own Mail-Order Business", Changing Times—The Kiplinger Magazine, (Oct. 1980), 66-68.
"Notice of Electronic Filing: Civil Inital Pleadings (Attorney/Credit Card) Use Case 33-1", US District Court, District of new Jersey [LIVE], (Jan. 18, 2013), 2 pgs.
"Notice of Paragraph IV Certification Concerning ANDA 203631 for Sodiium Oxybate Oral Solution, 500 mg/mL", Amneal Pharmaceuticals, LLC, (Dec. 7, 2012), 4 pgs.
"Notice of Paragraph IV Certification Concerning ANDA 203631 for Sodiium Oxybate Oral Solution. 500 mg/mL", Amneal Pharmaceuticals, LLC, (Dec. 12, 2012), 4 pgs.
"Peripheral and Central Nervous System Drugs Advisory Committee—Transcript", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland, (Jun. 6, 2001), 381 pgs.
"Xyrem Prescription and Distribution Process-Video Script", (Feb. 2, 2001), 10 pgs.
Deutsch, Sheryl, "The Verification and Information-Gathering Process", The Credentialing Handbook, Aspen Publishers, Inc., (1999), 231-275.
Mani, Ranjit, "Preliminary Clinical Safety Review of NDA No. 21196", Orphan Medical, Inc., (May 3, 2001), 122 pgs.
"U.S. Appl. No. 13/595,676, Notice of Allowance mailed Sep. 17, 2013", 8 pgs.
"Civil Cover Sheet", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC*, (United States District Court, District of New Jersey), (Sep. 12, 2013), 2 pgs.
"Complaint for Patent Infringement with Exhibit A", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey), (Sep. 12, 2013), 76 pgs.

(56) **References Cited**

OTHER PUBLICATIONS

"Fed. R. Civ. P. Rule 7.1 Disclosure Statement", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey), (Sep. 12, 2013), 2 pgs.
"Notice of Electronic Filing: Civil Inital Pleadings (Attorney/Credit Card) Use Case 33-1)", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey [LIVE]), (Sep. 12, 2013), 1 pg.
"U.S. Appl. No. 13/595,676 , Response filed May 31, 2013 to Non Final Office Action mailed Mar. 21, 2013", 14 pgs.
"U.S. Appl. No. 13/595,676, Examiner Interview Summary mailed May 30, 2013", 3 pgs.
"Notice of Paragraph IV Certification", Detailed Statement of the Factual and Legal Bases for Pars Paragraph IV Patent Certification and Offer of Confidential Access, (Nov. 20, 2013), 190 pgs.
Oxtoby, David W, et al., "", Principles of Modern Chemistry, Fort Worth : Saunders College Pub., (1996), 52-56.
"Civil Action No. 2:13-cv-00391-ES-SCM (consolidated)", Defendant Amneal Pharmaceuticals, LLC's Preliminary Invalidity Contentions (United States District Court of New Jersey), 182 pgs.
"Civil Cover Sheet", *Jazz Pharmaceuticals, Inc.* v. *Par Pharmaceuticals, Inc.*, (United States District Court, District of New Jersey), (Dec. 27, 2013), 1 pg.
"Complaint for Patent Infringement", *Jazz Pharmaceuticals, Inc.* v. *Par Pharmaceuticals, Inc*, (United States District Court, District of New Jersey), (Dec. 27, 2013), 26 pgs.
"Fed. R. Civ. P. Rule 7.1 Disclosure Statement", *Jazz Pharmaceuticals, Inc.* v. *Par Pharmaceuticals, Inc.*, (United States District Court, District of New Jersey), (Dec. 27, 2013), 2 pgs.
"Final Minutes: Peripheral and Central Nervous System Drugs Advisory Committee", [Online]. Retrieved from the Internet: <URL: http://www.fda.gov/ohrms/dockets/ac/01/minutes/3754m1.htm>, (Jun. 6, 2001), 6 pgs.
"Notice of Paragraph IV Certification", Detailed Statement of the Factual and Legal Bases for Pars Paragraph IV Patent Certification and Offer of Confidential Access, (Dec. 20, 2013), 190 pgs.
"Orphan Medical Slides: Xyrem (sodium oxybate) oral solution", Peripheral and Central Nervous System Drugs Advisory Committee Meeting, [Online]. Retrieved from the Internet: <URL: http://www.fda.gov/ohrms/dockets/ac/01/slides/3754s1_01_orphanmedical/index.htm>, (Jun. 6, 2001), 167 pgs.
"Report on the Filing or Determination of an Action Regarding a Patent or Trademark", *Jazz Pharmaceuticals, Inc.* v. *Par Pharmaceuticals, Inc.*, United States District Court, District of New Jersey Case No. 2:13-cv-07884-ES-JAD, (Dec. 27, 2013), 1 pg.
"Slides: Pediatric Subcommittee of the Peripheral and Central Nervous system Drugs Advisory Committee", [Online]. Retrieved from the Internet: <URL: http://www.fda.gov/ohrms/dockets/ac/01/slides/3754s1.htm>, (Jun. 6, 2001), 86 pgs.
"Summons in a Civil Case", *Jazz Pharmaceuticals, Inc.* v. *Par Pharmaceuticals, Inc.*, United States District Court, District of New Jersey Case No. 213-CV-07884-ES-JAD, (Dec. 31, 2013), 2 pgs.
Oxtoby, David W, et al., Principles of Modern Chemistry, Fort Worth: Saunders College Pub., (1996), 52-56.
U.S. Appl. No. 13/595,676, Non Final Office Action mailed Mar. 21, 2013, 16 pgs.
U.S. Appl. No. 13/595,757, Examiner Interview Summary mailed Mar. 12, 2013, 3 pgs.
U.S. Appl. No. 13/595,757, Notice of Allowance mailed Mar. 21, 2013, 68 pgs.
U.S. Appl. No. 13/595,757, Response filed Mar. 7, 2013 to Non Final Office Action mailed Jan. 17, 2013, 8 pgs.
"Roxane Laboratories, Inc.'s Amended Answer and Affirmative Defenses to Plaintiffs Complaint Regarding U.S. Patent No. 8,234,275", Exhibit 2, (Apr. 26, 2013), 15 pgs.
"Roxane Laboratories, Inc.'s Amended Answer, Affirmative Defenses and Counterclaims to Plaintiffs Complaint Regarding U.S. Patent No. 8,263,650", Exhibit 1, (Apr. 26, 2013), 23 pgs.
"Answer, Defenses, and Counterclaims", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC,* (United States District Court, District of New Jersey Civil Action No. 13-391 ES-SCM, (Apr. 15, 2013), 22 pgs.
"Notice of Voluntary Dismissal of Counterclaims Pertaining to U.S. Patent Nos. 7,668,730; 7,765,106; and 7,765,107 (Contained in Counts I, II) Pursuant to Fed. R. Civ. P. 41(a), (c)", *Jazz Pharmaceuticals, Inc.* v. *Amneal Pharmaceuticals, LLC*, (United States District Court, District of New Jersey Civil Action No. 13-391 ES-SCM, (Jul. 15, 2013), 2 pgs.

* cited by examiner

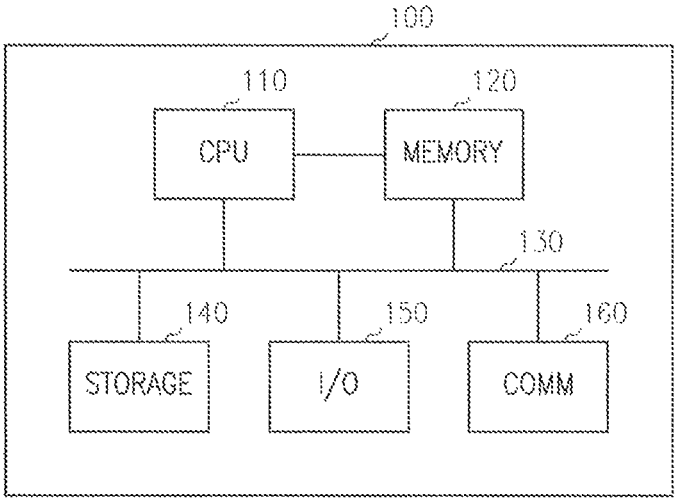


FIG. 1

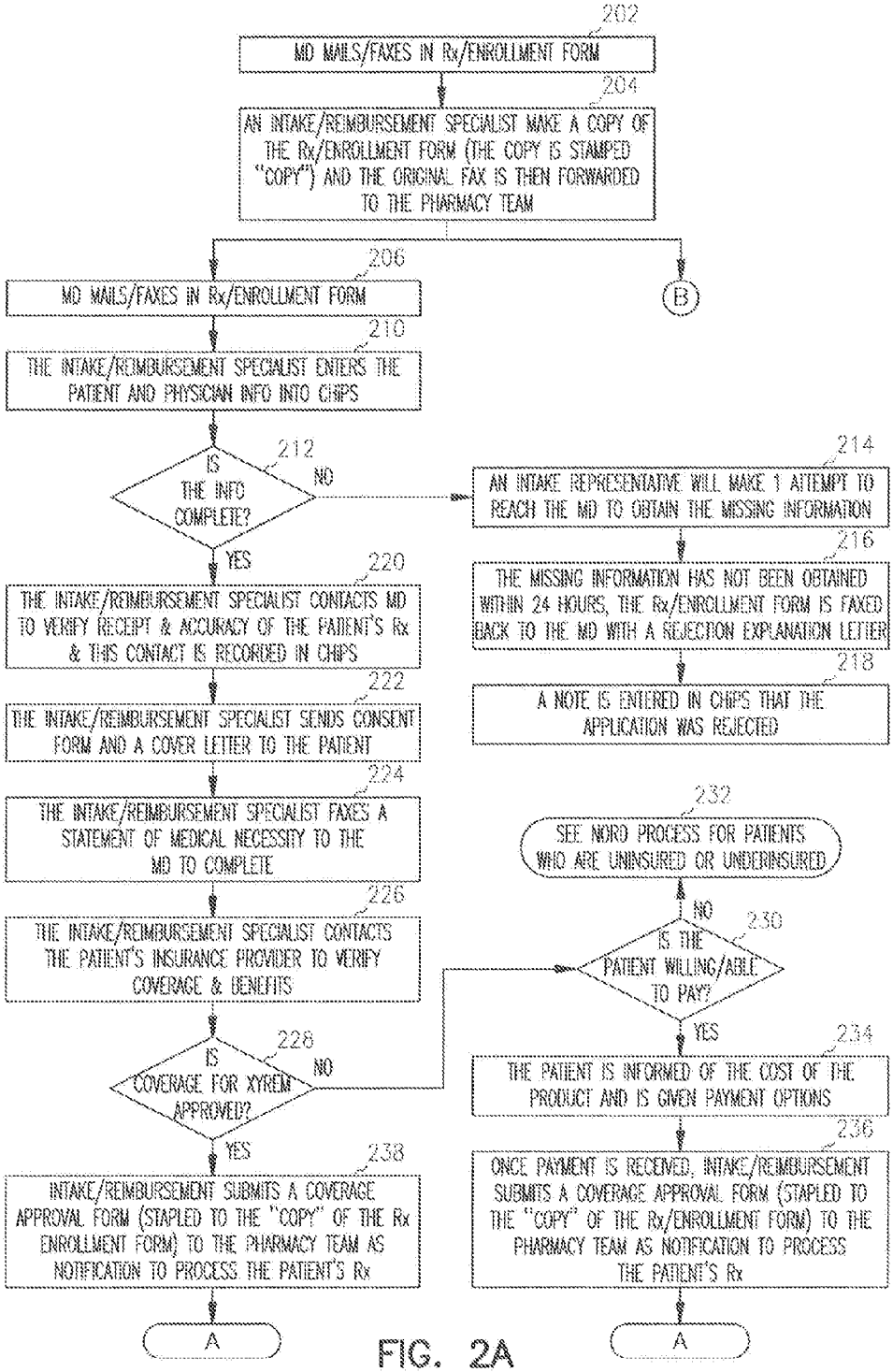

202
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
204
AN INTAKE/REIMBURSEMENT SPECIALIST MAKE A COPY OF THE Rx/ENROLLMENT FORM (THE COPY IS STAMPED "COPY") AND THE ORIGINAL FAX IS THEN FORWARDED TO THE PHARMACY TEAM
206
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
B
210
THE INTAKE/REIMBURSEMENT SPECIALIST ENTERS THE PATIENT AND PHYSICIAN INFO INTO CHIPS
212
IS THE INFO COMPLETE?
NO
214
AN INTAKE REPRESENTATIVE WILL MAKE 1 ATTEMPT TO REACH THE MD TO OBTAIN THE MISSING INFORMATION
216
THE MISSING INFORMATION HAS NOT BEEN OBTAINED WITHIN 24 HOURS, THE Rx/ENROLLMENT FORM IS FAXED BACK TO THE MD WITH A REJECTION EXPLANATION LETTER
218
A NOTE IS ENTERED IN CHIPS THAT THE APPLICATION WAS REJECTED
YES
220
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS MD TO VERIFY RECEIPT & ACCURACY OF THE PATIENT'S Rx & THIS CONTACT IS RECORDED IN CHIPS
222
THE INTAKE/REIMBURSEMENT SPECIALIST SENDS CONSENT FORM AND A COVER LETTER TO THE PATIENT
224
THE INTAKE/REIMBURSEMENT SPECIALIST FAXES A STATEMENT OF MEDICAL NECESSITY TO THE MD TO COMPLETE
226
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE & BENEFITS
228
IS COVERAGE FOR XYREM APPROVED?
NO
YES
232
SEE NORD PROCESS FOR PATIENTS WHO ARE UNINSURED OR UNDERINSURED
NO
230
IS THE PATIENT WILLING/ABLE TO PAY?
YES
234
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
236
ONCE PAYMENT IS RECEIVED, INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx/ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
238
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
A
A

FIG. 2A

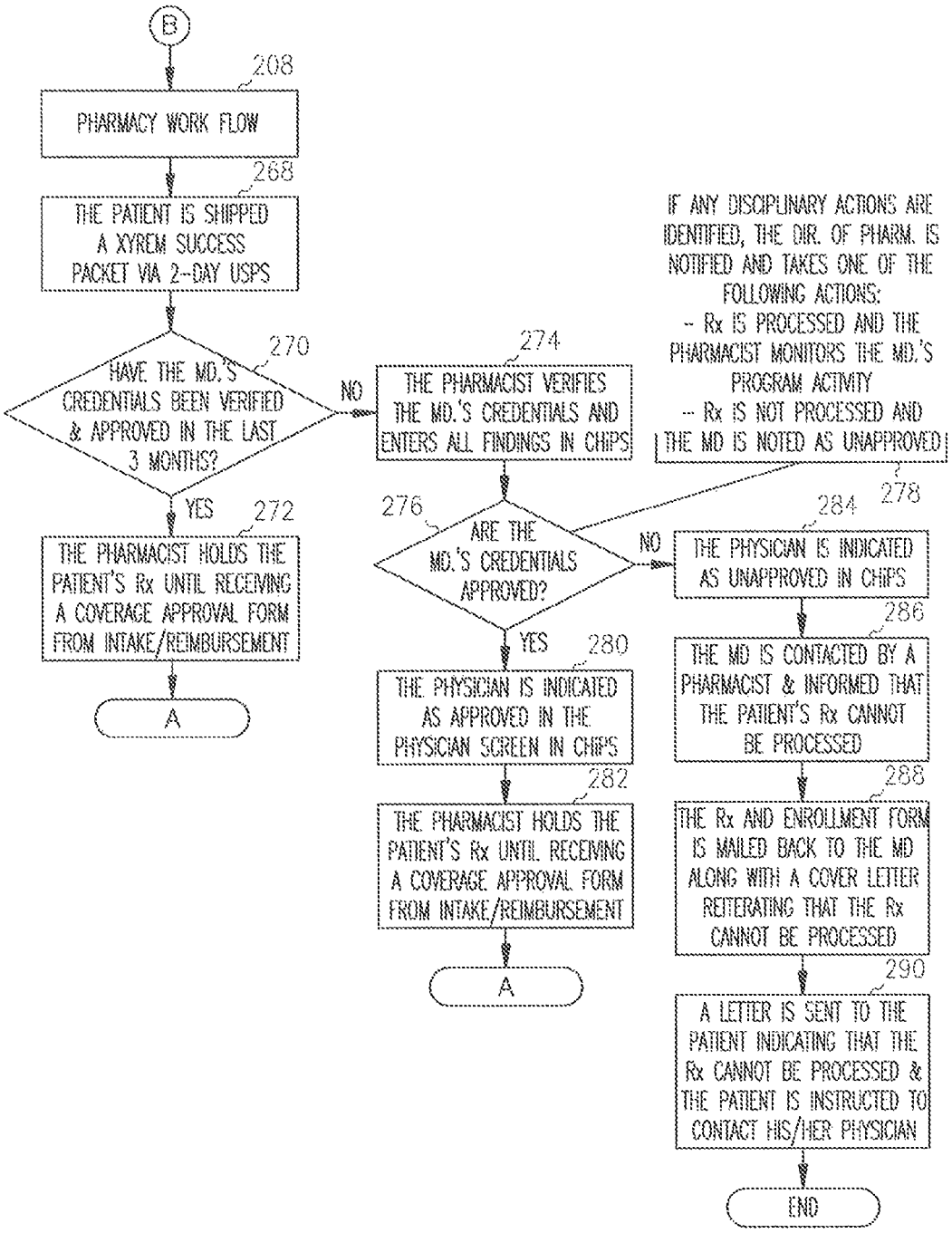

B
208
PHARMACY WORK FLOW
268
THE PATIENT IS SHIPPED A XYREM SUCCESS PACKET VIA 2-DAY USPS
270
HAVE THE MD.'S CREDENTIALS BEEN VERIFIED & APPROVED IN THE LAST 3 MONTHS?
NO
YES
272
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
274
THE PHARMACIST VERIFIES THE MD.'S CREDENTIALS AND ENTERS ALL FINDINGS IN CHIPS
276
ARE THE MD.'S CREDENTIALS APPROVED?
NO
YES
278
IF ANY DISCIPLINARY ACTIONS ARE IDENTIFIED, THE DIR. OF PHARM. IS NOTIFIED AND TAKES ONE OF THE FOLLOWING ACTIONS:
- Rx IS PROCESSED AND THE PHARMACIST MONITORS THE MD.'S PROGRAM ACTIVITY
-- Rx IS NOT PROCESSED AND THE MD IS NOTED AS UNAPPROVED
280
THE PHYSICIAN IS INDICATED AS APPROVED IN THE PHYSICIAN SCREEN IN CHIPS
282
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
284
THE PHYSICIAN IS INDICATED AS UNAPPROVED IN CHIPS
286
THE MD IS CONTACTED BY A PHARMACIST & INFORMED THAT THE PATIENT'S Rx CANNOT BE PROCESSED
288
THE Rx AND ENROLLMENT FORM IS MAILED BACK TO THE MD ALONG WITH A COVER LETTER REITERATING THAT THE Rx CANNOT BE PROCESSED
290
A LETTER IS SENT TO THE PATIENT INDICATING THAT THE Rx CANNOT BE PROCESSED & THE PATIENT IS INSTRUCTED TO CONTACT HIS/HER PHYSICIAN
END

FIG. 2B

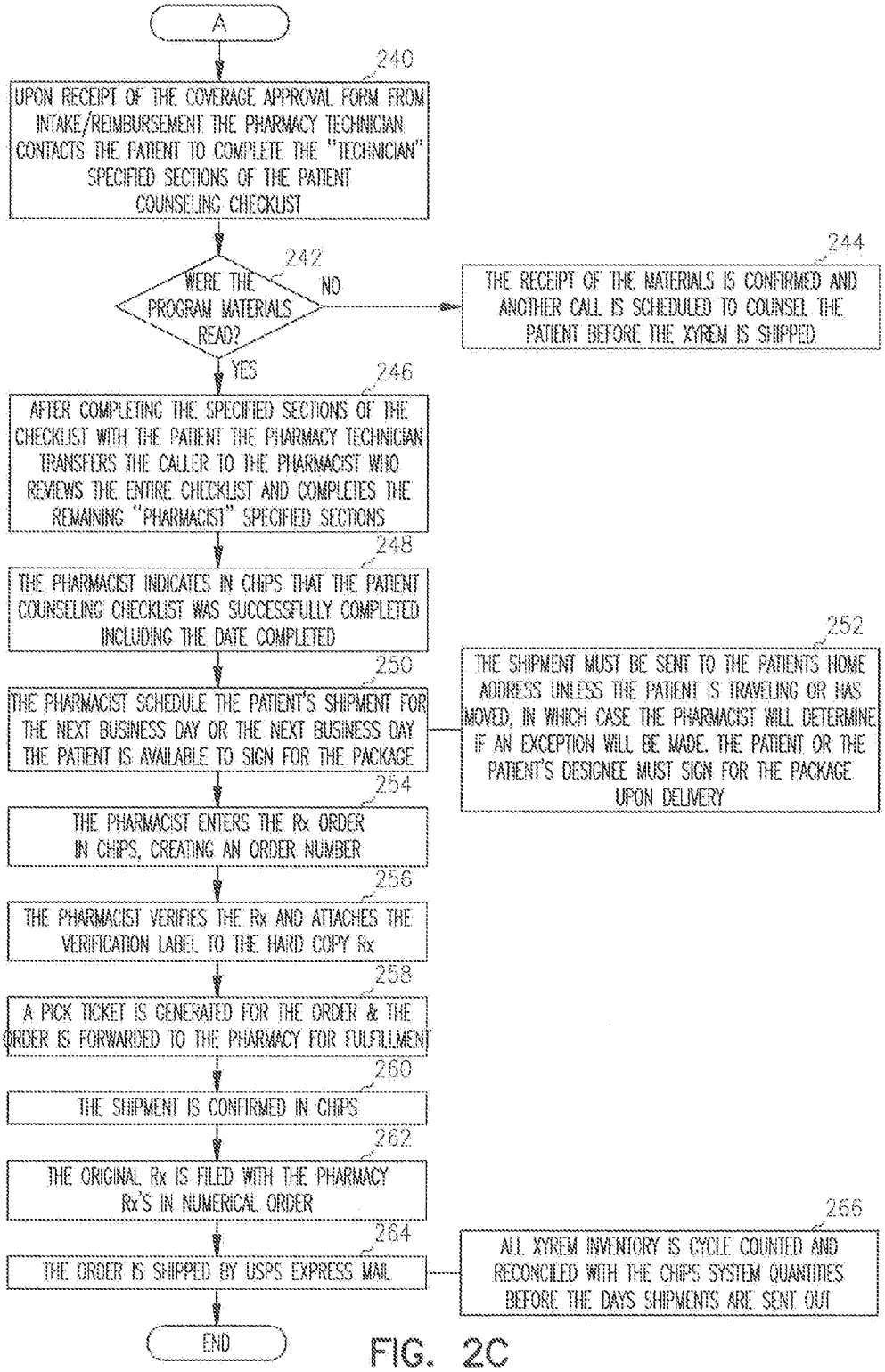

A
240
UPON RECEIPT OF THE COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE "TECHNICIAN" SPECIFIED SECTIONS OF THE PATIENT COUNSELING CHECKLIST
242
WERE THE PROGRAM MATERIALS READ?
NO
244
THE RECEIPT OF THE MATERIALS IS CONFIRMED AND ANOTHER CALL IS SCHEDULED TO COUNSEL THE PATIENT BEFORE THE XYREM IS SHIPPED
YES
246
AFTER COMPLETING THE SPECIFIED SECTIONS OF THE CHECKLIST WITH THE PATIENT THE PHARMACY TECHNICIAN TRANSFERS THE CALLER TO THE PHARMACIST WHO REVIEWS THE ENTIRE CHECKLIST AND COMPLETES THE REMAINING "PHARMACIST" SPECIFIED SECTIONS
248
THE PHARMACIST INDICATES IN CHIPS THAT THE PATIENT COUNSELING CHECKLIST WAS SUCCESSFULLY COMPLETED INCLUDING THE DATE COMPLETED
252
THE SHIPMENT MUST BE SENT TO THE PATIENTS HOME ADDRESS UNLESS THE PATIENT IS TRAVELING OR HAS MOVED, IN WHICH CASE THE PHARMACIST WILL DETERMINE IF AN EXCEPTION WILL BE MADE. THE PATIENT OR THE PATIENT'S DESIGNEE MUST SIGN FOR THE PACKAGE UPON DELIVERY
250
THE PHARMACIST SCHEDULE THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
254
THE PHARMACIST ENTERS THE Rx ORDER IN CHIPS, CREATING AN ORDER NUMBER
256
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
258
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
260
THE SHIPMENT IS CONFIRMED IN CHIPS
262
THE ORIGINAL Rx IS FILED WITH THE PHARMACY Rx'S IN NUMERICAL ORDER
266
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHIPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
264
THE ORDER IS SHIPPED BY USPS EXPRESS MAIL
END

FIG. 2C

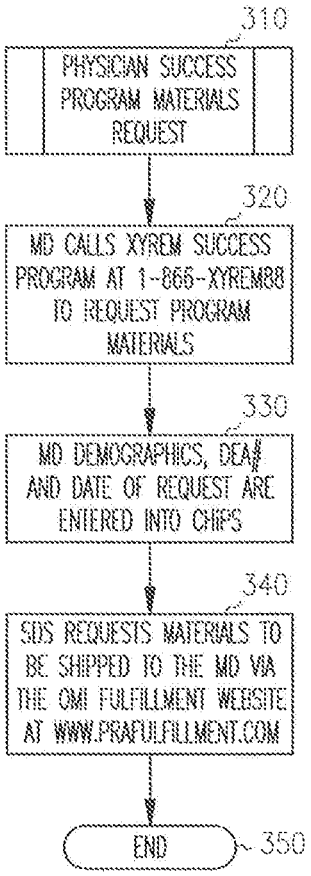

310
PHYSICIAN SUCCESS PROGRAM MATERIALS REQUEST
320
MD CALLS XYREM SUCCESS PROGRAM AT 1-866-XYREM88 TO REQUEST PROGRAM MATERIALS
330
MD DEMOGRAPHICS, DEA# AND DATE OF REQUEST ARE ENTERED INTO CHPS
340
SDS REQUESTS MATERIALS TO BE SHIPPED TO THE MD VIA THE OMI FULFILLMENT WEBSITE AT WWW.PRAFULFILLMENT.COM
END
350

FIG. 3

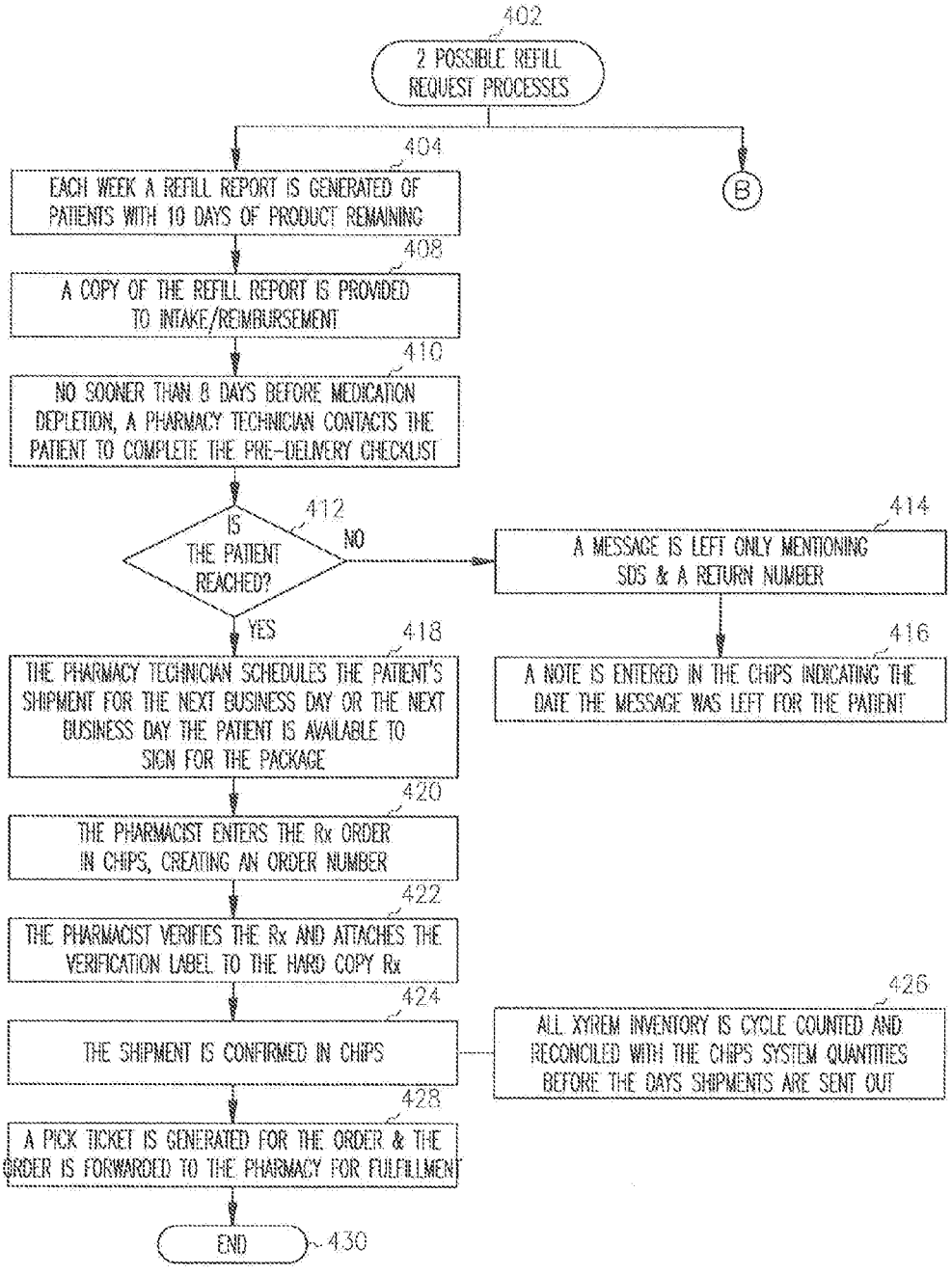

402
2 POSSIBLE REFILL REQUEST PROCESSES
404
EACH WEEK A REFILL REPORT IS GENERATED OF PATIENTS WITH 10 DAYS OF PRODUCT REMAINING
B
408
A COPY OF THE REFILL REPORT IS PROVIDED TO INTAKE/REIMBURSEMENT
410
NO SOONER THAN 8 DAYS BEFORE MEDICATION DEPLETION, A PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE PRE-DELIVERY CHECKLIST
412
IS THE PATIENT REACHED?
NO
YES
414
A MESSAGE IS LEFT ONLY MENTIONING SDS & A RETURN NUMBER
416
A NOTE IS ENTERED IN THE CHIPS INDICATING THE DATE THE MESSAGE WAS LEFT FOR THE PATIENT
418
THE PHARMACY TECHNICIAN SCHEDULES THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
420
THE PHARMACIST ENTERS THE Rx ORDER IN CHIPS, CREATING AN ORDER NUMBER
422
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
424
THE SHIPMENT IS CONFIRMED IN CHIPS
426
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHIPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
428
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
END
430

FIG. 4A

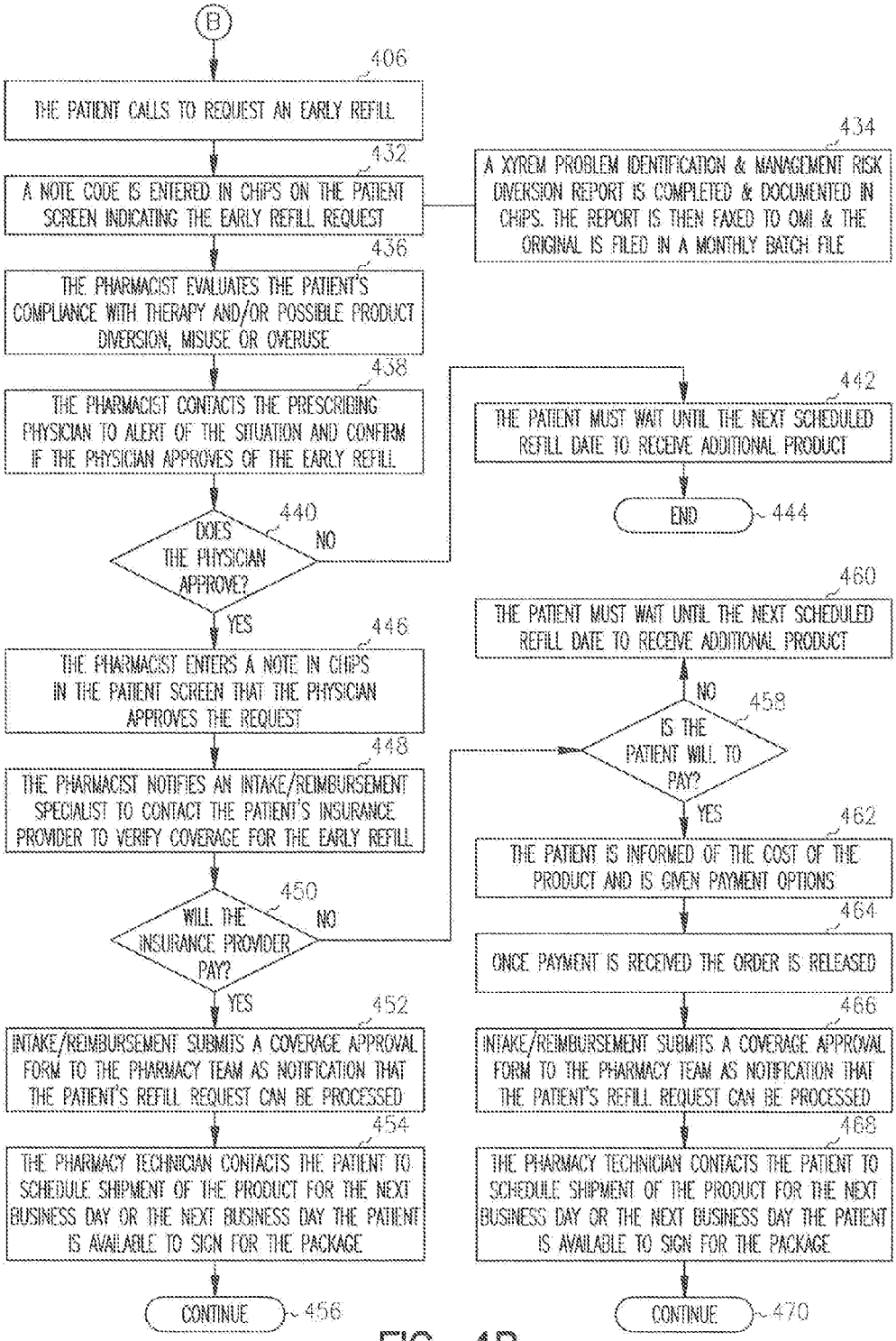

B
406
THE PATIENT CALLS TO REQUEST AN EARLY REFILL
432
A NOTE CODE IS ENTERED IN CHIPS ON THE PATIENT SCREEN INDICATING THE EARLY REFILL REQUEST
434
A XYROM PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORT IS COMPLETED & DOCUMENTED IN CHIPS. THE REPORT IS THEN FAXED TO OMI & THE ORIGINAL IS FILED IN A MONTHLY BATCH FILE
436
THE PHARMACIST EVALUATES THE PATIENT'S COMPLIANCE WITH THERAPY AND/OR POSSIBLE PRODUCT DIVERSION, MISUSE OR OVERUSE
438
THE PHARMACIST CONTACTS THE PRESCRIBING PHYSICIAN TO ALERT OF THE SITUATION AND CONFIRM IF THE PHYSICIAN APPROVES OF THE EARLY REFILL
440
DOES THE PHYSICIAN APPROVE?
NO
YES
442
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
END
444
446
THE PHARMACIST ENTERS A NOTE IN CHIPS IN THE PATIENT SCREEN THAT THE PHYSICIAN APPROVES THE REQUEST
448
THE PHARMACIST NOTIFIES AN INTAKE/REIMBURSEMENT SPECIALIST TO CONTACT THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE FOR THE EARLY REFILL
450
WILL THE INSURANCE PROVIDER PAY?
NO
YES
452
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
454
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
456
460
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
NO
458
IS THE PATIENT WILL TO PAY?
YES
462
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
464
ONCE PAYMENT IS RECEIVED THE ORDER IS RELEASED
466
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
468
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
470

FIG. 4B

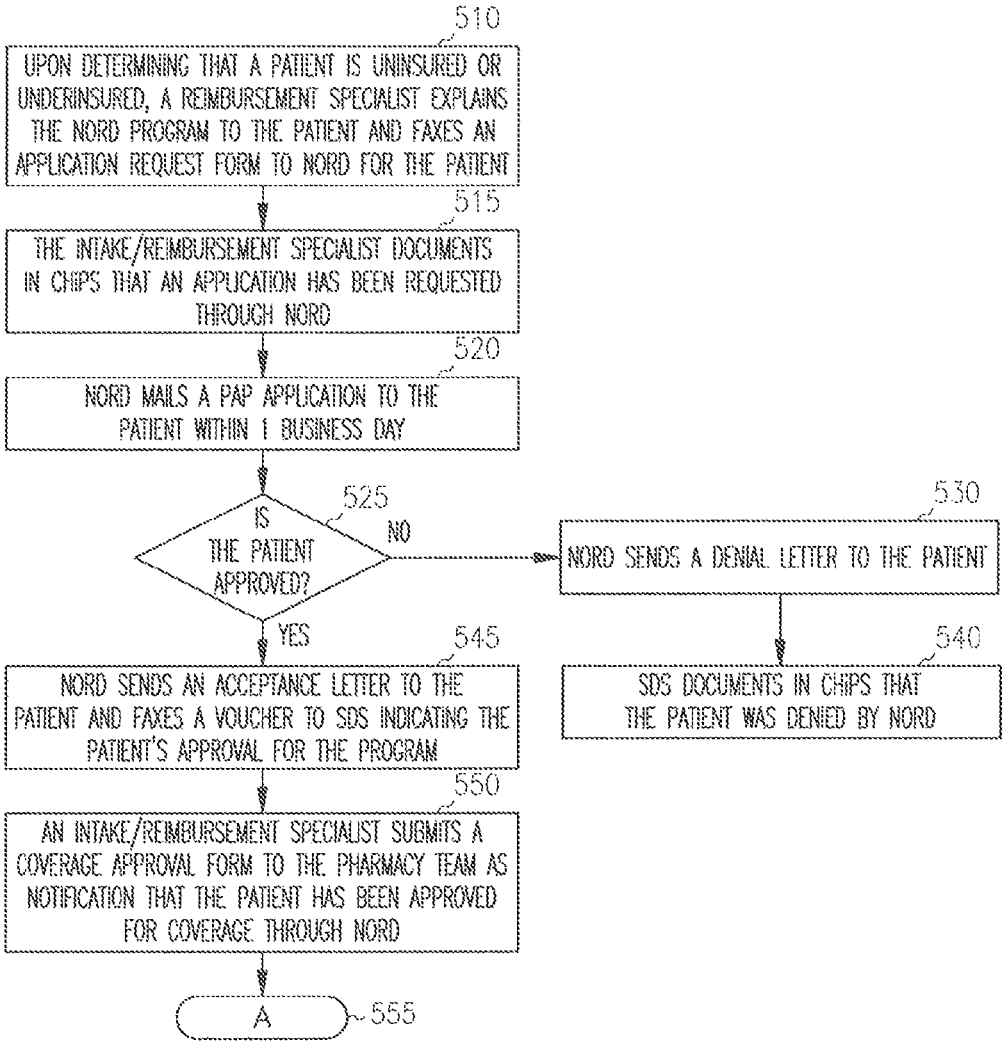

510
UPON DETERMINING THAT A PATIENT IS UNINSURED OR UNDERINSURED, A REIMBURSEMENT SPECIALIST EXPLAINS THE NORD PROGRAM TO THE PATIENT AND FAXES AN APPLICATION REQUEST FORM TO NORD FOR THE PATIENT
515
THE INTAKE/REIMBURSEMENT SPECIALIST DOCUMENTS IN CHIPS THAT AN APPLICATION HAS BEEN REQUESTED THROUGH NORD
520
NORD MAILS A PAP APPLICATION TO THE PATIENT WITHIN 1 BUSINESS DAY
525
IS THE PATIENT APPROVED?
NO
530
NORD SENDS A DENIAL LETTER TO THE PATIENT
YES
545
NORD SENDS AN ACCEPTANCE LETTER TO THE PATIENT AND FAXES A VOUCHER TO SDS INDICATING THE PATIENT'S APPROVAL FOR THE PROGRAM
540
SDS DOCUMENTS IN CHIPS THAT THE PATIENT WAS DENIED BY NORD
550
AN INTAKE/REIMBURSEMENT SPECIALIST SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT HAS BEEN APPROVED FOR COVERAGE THROUGH NORD
A
555

FIG. 5

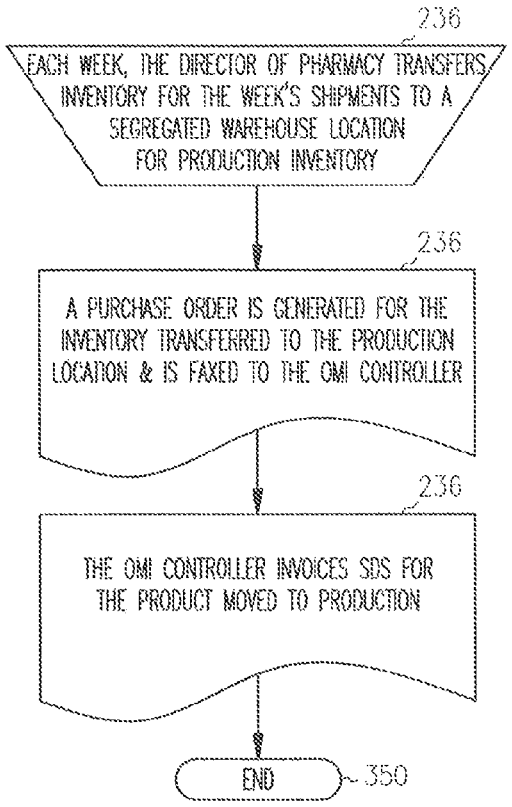


FIG. 6

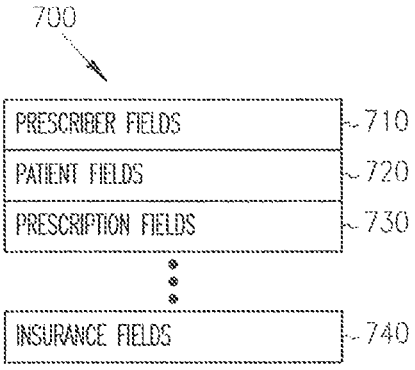


FIG. 7

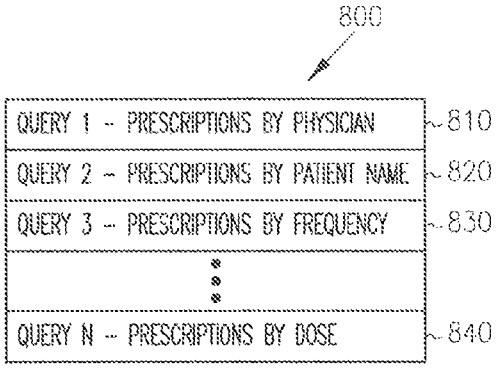


FIG. 8

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

☐ I HAVE READ THE MATERIALS IN THE XYREM PHYSICIAN SUCCESS PROGRAM
☐ I VERIFY THAT THE PATIENT HAS BEEN EDUCATED WITH RESPECT TO XYREM PREPARATION, DOSING AND SCHEDULING.
☐ 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.
☐ I UNDERSTAND THAT THE SAFETY OF DOSES GREATER THAN 9gm/DAY HAS NOT BEEN ESTABLISHED

PATIENT INFORMATION

BEST TIME TO CONTACT PATIENT: ☐ DAY ☐ NIGHT
DAY #: ..... EVENING #: .....
INSURANCE COMPANY NAME: ..... PHONE #: .....
INSURED'S NAME: ..... RELATIONSHIP TO PATIENT: .....
IDENTIFICATION NUMBER: ..... POLICY/GROUP NUMBER: .....
PRESCRIPTION CARD: ☐ NO ☐ 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

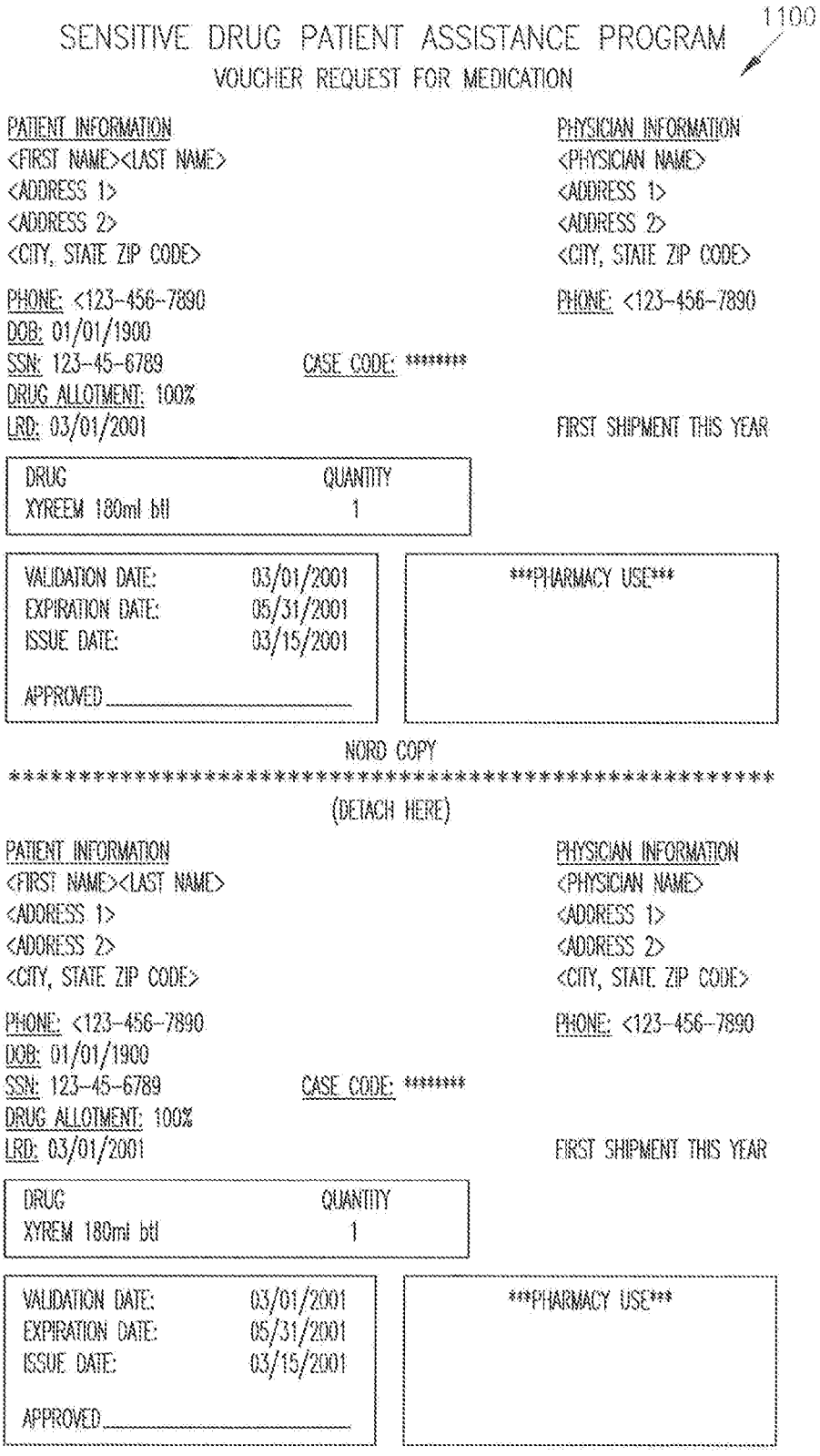

SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM
1100
VOUCHER REQUEST FOR MEDICATION
PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>
PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
CASE CODE: ********
DRUG ALLOTMENT: 100%
LRD: 03/01/2001
PHYSICIAN INFORMATION
<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
CASE CODE: ********
DRUG ALLOTMENT: 100%
LRD: 03/01/2001
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
SALES			
Rx BY ZIP (NEW AND TOTAL)	X	X	X
Rx BY PHYSICIAN BY ZIP	X	X	
$ BY ZIP	X	X	X
REGULATORY			
# 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	
QUALITY ASSURANCE			
# OF PRODUCT DEFECTS/COMPLAINTS REPORTED, TYPE AND LOT #		X	
CALL CENTER			
# 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	
PHARMACY			
# OF FAXED RxENROLLMENT FORMS		X	
# OF MAILED RxENROLLEMENT FORMS		X	
# OF RxS SHIPPED WITH 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			
# 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

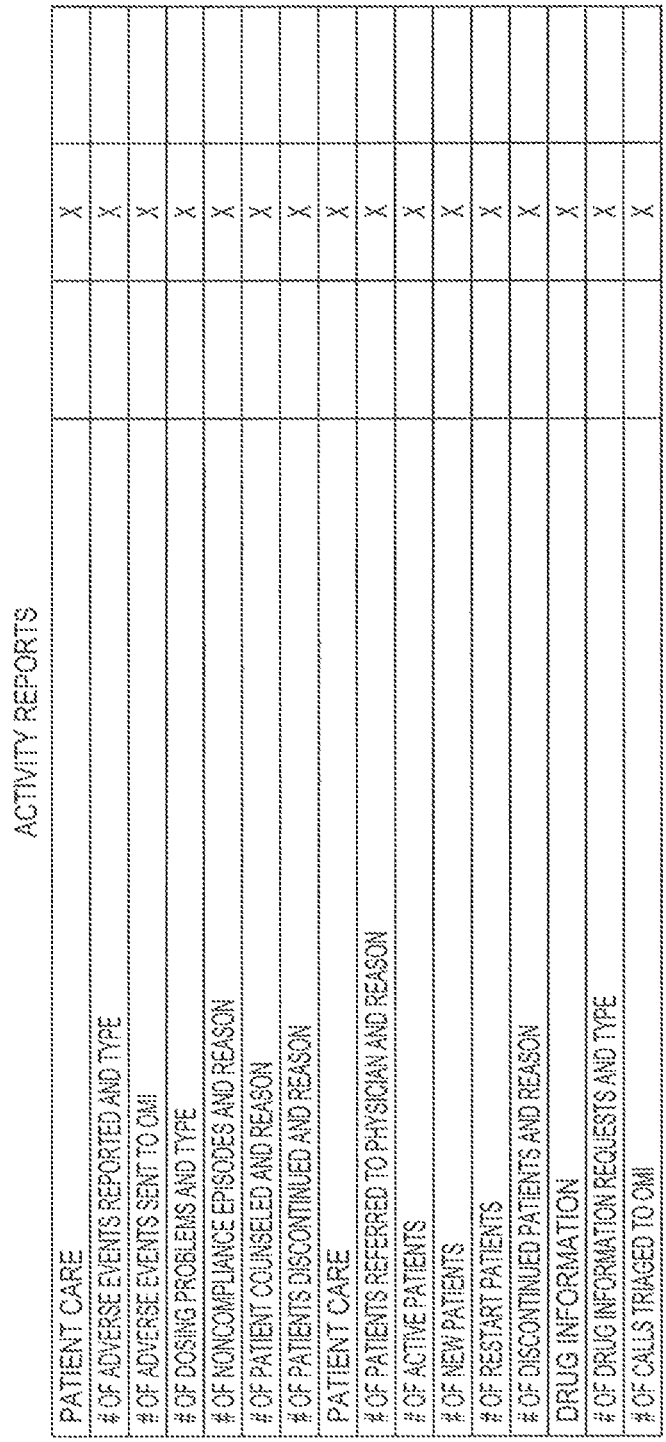

ACTIVITY REPORTS
PATIENT CARE
OF ADVERSE EVENTS REPORTED AND TYPE
OF ADVERSE EVENTS SENT TO OMI
OF DOSING PROBLEMS AND TYPE
OF NONCOMPLIANCE EPISODES AND REASON
OF PATIENT COUNSELED AND REASON
OF PATIENTS DISCONTINUED AND REASON
PATIENT CARE
OF PATIENTS REFERRED TO PHYSICIAN AND REASON
OF ACTIVE PATIENTS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

FIG. 13C

SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

RELATED APPLICATION

This application a Continuation of U.S. application Ser. No. 13/013,680, filed on Jan. 25, 2011, which is a Continuation of U.S. application Ser. No. 12/704,097, filed on Feb. 11, 2010 and issued on Feb. 22, 2011 as U.S. Pat. No. 7,895,059, 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

The present invention relates to distribution of drugs, and in particular to the distribution of sensitive drugs.

BACKGROUND OF THE INVENTION

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.

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.

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

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.

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.

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.

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.

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

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

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

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**.

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

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

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**.

FIG. **7** is a block diagram of database fields.

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

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

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

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

FIG. **12** is a copy of certificate of medical need.

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

DETAILED DESCRIPTION OF THE INVENTION

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.

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.

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.

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.

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.

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.

FIGS. **2**A, **2**B and **2**C 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.

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.

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.

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.

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.

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**.

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**.

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.

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.

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 pharmacists indicates in the database that the patient counseling and checklist was successfully completed, indicating the date completed.

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.

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.

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.

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**.

A refill request process begins at **302** in FIGS. **4**A and **4**B. 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.

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 **30** 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**.

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**.

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**.

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**.

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**.

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.

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**.

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**.

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.

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.

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.

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.

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.

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.

FIGS. **13**A, **13**B and **13**C 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.

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.

The invention claimed is:

1. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing 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;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing 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;

a data processor configured to:

process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and

reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using

said database query to identify information in the prescription fields and patient fields;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

2. The system of claim **1**, wherein the data processor selectively blocks shipment of the prescription drug to the patient based upon said identifying by the database query.

3. The system of claim **1**, wherein the prescription drug is shipped to the narcoleptic patient if no potential misuse, abuse or diversion is found for the narcoleptic patient.

4. The system of claim **1**, wherein the single computer database is an exclusive database that receives data associated with all patients being prescribed the prescription drug that is associated with the company.

5. The system of claim **1**, wherein an exclusive central pharmacy controls the single computer database.

6. The system of claim **1** wherein the prescription drug comprises gamma hydroxyl butyrate (GHB).

7. The system of claim **1**, wherein the single computer database comprises a relational database.

8. The system of claim **1**, wherein the single computer database is distributed among multiple computers and the database query operates over all data relating to said prescription fields, prescriber fields, and patient fields for the prescription drug.

9. The system of claim **1**, wherein the data processor is configured to initiate an inquiry to a prescriber when one or more prescription fields, patient fields, or prescriber fields are incomplete in the computer database.

10. The system of claim **1**, wherein the data processor is configured to process a third database query that identifies an expected date for a refill of the prescription drug.

11. The system of claim **10**, wherein the expected date is based on a prescription for the prescription drug and a date of a previous filling of the prescription.

12. The system of claim **11**, wherein the prescription identifies an amount of the prescription drug to be provided and a schedule for consumption of the prescription drug.

13. The system of claim **1**, wherein the database schema further contains and interrelates insurance fields, wherein the insurance fields, contained within the database schema, store information sufficient to identify an insurer to be contacted for payment for prescription drugs of an associated patient.

14. The system of claim **1**, wherein the single computer database is used to identify a current pattern or an anticipated pattern of abuse of the prescription drug; wherein the current pattern or the anticipated pattern are identified using periodic reports generated from the single computer database.

15. The system of claim **14**, wherein one or more controls for distribution of the prescription drug are selected based on the identified pattern.

16. The system of claim **15**, wherein the one or more controls are submitted to an approval body for approval of distribution of the prescription drug.

17. The system of claim **1**, wherein additional controls for distribution are selected in a negotiation with an approval body to garner the approval of distribution.

18. The system of claim **17**, wherein the data processor is used to add further controls until approval is obtained.

19. The system of claim **18**, wherein the approval body is the Food and Drug Administration (FDA) or the Drug Enforcement Agency (DEA).

20. The system of claim **1**, wherein current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent.

21. The system of claim **1**, wherein the single computer database comprises an exclusive computer database of the company that obtained approval for distribution of the prescription drug, wherein all prescriptions for the company's prescription drug are stored only in the exclusive computer database of the company, and wherein the company's prescription drug is sold or distributed by the company using only the exclusive computer database of the company.

22. The system of claim **1**, wherein the single computer database comprises a single computer database of the company that obtained approval for distribution of the prescription drug, wherein the prescription fields store all prescription requests, for all patients being prescribed the company's prescription drug, only in the single computer database of the company, from all physicians or other prescribers allowed to prescribe the company's prescription drug, such that all prescriptions for the company's prescription drug are processed using only the single computer database of the company.

23. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing 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;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing 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;

a data processor for processing a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug;

said database query identifying information in the prescription fields and patient fields for reconciling inventory of the prescription drug before the shipments for a day or other time period are sent, wherein an inventory reconciliation is performed where current inventory is counted and reconciled with database quantities before shipments for a day or other time period are sent, and wherein the data processor is configured to selectively block shipment of the prescription drug based on the inventory reconciliation;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

24. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug, comprising:

one or more computer memories for storing a central computer database of the company that obtained approval for distribution of the prescription drug, for receiving prescriptions from any and all patients being prescribed the company's prescription drug, said central computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said central computer database being distributed over multiple computers;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify any and all physicians or other prescribers of the company's prescription drug and information to show that the physicians or other prescribers are authorized to prescribe the company's prescription drug;

one or more data processors for processing one or more database queries that operate over data related to the prescription fields, prescriber fields, and patient fields for the prescription drug;

said one or more database queries checking for abuse within the central computer database, wherein the filling of the prescriptions is authorized for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient and prescriber and if there is a record of such incidents, the central computer database indicates that such incidents have been investigated, and the central computer database indicates that such incidents do not involve abuse, misuse or diversion.

25. The system of claim **24**, wherein the one or more database queries are processed by the one or more data processors for identifying: that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

26. The system of claim **24**, where the central computer database is distributed among multiple computers, and where the one or more database queries operate over all data relating to said prescription fields, prescriber fields, and patient fields for the prescription drug.

27. The system of claim **24**, wherein the central computer database is used to identify a current pattern or an anticipated pattern of abuse of the prescription drug;

wherein the current pattern or the anticipated pattern are identified using periodic reports generated from the single computer database.

28. The system of claim **24**, wherein current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent.

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