



US 20050150806A1

(19) **United States**(12) **Patent Application Publication**
Lorenzato(10) **Pub. No.: US 2005/0150806 A1**(43) **Pub. Date: Jul. 14, 2005**(54) **MEDICATION DISTRIBUTION SYSTEM**(52) **U.S. Cl. 206/534**(76) **Inventor: Raymond Mark Lorenzato, Paradise,
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(21) **Appl. No.: 11/063,901**(22) **Filed: Feb. 23, 2005****Related U.S. Application Data**(62) **Division of application No. 09/620,891, filed on Jul.
21, 2000.****Publication Classification**(51) **Int. Cl.⁷ B65D 85/42**(57) **ABSTRACT**

A unique medication distribution system for compliance packaging of medications, designed to contain each individual's unique daily medications and supplements and enhance the timely administration of the medications. The production and distribution of the system is automated and highly integrated with the database software as well as business software managed and operated by a pharmacy. The system comprises of a card made up of plastic, paper or composite materials with blister components containing the medication. The card can be bipartite or multipartite according to the medication needs of a user, with foldable side panels. An array of the timing corresponding to each medication is printed on the card. Corresponding to each medication is also an array listing the name of the doctor, the name of the medication and the rationale for its administration. A side panel may have sleeves or pockets containing salves, ointments, patches, lotions or milks, when prescribed to the user. A side panel may be customized to advertising targeting the market defined by individuals who take several medications in a day.

Pharmacy's Name Here	User's Name Here Sunday December 31, 2002	Prescription Number Here
For Acid Reflux 106	7:00 am	10000001 #1 Omeprazole 20mg Dr. PrimaryDoc
For circulation	7:30 am	10000002 #1 Pentoxifylline 400mg Dr. SurgeryDoc
To prevent clots	7:30 am	10000003 #1 Asprin 80mg Dr. PrimaryDoc
For Blood Pressure 108	12:00 noon	10000004 #1 Lisinopril 20mg Dr. PrimaryDoc
For digestion	6:00 pm	10000005 #1 Pancrease Dr. Gastroenterology
For circulation	6:30 pm	10000006 #1 Pentoxifylline 400mg Dr. SurgeryDoc
Lower Cholesterol	6:30 pm	10000007 #1 Simvastatin 10mg Dr. PrimaryDoc
For insomnia	10:30 pm	10000008 #1 Zolpiden tart. 5mg Dr. PrimaryDoc

Pharmacy's Name Here	User's Name Here Sunday December 31, 2002			Prescription Number Here
For Acid Reflux 106		7:00 am	10000001 #1 Omeprazole 20mg Dr. PrimaryDoc	114
For circulation		7:30 am	10000002 #1 Pentoxifylline 400mg Dr. SurgeryDoc	
To prevent clots		7:30 am	10000003 #1 Asprin 80mg Dr. PrimaryDoc	
For Blood Pressure 108		12:00 noon	10000004 #1 Lisinopril 20mg Dr. PrimaryDoc	
For digestion		6:00 pm	10000005 #1 Pancrease Dr. Gastroenterology	
For circulation		6:30 pm	10000006 #1 Pentoxifylline 400mg Dr. SurgeryDoc	
Lower Cholesterol		6:30 pm	10000007 #1 Simvastatin 10mg Dr. PrimaryDoc	
For insomnia		10:30 pm	10000008 #1 Zolpiden tart. 5mg Dr. PrimaryDoc	

100

FIG. 1

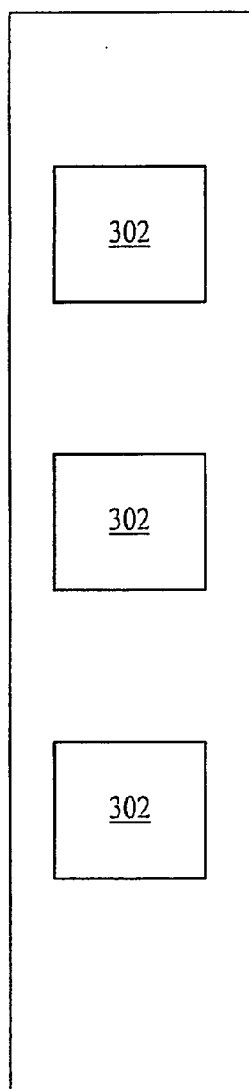


FIG. 2

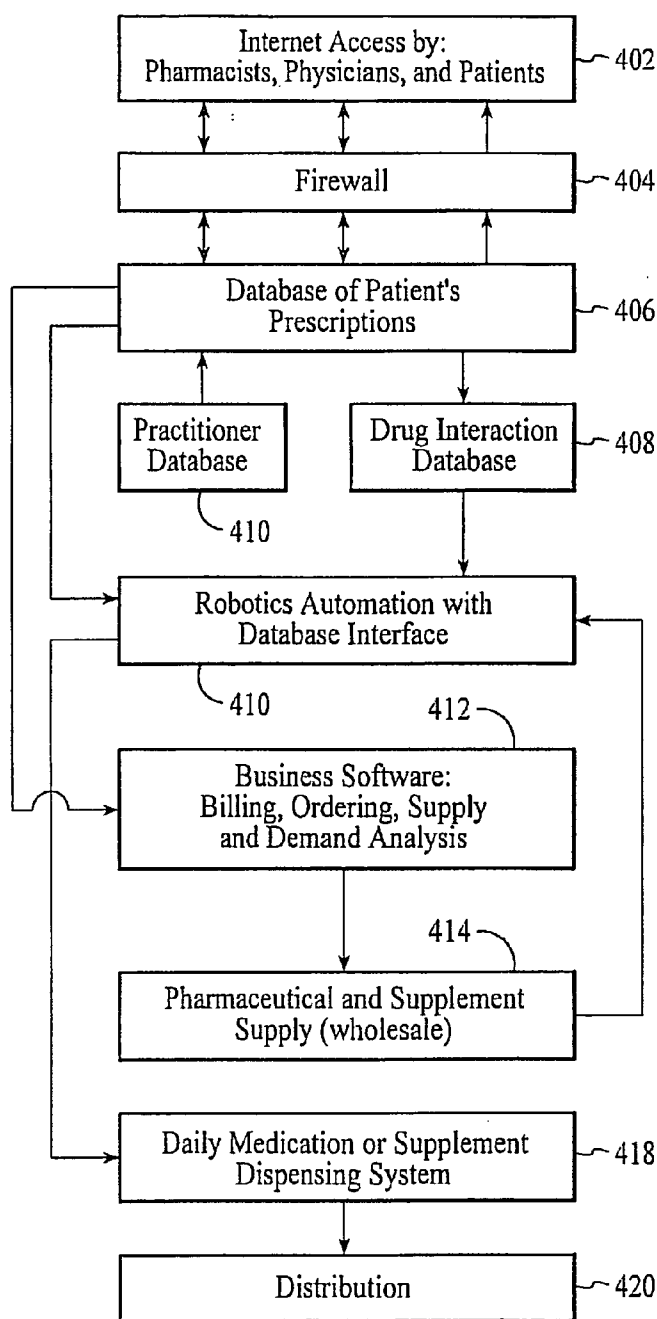


FIG. 4 400

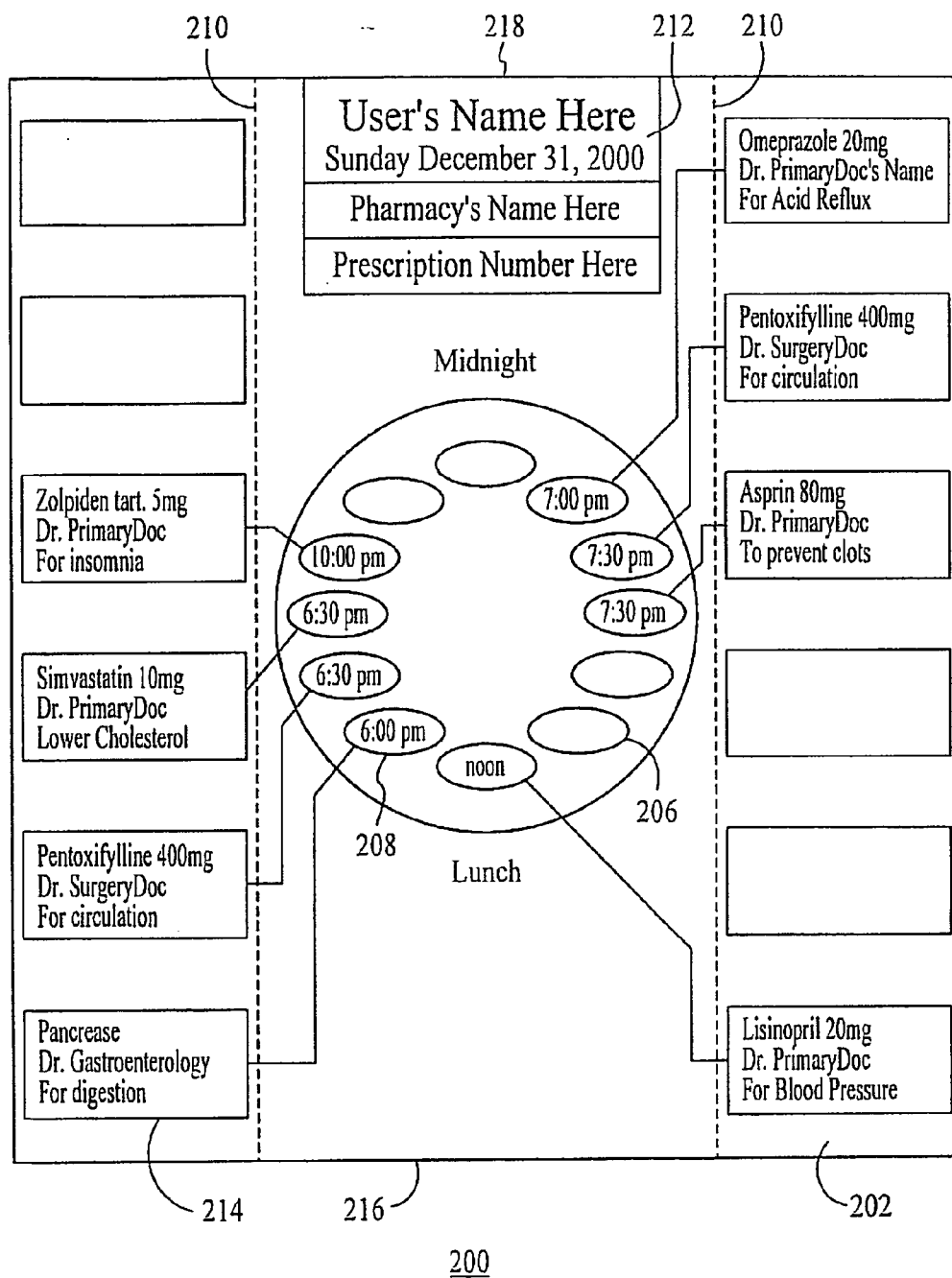


FIG. 3

MEDICATION DISTRIBUTION SYSTEM

FIELD OF THE INVENTION

[0001] The present invention is related to medication distribution systems, in particular compliance packaging of medications or supplements that make it possible to confirm that a dispensation of a medication regimen customized to an individual's daily needs has actually been adhered to during the course of a day as prescribed by the practitioner.

BACKGROUND OF THE INVENTION

[0002] A major problem confronted by people, particularly the disabled, chronically ill, home bound and psychiatric patients on multiple drugs, is the implementation of the necessary drug regimen in a safe, accurate and a timely manner. During pharmacological training of nurses and doctors, great emphasis is placed on the absolute necessity for maintaining perfect accuracy in the administration of medications. Errors and misuse can undermine the effectiveness of these drugs and can indeed be dangerous to the patient, causing fatal results and costing billions of dollars annually to our national health care system. In many instances, the patient's drug regimen includes up to six or more medications to be taken daily, each medication having its own time table and dosage, and each with accompanying supplements, instructions and warnings. The timing and dosage of medicines is subject to frequent change and may vary from day to day, particularly among the elderly patients. The effort to keep track of such a complexity of information can be confusing and threatening to the patient, causing distress and often prolonging recovery.

[0003] There are numerous prior art examples of medication containers provided with time reminder or calendar devices. Generally, the containers have reminder devices affixed to them which bear a plurality of indicia corresponding to desired time periods. The indicia used on such dispensers are an integral part of the dispensers and, if for some reason a different time schedule is desired, the dispenser is unusable for such different schedule and a whole new dispenser/indicia package must be prepared for each new schedule. Charts currently in use by medical professionals are often difficult for anyone outside the profession to read and understand. Many patients are already disquieted simply by being ill and can become additionally concerned and/or confused with the added burden of having to follow the doctor's orders. Plastic box containers work only for those using relatively few medications; they do not accommodate a large multiplicity of medications, for example, 6 to 12 to be taken several times daily, 7 days a week, and of course the medication must be in pill form to be placed in the slots of the plastic containers. Systems such as these are not useful for medications that are sensitive to light or air; neither are they practical for the use of patches, salves, liquid medications or medications that need to be refrigerated. The plastic box containers do not reinforce the name of the medication, the dosage, the usage or indication, and any pertinent information about the medication. In some instances, licensed physicians must prescribe medication so that the proper dosages may be taken by the patient at uncommon although prescribed intervals (not simply daily) under proper supervision. In such a case it has been found that the devices to assist the user in taking the dosage are either not available or are not alterable to vary the dispensing

time schedule in response to certain conditions which may require a different regimen. It would be desirable to provide the physician with a time-reminding and dispensing device, for particular patients for his/her daily dosages. Also where medication is prescribed on a varying schedule in order for the patient to be slowly introduced to or withdrawn from an efficacious medication level, it would be desirable to provide the physician with a variety of time-reminding and dispensing devices, so that the regimen for taking the medication would be easily variable to reflect the elements of dosage quantity and frequency of the various desirable stages.

[0004] One prior art U.S. Pat. No. 6,062,420 issued May 16, 2000 to Krouwel et al is an apparatus for dispensing pills from a blister pack in which cavities containing pills are distributed.

[0005] A further prior art U.S. Pat. No. 4,126,247 issued Nov. 21, 1978 to Majka is an upright housing having a transparent side and a plurality of compartments positioned in rows and columns. Each column represents a day of the week and each row represents a week of a month. Each compartment is adapted to store a day's medication and a calendar on the transparent side labels each compartment as a different day of the month. A key-operated control device releases medication from a selection compartment to the opening through the bottom of the transparent side of the housing. But this pill dispenser does not suggest any system for storing the medication before use except manually by the user or someone for him, which is not free from error.

[0006] One prior art U.S. Pat. No. 5,431,450 issued Jul. 11, 1995 to Coleman teaches a chart or a board listing medications, dosages and times to be taken; its surface serving as a dry continuous basis, marked by a marker, subject to erasing and geared toward flexible daily use. There is a medication-recessed tray that organizes the user's medicines into one central location. It has a calendar section having square boxes that are to be marked after medication is ingested or applied. It has a refill column, where refill dates and other refill information is placed. But this medication board does not guarantee an accurate ingestion of medication as errors in scheduling, refilling, and marking are quite a possibility. Additionally, this medication board becomes very vulnerable to user error, especially when the patient is himself administering the medication and is partially or more or less debilitated or infirm.

[0007] Another prior art U.S. Pat. No. Des. 375,526 issued Nov. 12, 1996 to Londino teaches an ornamental design for a calendar for a medicine reminder.

[0008] A further prior art U.S. Pat. No. 4,819,352 issued Apr. 11, 1989 to Maunand et al discloses a dosage calendar comprising at least two time scales; the units of the first scale being the day in the month or week or else a fraction of a day in the month, week or day, and the second scale having a number of unit elements with a value of seven or a multiple of seven, with at least one of the scales including a recognition mark which can be changed by the user during the treatment. These two scales, which are interchangeable and can also have unit elements in common, make it possible to identify three moments in time by virtue of the recognition marks or signs: the start of the treatment, the time of the last dose and the time of the next dose. However, the calendar does not teach an automatic distribution system for the

administration of drugs. The scales have to be adjusted by the patients or the caretakers and the adjustment is subject to error.

[0009] A further prior art, U.S. Pat. No. 4,974,729 issued Dec. 4, 1990 to Steinnagel discloses a calendar type dispenser in association with a separable indicia means, the combination comprising a reminder system for the patient to take a particular dosage of medication.

[0010] One prior art, U.S. Pat. No. 5,031,937 issued Jul. 16, 1991 to Nellhaus teaches a pictorial system to assist in the administration of medication, The picture stamps, each reflecting a unit of a medication, are to be pasted into discrete spaces of a sheet, card, label or box cover divided into columns and rows identified by icons for the time of day one or more units of the medication are to be taken. However, this system involves associating the appearance of the drug with its name and strength, thereby enhancing the risks of improper administration of medication by the user. It also creates the problem of reproduction of the visual depictions of the medications.

ADVANTAGES AND SUMMARY OF THE INVENTION

[0011] In view of the above, a principal object and advantage of this invention is to provide a convenient and inexpensive means of supplying a daily regimen of multiple medications and/or health supplements organized by time of day and period.

[0012] It is a further object and advantage of this invention to provide a time reminding system.

[0013] A further object and advantage of the present invention is to provide a medication distribution system which assists in self-administration or the giving of medications while reducing the risks of improper ingestion of medication or poor compliance that could result in serious consequences.

[0014] Another object and advantage of the present invention is to provide a means for assessing each patient's daily regimen, allowing a physician or other health practitioner to monitor compliance, the ability of an individual to take medications and supplements as prescribed.

[0015] Yet another object and advantage of the present invention is to provide a form to give the patient specific information relative to the medications and supplements ingested.

[0016] It is also an object and advantage of the present invention to contribute to the success of scientific evaluation of the use of medications (evidence based medicine) by facilitating a clear understanding of compliance.

[0017] Thus, a preferred embodiment of the system and method of the present invention includes compliance packaging of medications and supplements in a distribution system for individuals taking multiple medications during the course of a day so that compliance with a prescribed regimen is enhanced. The system comprises a card made of paper, plastic or composite material studded with blister pack components. The card may be bipartite or multipartite, customized to an individual's daily medication and supplement requirements. The repositories of medications and supplements are adhered either directly or indirectly (with

tape, glue or other means) to the card. Pills, tablets and capsules are arranged in an array or in a circular or oval fashion, corresponding to time of ingestion. The side panels may have sleeves or pockets, when needed by the user, containing salves, patches, ointments and other pharmaceutical products. The card has printed on it the name of the user, the day and date for which it is to be used, the timing and quantity and amount of each dose, the name of the prescribing physician, the appropriate identification information for pharmacy and prescription, as well as pertinent therapeutic information.

[0018] The method of the present invention also includes, in a most preferred embodiment, "web based" information input, database management, and robotics designed to fill each medication distribution system card or system with medications and supplements as well as to orchestrate the printing of each system. Security will be engineered at all levels of software design and product production.

[0019] In a preferred embodiment, the method of the present invention includes a website in which, optionally and as may be desirable or indicated, the pharmacists, physicians, and patients have access to the website, such as to different portions thereof or with different levels of security. In the preferred embodiment, the website can be operated by a pharmacy responsible for the management of the databases for an individual's daily medications, patient records, practitioner's prescriptions, pharmaceutical operations, and the production and distribution of system of the present invention. The website is equipped with business software for handling billing and ordering, and analyzing demand and supply. It is linked with a drug interaction database. The site is coordinated and directed with the help of Mechatronic Engine (Robotic automation with database interface). It will be understood, however, that while the mechanism for implementation of such paradigm shift in the pharmaceutical industry can be modified as desired or considered most economically or otherwise feasible, any variations in the descriptions herein will be considered within the scope of the present invention.

[0020] Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention and the embodiments thereof, from the claims and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is a front perspective view of a foldable card, containing an array of medication repositories embodying the principles of the preferred embodiment of the present invention.

[0022] FIG. 2 is a representative section of the side panel of the device of FIG. 1.

[0023] FIG. 3 is a plan view of an alternate preferred embodiment of the present invention shown in FIG. 1, with the medication repositories arranged in a circular or oval fashion.

[0024] FIG. 4 is the schematic representation of the operational mechanism and overall administration of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0025] The description that follows is presented to enable one skilled in the art to make and use the present invention, and is provided in the context of a particular application and its requirements. Various modifications to the disclosed embodiments will be apparent to those skilled in the art, and the general principals discussed below may be applied to other embodiments and applications without departing from the scope and spirit of the invention. Therefore, the invention is not intended to be limited to the embodiments disclosed, but the invention is to be given the largest possible scope which is consistent with the principals and features described herein.

[0026] It will be understood that in the event parts of different embodiments have similar functions or uses, they may have been given similar or identical reference numerals and descriptions. It will be understood that such duplication of reference numerals is intended solely for efficiency and ease of understanding the present invention, and are not to be construed as limiting in any way, or as implying that the various embodiments themselves are identical.

[0027] FIG. 1 is a representative schematic drawing of a preferred embodiment of the device 100 showing a time reminding and dispensation system for medications and supplements. The system 100 comprises of a card 116 made up of paper, plastic or composite materials with blister pack components. It may be bipartite or multipartite, foldable at the folds 110 and may vary in size to meet the medication needs of an individual patient. The repositories 106 may be blister packs, pockets, envelopes or medications and supplements adhered either directly or indirectly (with tape, and adhesive film or other device) to the card 116.

[0028] The head 112 of the main panel 118 has the user/patient's name as well as the day and date for which the card 116 is created. The date and day are important for the user to keep track of his/her medication over a period of time. The array 114 on the main panel 118 lists the name of the medication and the quantity prescribed, name of the physician and the reason for which the medication is prescribed. This information is provided to keep the patient or the caregiver educated as well as to assist them in using the website for having a new prescription or giving a new order. Also, such information is needed the most in case of emergencies. Additionally, it will be understood that the required 8-digit reference code for the particular prescription must be indicated alongside each of the medication repositories 106.

[0029] The repositories of medication 106 in the main panel 118 are arranged in an array in sequential order i.e. the order the medication has to be taken in succession during the passage of a day. The timing of the medication is printed on the tabs 108. The timing can be set by hours or meal times or with other medications. When a medication is ingested as it becomes due, the tab 108 is pulled to indicate that the medication for that particular hour has been ingested or applied.

[0030] FIG. 2 is a representative section of the side panel 102 of the device 100 of FIG. 1. It illustrates the sleeves or pockets 302 to put ointments, salves, patches, eye drops, lotions, milks or other pharmaceutical forms of medications

or supplements. The sleeves or pockets 302 can be made up of polythene or other suitable material.

[0031] Also, the side panel 102 of the card 116 can be used by the user for putting important notes such as the doctor's phone number or noting any adverse effects caused by the ingestion of a medication, etc.. The side panel 104 of the card 116 provides a unique opportunity for graphic and text advertising customized for a market defined by those individual taking several medications or supplements daily.

[0032] FIG. 3 is a preferred alternate embodiment of the invention shown is FIG. 1., illustrating a time reminding and dispensation system for medications and supplements. The system 200 comprises of a card 216 made up of paper, plastic and composite materials with blister pack components. It may be bipartite or multipartite, foldable at the folds 210 and may vary in size to meet the medication needs of an individual patient. The repositories may be blister packs, pockets, envelopes or medications and supplements adhered either directly or indirectly (with tape, and adhesive film or other device) to the card 216.

[0033] The header 212 on the main panel 218 has the user/patient's name, the day and date for which the card 216 is created. The date and day are important for the user to keep track of his/her medication. The timing 208 of the medication is printed on the respective repository 206. The timing can be set by hours or meal times or with other medications. When the time is due the blister 208 is pushed and the medication is ingested.

[0034] The repositories of medication 206 are arranged in a circular or oval fashion on the main panel 218, in a sequential order, clockwise or anticlockwise, in which the medications have to be taken in succession during the passage of a day. The array 214 lists the name of the medication and the quantity prescribed, the name of the physician and the rationale for which the medication is prescribed. This information is provided to keep the patient or the caregiver educated as well as to assist them in using the website for having a new prescription or giving a new order. Also, such information is needed the most in case of emergencies.

[0035] The side panel 202 of the card 216 has sleeves for putting for putting patches, salves, ointments, eye drops or other pharmaceutical forms of medications. Also, the side panel 202 of the card 216 can be used by the user for putting important notes such as the doctor's phone number or noting any adverse effects caused by the ingestion of a medication, etc.

[0036] FIG. 4 is the schematic representation of the operational mechanism and overall administration of the present invention. The device of FIG. 1 is an industrial product whose production, distribution and marketing can be internet-based or assisted. The operational mechanism will be managed and directed by a website overseen by a pharmaceutical company, insurance company, healthcare maintenance organization, provider network or other administrative scheme. FIG. 4 shows a block diagram of the same. The internet website 402 will be designed to allow physicians and pharmacists to enter a patient's daily medication prescription directly, and to allow patients to preview their system and to add over the counter supplements.

[0037] The website 402 is protected by and interfaced with a firewall 404 or other server means which allows exclusive

and selective access by the practitioners and their patients. The website **402** is loaded with the Database of Patients Prescription **406**, the Practitioner Database **410**, Drug Interaction Database **408**, and Business Software for billing, orders, and Demand and Supply analysis **412**. All these Databases (**406**, **410**, **408**, **412**) are directed and coordinated by a Mechatronic Engine (Robotic automation with database interface) **416** and are led into the production of the medication distribution system **418**. The Mechatronic Engine **416** in turn is connected with Pharmaceutical and Supplement Supply **414**. The Distribution **420** of the system **418** is then done at the retail level to various pharmacies.

[0038] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present invention belongs. Although any methods and materials similar or equivalent to those described can be used in the practice or testing of the present invention, preferred methods and materials are now described. All publications and patent documents referenced in the present invention are incorporated herein by reference.

[0039] While the principles of the invention have been made clear in illustrative embodiments, there will be immediately obvious to those skilled in the art many modifications of structure, arrangement, proportions, the elements, materials, and components used in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from those principles. The appended claims are intended to cover and embrace any and all such modifications, with the limits only of the true purview, spirit and scope of the invention.

I claim:

1. A medication and healthcare supplements distribution system to ensure compliance packaging, customized to the needs of an individual patient and industry supported so as to enable the user to take medications as prescribed on a daily basis.

2. The medication distribution system of claim 1 comprising a foldable bipartite or multipartite card with blister pack or other medication repository components.

3. The medication distribution system of claim 1 in which the size of the card is variable to meet the individual medication requirements of the user.

4. The medication distribution system of claim 1 further comprising means for enhanced compliance by a user taking several medications in a day.

5. The medication distribution system of claim 1 adapted for containing all forms of pharmaceuticals including salves, ointments and patches, and medications that are sensitive to light and air, etc.

6. The customized medication dispensation system of claim 1 in which the medications are ordered for use chronologically through a given day.

7. The medication distribution system of claim 2 further comprising at least three panels.

8. The medication distribution system of claim 2 in which the repository means may be adhered either directly or indirectly, such as with tape, glue, adhesive film or any other attachment means, to the card.

9. The medication distribution system of claim 2 further comprising pull-tabs with time for each medication printed on it, whereas the tab is pulled when the respective medication is ingested or applied to indicate the same.

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