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(54) Title: PACKAGE OF PILLS USEFUL FOR TITRATION AND METHOD OF TITRATING A PATIENT

colA	colB	colC	colD	colE	colF	colG	colH
A 1	B 1	C 1	D 1	E 1	F 1	G 1	H 1
A 2	B 2	C 2	D 2	E 2	F 2	G 2	H 2
A 3	B 3	C 3	D 3	E 3	F 3		
A 4	B 4	C 4	D 4	E 4	F 4		
A 5	B 5	C 5	D 5	E 5	F 5		
A 6	B 6	C 6	D 6	E 6	F 6		
A 7	B 7	C 7	D 7	E 7	F 7		
20mg	30mg	20mg	20mg	30mg	20mg	30mg	30mg

Fig. 2

(57) Abstract: A package of medication in the form of pills of differing dosages and a computer programmed to receive patient medical condition input, medical professional criteria for changing or maintaining dosage, and means to indicate to the patient recommended dosage is disclosed. A method of titrating a patient on a medication which uses the novel package is also disclosed

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PACKAGE OF PILLS USEFUL FOR TITRATION AND METHOD OF TITRATING A PATIENT

CROSS-REFERNCE TO RELATED APPLICATIONS

[0001]   Benefit of U.S. Provisional Application Serial No. 61/1 11,977, filed November 6, 2009, is claimed.

BACKGROUND OF THE INVENTION

[0002]   This invention relates to packaging systems for medications and the interface between the packaging and the patient and his or her physician.

[0003]   When a patient starts on new medication for which there are a multitude of possible dosing strategies, it is impossible for the physician to know with certainty which dosing of medication is going to optimize efficacy and minimize side effects for each patient. There needs to be an ongoing balance between optimizing efficacy and minimizing side effects which requires titration of dosing especially over the first weeks or the first few months that a medication is prescribed.

[0004]   Titration packs and starter packs are known in the art, however prior titration packets for placing a patient on a medication are solely focused on the upward titration of dosing or solely focused on the downward titration of medication or solely focused on starting and maintaining the dose of medication at one stable dose. The packets that focus on the upward titration of dosing increase to an optimal dose at a rate that research studies suggest will keep side effects at a minimum. These titration packs often mimic the titration of the clinical research studies that the pharmaceutical company has conducted. Research patients are hand picked for their homogeneity and compliance. Research patients are reimbursed for their participation in research studies. Therefore, they are often willing to take a medication according to a predetermined dosing schedule even though that dosing schedule may not be perfectly suited to them. Research patients are often seen far more frequently than patients in a clinical practice who often try to keep their visits to their physician at a minimum because they have to pay for each visit and pay a co-pay for every new prescription that is filled. The titration packets that focus on the downward titration of medication are used to reduce the medication according to a schedule until no more medication is taken. Starter packs that are given to help get a

patient started on a steady dose of medication are a way of giving patient a sample of medication that demonstrates the way that the one stable dose of medication is to be taken.

[0005]   An example of a known titration pack is disclosed in U.S. Pat. 7,086,532, assigned to Allergan, Inc.

[0006]   According to the World Health Organization, 50% of patients do not take medication as it is prescribed. This applies to all illnesses. In regard to ADHD medication, compliance is a major issue as within the first 3 months of treatment 50% of patients were no longer taking the medication at all and by the end of the 18-month observation period, an astonishing 80% of patients had dropped out of treatment. A significant proportion of this poor compliance is related to patient education and side effects. When a medication is first started, as the doctor and patient attempt to titrate the patient to the most effective dose, there are a multitude of factors that will affect the patient staying on the medication. These include the side effects, the patient's frustration tolerance in dealing with the side effects, the patient's frustration tolerance in dealing with the delay to onset of efficacy, the patient's knowledge about the illness, the patient's knowledge about the medication, the patient' s knowledge about optimal functioning and its benefits, and the efficacy of the medication.

[0007]   Therefore there is a need for a method which will help improve compliance, increase the number of patients who achieve efficacy, and diminish problems that occur while a patient is adjusting dose to optimize efficacy. There is also a need for a packaging system which will allow for an easy and efficient adjusting of dose downward to decrease the impact and frequency of the side effects that have resulted from a medication dosage that had been increased. Decreasing the dose of medication to reduce side effects is a way to avoid a patient's desire to precipitously discontinue the medication. This method is portable, it will save patients money, it will save insurance companies money, there will be less wasted medication, and patients will have improved compliance as a result of a packet that is readily adaptable to the dispensing of a variety of dosage regimens. Improved compliance is better for the patient as the patient will often have a better quality of life if they take an effective medication at the proper dose. Improved

compliance is better for the pharmaceutical manufacturer's bottom line; the longer a patient stays on medication the more prescriptions are filled.

SUMMARY OF THE INVENTION

[0008]   These needs and others which will become apparent from the following disclosure and drawings are achieved by the present invention which comprises in one aspect a computer-implemented method to achieve an upward titration of medication until efficacy is achieved while also achieving a stabilization of dose if efficacy is achieved sooner than at maximal dosing, while also achieving a reduction of dosing when medically appropriate to accommodate for side effects.

[0009]   In some embodiments, the invention comprises a titration packaging system which comprises a plurality of dosages of a medication and also comprises a processor programmed to receive input from a patient and a medical professional and to indicate which dosage of medication should be taken by a patient on a given day based on patient input and medical professional criteria for that patient. The packaging system can have self-contained, integral input means and an integral indicator of dosage selection, or can have an integral means of communicating with a remote computer system. The medical professional input can be pre-programmed so that when the patient obtains the package and responds to questions regarding patient condition, the dosage selection is instantly indicated by the package itself or the remote computer which is in communication with the package.

[0010]   The method allows for improved compliance of medication by use of a novel titration package that requires a patient to only have one prescription filled the first month and to pay for medication only one time the first month. The titration package will allow for an upward titration of medication if the patient is able to tolerate increasing doses of medication as the optimal dose is sought. The titration package will also allow for a maintenance dosage if the patient is stabilized at a given dose. The titration package will also allow for a reduction of dosage if the upward titration results in, among a number of reasons, either intolerable side effects, unacceptable side effects, less patient satisfaction, less physician satisfaction, or a decrease in efficacy. As a result, this titration pack results in a minimal amount of wasting of the medication that was originally dispensed in the

first prescription of medication if a predetermined titration is intolerable to a patient and the patient needs to be either stabilized at a dose that is lower than maximal dose or down titrated to a variety of less than maximal dosages.

[0011]   Another aspect of the invention is a titration pack which will allow for improved compliance by allowing for upward titration of dosage until there is optimum efficacy while allowing for downward titration of dose of dose as needed to adjust for side effects or stabilization of dose as desired to optimize efficacy.

[0012]   Another aspect of the invention is a computer system programmed with a set of instructions to process responses from a patient regarding a rating scale regarding current symptoms and mental state and current side effects of a medication according to a set of criteria received from the patient's physician and to automatically indicate next dosage of medication to be taken from a titration package which comprises a plurality of dosages of a medication.

[0013]   In some embodiments, the invention comprises a package comprising a plurality of dosages of at least one medication and a computer system programmed with the aforementioned set of instructions, wherein the package has means to ask questions regarding the patient's current mental state and current side effects, to receive patient responses, and to indicate which pill or dose of medication should be taken based on responses to the questions and programmed criteria.

[0014]   The questions and processing can be according to a standard rating scale, for example one selected from ADHD RS IV for attention deficit disorder, HAMD for depression, Beck depression inventory, Young mania rating scale, PANSS rating scale, MADRAS rating scale. Other rating scales can be used when appropriate for the medical condition.

[0015]   In embodiments which include a package of medication in the form of pills of differing dosages arranged in at least columns consisting of a first column and at least one additional column, said pills in each column being of a specific dosage and said pills in at least one additional column being of a different dosage from said pills of said first column, the package can comprise a processor programmed with a set of instructions to process patient medical condition input according to criteria selected by a medical professional and to indicate which of pills should be taken by said patient. The patient

medical condition input, in some embodiments, comprises answers to a standardized test. There are many current and will likely be many future standardized tests which can be used in the invention, for example ADHS RS IV for attention deficit disorder, HAMD for depression, Beck depression inventory, Young mania rating scale, PANSS rating scale, and the MADRAS rating scale.

[0016]   The package can include means such as a USB port, wireless interface, or the like to communicate with a remote computer, means such as a touch screen, keypad, or voice recognition to report the patient medical condition input, indicated changes in dosage, and/or compliance with said indications of which pills should be taken by said patient, and capability such as by email, fax, text messaging, a smartphone "app", and the like, to receive changes in criteria from said medical professional.

[0017]   The criteria selected and inputted by the medical professional can be score levels on a rating scale and levels of side effect responses, and can be employed to cause the package to indicate a selected dosage level corresponding to the rating score level and side effect responses.

[0018]   In an embodiment of the method aspect of the invention, dosage of a prescribed medication can be adjusted by programming a computer with a set of instructions to enable indication to the patient of changes to medication dosage levels from a package which comprises a plurality of dosage levels of the medication according to a set of criteria inputted to the computer by the patient's medical professional, wherein the patient inputs responses to medical questions to the computer and the computer processes the responses according to the criteria. The medical questions can be responses to a standardized rating test and can also include questions about level of side effects being experienced. Again, the responses can be according to the ADHS RS IV for attention deficit disorder, HAMD for depression, Beck depression inventory, Young mania rating scale, PANSS rating scale, MADRAS rating scale, or any other rating scale selected by the medical professional or the manufacturer of the titration package.

[0019]   In some embodiments the computer is integral to the package, and the patient indicates responses to a local or remote computer, in which case the local or remote computer communicates to the package through means such as USB, wireless, and the

like, to receive input on or in the package, and the package generates an audible or visual indication or instruction to the patient.

[0020]   The computer can be integral to the package, and wherein the patient can indicate responses directly on the package through means to receive patient input on or in the package.

[0021]   In other embodiments the package of medication in the form of pills may not necessarily include a plurality of dosage forms of pills, tablets, or capsules, in which case the computer system indicates which or how many pills from the package should be taken by the patient.

[0022]   Another embodiment of the method of treating a patient with a medical condition which requires periodic monitoring of the medical condition and adjustment of dosage of a prescribed medication comprises programming a computer with a set of instructions to enable indication to the patient of changes to medication dosage levels from a package which comprises a plurality pills, capsule, and/or tablets of medication according to a set of criteria inputted to the computer by the patient' s medical professional, wherein the patient inputs responses to medical questions to the computer and the computer processes the responses according to the criteria and generates an audible or visual indication or instruction to the patient. In such embodiments, the audible or visual indication or instruction can be communicated by the remote computer to the package.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023]   **Fig. 1** is a schematic view of an embodiment of a titration pack according to the invention.

[0024]   **Fig. 2** is a schematic view of a second embodiment of a titration pack according to the invention.

[0025]   **Fig. 3** is a schematic view of a third embodiment of a titration pack according to the invention.

[0026]   **Fig. 4 is** an embodiment of **a** questionnaire for patients to respond according to **a** rating scale.

[0027]   **Fig. 5** is an embodiment of instructions on a titration package of medication.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Certain preferred embodiments to illustrate how the invention can be carried out will be described with reference to the drawings.

[0029] Referring first to Fig. 1, a titration package may have columns A-H having 20 or 30 mg. capsules in each column.

[0030] In Fig. 2, cols. A-H are arranged by 20 or 30 mg dose pills, but each pill is identified with a col./row number.

[0031] In Fig. 3, cols. A-K each have 20 or 30 mg. pills.

[0032] Fig. 4 is an embodiment of a questionnaire for patients to respond to according to a rating scale.

[0033] Fig. 5 is an embodiment of a set of instructions on a titration package of medication.

[0034] When patients are started on a new medication, the most common prescriptions written by physicians are for a one-month supply of medication with a specific and unvarying dosing schedule noted, for instance, directions are given to take, by mouth, one pill daily for the month. Alternately, another way that patients are started on medication is for a prescription to be written for a titration pack to be dispensed. The titration pack standardizes the amount of pills to be taken each day by clearly demarcating the amount of pills to be taken each and every day of the month in a way that either increases or decreases the doses day by day or, week by week.

[0035] Each titration package will have a unique identification number so that the patient can self-assess weekly or more frequently while the dose is being titrated and the scores can be safely stored on-line anonymously. The unique identification number in, and optionally on, the titration package, is read by a local or remote computer in certain embodiments.

[0036] There are alternatives available for the titration of dosing without using a titration pack under some circumstances. Physicians, for instance, could write a prescription with the directions given to take, by mouth, one pill daily for the first week, two pills daily for the second week, three pills daily for the third week and four pills daily for the rest of the month. Writing one prescription (with the resultant benefit of having only one co-pay) with directions for titration can occur only when a pill, tablet, capsule or liquid is available in the milligram dosing that is equivalent to the least the common

denominator that will be used during the titration. While writing a prescription for the titration of dosing can be a simple matter when the lowest milligram dosage is one that divides evenly into every possible dosage, pharmaceutical companies do not necessarily manufacture medication in a dosing amount that conforms to the least common denominator or in a dosing amount that allows for the convenience of titration. When this is not possible, a method needs to be available to be able to prescribe a medication in a way that allows for the adjusting of dosing in a way that would accommodate for any and every available dose for therapeutic optimization.

[0037]   In the case with Vyvanse, a medication approved for the treatment of **ADHD,** (Attention-Deficit/Hyperactivity Disorder) the dose with the least common denominator, 10 mg, is not available. Vyvanse doses are available at a number of different doses, including 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules, but a lOmg dose would need to be available for a physician to be able to order a titration that would allow for every possible dose. Shire Pharmaceutical recognized the importance of having a multitude of doses available after first manufacturing only the 30-mg, 50-mg, and 70-mg doses. The 20 mg, 40 mg, and 60 mg capsules doses were found to be necessary to meet the needs of more patients. Physicians now often start dosing with a single 30-mg capsule and then increase to two of the 30-mg capsules. Titration then needs to be adjusted up or down from that point. While for some patients, 30 mg or 60 mg may be optimal, there are many for whom a 20-mg, 40-mg, 50-mg or 70-mg dose is the optimal dose. For some patients, first starting a patient on 30-mg dose or the subsequent upward titration from 30mg to 60mg may result in such a severe amount of side effects that patients refuse to try other dosing regimens and become non-compliant with their treatment.

[0038]   In the first embodiment disclosed, a titration packet is shown in Figure 1. This packet will contain 20-mg and 30-mg Vyvanse capsules to allow for dosing over the first month between 20 and 60 mg as determined by efficacy and side effects. Medication will be displayed in a number of rows and columns. In the first embodiment, the columns will be labeled by letters A through H. In the first embodiment Columns A, C, D, and F will each contain seven of the 20 mg capsules of Vyvanse. Columns B and E will each contain seven of the 30-mg capsules of Vyvanse. Columns G and column H will each

have two of the 30-mg capsules. Every pill in every row is given a unique identifying number.

[0039]   In the first embodiment, a patient is started on medication with the expectation that he or she is to theoretically take medication according to the following regimen for 30 days:

Week 1: 20 mg (Days 1 to 7)

Week 2: 30 mg (Days 8 to 14)

Week 3: 40 mg (Days 15 to 21)

Week 4: 50 mg (Days 22 to 28)

Week 5: 60 mg (Days 29 and 30).

[0040]   To achieve this titration, heretofore to be called the standard titration, the following regimen would be used as noted in Figure 1.

Week 1: Column A, 1 pill daily

Week 2: Column B, 1 pill daily

Week 3: Columns C and D, 1 pill daily from each column

Week 4: Columns E and F, 1 pill daily from each column

Week 5: Columns G and H, 1 pill daily from each column.

[0041]   It is prohibitively expensive to prescribe 5 different doses of medication to this patient as this would require five prescriptions and five co-pays. It is time consuming on the part of the physician and the physicians staff to write five different prescriptions and to monitor their usage. According to our invention, a patient will be given a prescription for one starter pack and a patient would have the one starter pack dispensed at the pharmacy. The physician would tell the patient to take the pills in Column A, 1 pill daily, for the first week. At the end of the first week the patient would be assessed in a number of ways. If the medication is not working satisfactorily, either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD, the physician would want the patient to increase the dose the following seven days and to take the pills in Column B, 1 pill daily, for the second week, in which case the physician would notify the patient via email, phone, fax, computer, or text message, for example. At the end of week two if the

medication is not working satisfactorily, either by patient report, family report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD, the physician would want the patient to increase the dose the following seven days and to take the pills in Columns C and D, 1 pill daily from each column for the third week. At the end of week three if the medication is not working satisfactorily, either by patient report, family report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD, the physician would want the patient to increase the dose the following seven days and to take the pills in Columns E and F, 1 pill daily from each column for the fourth week. At the end of week four if the medication is not working satisfactorily, either by patient report, family report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD, the physician would want the patient to increase the dose the following seven days and to take the pills in Columns G and H, 1 pill daily from each column for the fifth week.

[0042]   However, in many patients, after they start to take the standard titration of medication it will be obvious that the standard titration of medication will not be applicable. There are many different options that can occur in a clinical practice.

[0043]   The following are some of the options that are anticipated:

[0044]   Option one: After Week 1 of the standard titration the medication is working excellently, either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD and as a result neither the physician nor the patient wanted to increase the dose. As a result of the desire to maintain the medication at the week 1 dose the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack:

> Week 2: Column C, 1 pill daily
>
> Week 3: Column D, 1 pill daily
>
> Week 4: Columns F, 1 pill daily

[0045]   Option two: After Week 2 of the standard titration the medication is working excellently, either by patient report, physician observation, and/or by the completion of a

rating scale(s) for the symptoms of ADHD and as a result neither the physician nor the patient wanted to further increase the dose, the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram:

> Week 3: Column E, 1 pill daily
>
> Week 4: Columns G, 1 pill daily for two days and then Columns H, 1 pill daily for two days

[0046]   Option three: After Week 3 of the standard titration the medication is working excellently, either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD and as a result neither the physician nor the patient wanted to increase the dose any more, the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack:

> Week 4: Columns F, 2 pill daily from this column

[0047]   Option four: After two weeks of the standard titration, Week 1 of 20 mg and Week 2 on 30 mg, it is determined either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD that 30 mg is no better than 20 mg and/or is causing more side effects and as a result neither the physician nor the patient wanted to increase the dose any further, and in fact want to decrease the dose back to 20 mg. As a result the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack:

> Week 3: Column C, 1 pill daily
>
> Week 4: Column D, 1 pill daily
>
> Week 5: Columns F, 1 pill daily

[0048]   Option five: After three weeks of the standard titration, Week 1 of 20 mg, Week 2 on 30 mg, and Week 3 on 40 mg, it is determined either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD that 40 mg is no better than 30 mg and/or

is causing more side effects and as a result neither the physician nor the patient wanted to increase the dose, and in fact want to decrease the dose back to 30 mg. As a result the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack:

Week 4: Column E, 1 pill daily

Week 5: Columns G, 1 pill daily for two days and then

Columns H, 1 pill daily for two days

[0049]   Option six: After two weeks of the standard titration, Week 1 of 20 mg and Week 2 on 30 mg, it is determined either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD that 30 mg is optimal and as a result neither the physician nor the patient want to increase the dose. It is determined that for now the dose is to remain at 30 mg. As a result the following information could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack:

Week 3: Column E, 1 pill daily

Week 4: Columns G, 1 pill daily for two days and then

Columns H, 1 pill daily for two days

[0050]   Option seven: After a period of time on the standard titration that did not exactly correspond to a full week, if a patient were to complain of lack of efficacy or side effects and/it were determined either by patient report, physician observation, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of ADHD that a dose adjustment were needed before the end of a full week, it could be transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack the future dosing regimen to be taken according to the symptoms, the dosing plan, and the available pills, tablets, or capsules in the titration pack. Additionally, by having the columns labeled by letters and each of the pills identified both by its mg amount as well by an identifying number, see Figure 2, modifications can be made mid week as well as at the end of each week.

[0051]   The titration packet would allow for other modifications as well, such as the following, but not limited to these adjustments: a reduction in dosing after two weeks on a steady dose of 30 mg; a reduction in dosing after two weeks on a steady dose of 40 mg; two successive reductions in dosing after reaching 40 mg on week three; or a variety of other combinations of problems. New directions can be transmitted to patients verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack.

[0052]   In the second embodiment, Figure 3, the columns will be labeled by letters A through J. In the second embodiment Columns A, B, C, F, and I will each contain seven of the 30 mg capsules of Vyvanse. Columns D, E, G, H, J, and K and will each contain seven of the 20-mg capsules of Vyvanse.

[0053]   In the third embodiment, Figure 4, the columns will be labeled by letters A through K. In the third embodiment Columns A, B, C, E, and H will each contain seven of the 30 mg capsules of Vyvanse. Columns F, G, I, and J and will each contain seven of the 20-mg capsules of Vyvanse. Column D will have seven of the capsules 40-mg capsules.

[0054]   In the fifth embodiment, the packet containing 20 mg and 30 mg capsules will allow for titration up and down between 20 and 60 mg.

[0055]   In the sixth embodiment, the packet containing 20 mg, 30, and 40 mg capsules will allow for titration upward from 60 mg to 70mg and downward from 60 and 20 mg and at a variety of combinations between 20 mg and 70 mg.

[0056]   In the seventh embodiment, a computer program will let a patient and a doctor know which medications for the patient to take on which day and which week based on the patient's side effect profile.

[0057]   In the eighth embodiment, a computer program will let a patient and a doctor know which medications for the patient to take on which day and which week based on the patient's and/or the patient's family members'/significant others' impression of patient's functioning.

[0058]   In the ninth embodiment, a computer program will let a patient and a doctor know which medications for the patient to take on which day and which week based on the physician's impression of patient's functioning.

[0059]   In the tenth embodiment, a computer program will let a patient and a doctor know which medications for the patient to take on which day and which week based on a scale(s) completed by the physician which rates the patient's functioning.

[0060]   In the eleventh embodiment, a computer program will let a patient and a doctor know which medications for the patient to take on which day and which week based on a scale(s) completed by the patient which rates the patient's functioning.

[0061]   In the twelfth embodiment, medication in the starter pack will include a medication that is in a mg amount that is the least common denominator while allowing for an upward and downward titration of medication.

[0062]   In the thirteenth embodiment, the packet containing two different mg doses of medication capsules, tablets or pills will allow for titration up, titration down, and a steady state dosing.

[0063]   In the fourteenth embodiment, the packet containing three different mg doses of medication capsules, tablets or pills will allow for titration up, titration down, and a steady state dosing.

[0064]   In the fifteenth embodiment, the packet containing four or more different mg doses of medication capsules, tablets or pills will allow for titration up, titration down, and a steady state dosing.

[0065]   In the sixteenth embodiment, the packet containing only one dose of medication capsules, tablets or pills will allow for titration up, titration down, and a steady state dosing.

[0066]   In the seventeenth embodiment, the packet containing 20 mg and 30 capsules will allow for titration upward from 60 mg to 70 mg and downward from 60 and 20 mg and at a variety of combinations between 20 mg and 70 mg.

[0067]   In the eighteenth embodiment, the columns will be labeled by letters A through Z as needed and the row numbered 1 to 7 and there will be seven capsules in each column.

[0068]   In the nineteenth embodiment, the columns will be labeled by letters A through Z as needed and the rows will be labeled numerically as needed and there will be enough capsules in each column and enough rows in each column to allow for a titration up, titration down, or a stabilization of doses.

[0069]   In the twentieth embodiment, the columns will be labeled by letters A through Z as needed and there will be enough capsules in each column and enough rows to give medication to last one week.

[0070]   In the twenty-first embodiment, the columns will be labeled by letters A through Z as needed and there will be enough capsules in each column and enough rows to give medication to last one month.

[0071]   In the twenty-second embodiment, the columns will be labeled by letters A through Z as needed and there will be enough capsules in each column and enough rows to give medication to last three months.

[0072]   In the twenty-third embodiment, the columns will be labeled by letters A through Z as needed and there will be enough capsules in each column and enough rows in each column to give medication to last a predetermined period of time.

[0073]   In the twenty-fourth embodiment, the medication will be in columns and rows and each tablet, capsule, or pill will be labeled with a unique identifier.

[0074]   In the twenty-fifth embodiment, a physician will let a patient know verbally which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0075]   In the twenty-sixth embodiment, a physician will let a patient know in writing which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0076]   In the twenty-seventh embodiment, a physician will let a patient know electronically which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0077]   In the twenty-eighth embodiment, a physician will communicate directly to the titration pack which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0078]   In the twenty-ninth embodiment, a physician will let a patient know through a diagram which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0079]   In the thirtieth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package

which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness.

[0080]   In the thirty-first embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for all illnesses.

[0081]   In the thirty-second embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for all psychiatric illnesses.

[0082]   In the thirty-third embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for ADHD.

[0083]   In the thirty-fourth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for depressive disorders.

[0084]   In the thirty-fifth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report,

laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for anxiety disorders.

[0085]   In the thirty-sixth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for psychotic disorders.

[0086]   In the thirty-seventh embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for impulse control disorders.

[0087]   In the thirty-eighth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for pain disorders.

[0088]   In the thirty-ninth embodiment, a physician will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for patients of all ages.

[0089]   In the fortieth embodiment, a computer will let a patient know verbally which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0090]   In the forty-first embodiment, a computer will let a patient know in writing which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0091]   In the forty-second embodiment, a computer will let a patient know electronically via fax, phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0092]   In the forty-third embodiment, a computer will communicate directly to the titration pack which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0093]   In the forty-fourth embodiment, a computer will let a patient know through a diagram which medications from a titration pack for the patient to take on which day and which week based on the patient's functioning.

[0094]   In the forty-fifth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness.

[0095]   In the forty-sixth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for all illnesses.

[0096]   In the forty-seventh embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a

titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a

device and/or by the completion of a rating scale(s) for the symptoms of their illness for all psychiatric illnesses.

[0097] In the forty-eighth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for ADHD.

[0098] In the forty-ninth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for depressive disorders.

[0099] In the fiftieth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for anxiety disorders.

[0100] In the fifty-first embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for psychotic disorders.

[0101] In the fifty-second embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a

device and/or by the completion of a rating scale(s) for the symptoms of their illness for impulse control disorders.

[0102]   In the fifty-third embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for pain disorders.

[0103]   In the fifty-forth embodiment, a computer will let a patient know via phone, internet, interactive voice recognition, or direct communication to the titration package which medications from a titration pack for the patient to take on which day and which week based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) for the symptoms of their illness for patients of all ages.

[0104]   In the fifty-fifth embodiment, a patient will have a baseline assessment based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s) prior to taking medication from the titration pack. The patient will then take one or more days or weeks worth of medication. The patient will then have a subsequent assessment(s) based on patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s). The results of the baseline assessment(s) will then be compared with the subsequent assessment(s) and a determination as to the next dosing strategy will be made by the physician, the patient, the family, and/or a computer program and transmitted to the patient verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack. This subsequent dosing regimen may be determined according to the symptoms, the dosing plan, and the available pills, tablets, or capsules in the titration pack, the diagnosis, age of patient, the gender of patient, other known health factors, the type of titration pack, the duration of illness, the number of pills taken, the time a patient has been taking medication, or other factors known or not yet known in the art. This subsequent dosing regimen may be determined according to a specific score(s), number(s), or observation(s)

to be achieved through patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s). This subsequent dosing regimen may be determined according to a specific percent improvement to be achieved through patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s). This subsequent dosing regimen may be determined according to any number of factors to be achieved through patient report, physician observation, family report, observer report, laboratory test, testing by a device and/or by the completion of a rating scale(s). The physician or computer or some other method of communication will let a patient know through a variety of means, including but not limited to verbally, in writing, electronically, and/or by a diagram and/or transmitted directly to the titration pack which medications from a titration pack for the patient to take on which day and which week for the symptoms of their illness for ADHD, anxiety disorders, depressive disorders, impulse control disorders, psychotic disorders, all psychiatric disorders, and/or all medical disorders. Subsequent assessments will be repeated as needed to optimize dose, optimize compliance, and/or minimize side effects.

[0105]   Use of the automated titration packet or the automation at the remote server, which includes an ADHD rating scale, allows titration to occur on a weekly basis, based on a reliable objective measure, rather than the present art which is titration based on subjective information on a monthly basis. With the titration packet, titration from 5 mg to up to 20 mg would take 1 month, whereas it could take up to 3 months or more if a patient was prescribed each individual dose each month (5 mg, 10 mg, 15 mg, and 20 mg) after monthly follow-up. A shorter titration period (with the titration packet) with objective information (from an ADHD rating scale) on patient progress may motivate patients to adhere to their medication. With improved adherence (and outcomes), the patient may persist on their medication for longer. The present longer titration period may decrease the initial "buy in" of parents/patients into the patient's medication therapy due to less than optimal outcomes when not on the optimal dose. This may be a significant factor resulting in the present art of poor compliance on the part of the patient and less support of compliance on the part of the family. The decrease in "buy in" in the present state of the art may be compounded if titration is based primarily on subjective information. Over time, the lack of initial "buy in" may decrease adherence and/or persistence.

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[0106]   The present invention, therefore, is well adapted to carry out the objects and attain the ends and advantages mentioned, as well as others inherent therein. While the invention has been depicted and described and is defined by reference to particular preferred embodiments of the invention, such references do not imply a limitation on the invention, and no such limitation is to be inferred. The invention is capable of considerable modification, alteration and equivalents in form and function, as will occur to those ordinarily skilled in the pertinent arts. The depicted and described preferred embodiments of the invention are exemplary only and are not exhaustive of the scope of the invention. Consequently, the invention is intended to be limited only by the spirit and scope of the appended claims, giving full cognizance to equivalents in all respects.

CLAIMS

What is claimed is:

1. A package of medication in the form of pills of differing dosages arranged in at least columns consisting of a first column and at least one additional column, said pills in each column being of a specific dosage and said pills in at least one additional column being of a different dosage from said pills of said first column, comprising a processor programmed with a set of instructions to process patient medical condition input according to criteria selected by a medical professional and to indicate which of pills should be taken by said patient.

2. The package according to claim 1 wherein said patient medical condition input comprises answers to a standardized test.

3. The package according to claim 1 wherein said patient medical condition input comprises answers to a standardized test selected from said group consisting of ADHS RS IV for attention deficit disorder, HAMD for depression, Beck depression inventory, Young mania rating scale, PANSS rating scale, and MADRAS rating scale.

4. The package according to claim 1 comprising means to communicate with a remote computer, means to report said patient medical condition input, indicated changes in dosage, and/or compliance with said indications of which pills should be taken by said patient, and means to receive changes in criteria from said medical professional.

5. The package according to claim 1 wherein said criteria selected by said medical professional comprise score levels on a rating scale and levels of side effect responses, and are adapted to cause said package to indicate a selected dosage level corresponding to said rating score level and side effect responses.

6. A method of treating a patient with a medical condition which requires periodic monitoring of said medical condition and adjustment of dosage of a prescribed medication comprising programming a computer with a set of instructions to enable indication to said patient of changes to medication dosage levels from a package which comprises a plurality of dosage levels of said medication according to a set of criteria inputted to said computer by said patient's medical professional, wherein said

patient inputs responses to medical questions to said computer and said computer processes said responses according to said criteria.

7. The method of claim 6 wherein said medical questions are responses to a standardized rating test.

8. The method of claim 6 wherein the responses are according to the ADHS RS IV for attention deficit disorder, HAMD for depression, Beck depression inventory, Young mania rating scale, PANSS rating scale, or MADRAS rating scale.

9. The method of claim 6 wherein said computer is integral to said package, and wherein said patient indicates responses to a local or remote computer, and said local or remote computer communicates to said package through means to receive input on or in said package, and said package generates an audible or visual indication or instruction to said patient.

10. The method of claim 6 wherein said computer is integral to said package, and wherein said patient indicates responses directly on said package through means to receive patient input on or in said package.

11. A package of medication in the form of pills comprising a processor programmed with a set of instructions to process patient medical condition input according to criteria selected by a medical professional and to indicate which or how many pills from said package should be taken by said patient.

12. A method of treating a patient with a medical condition which requires periodic monitoring of said medical condition and adjustment of dosage of a prescribed medication comprising programming a computer with a set of instructions to enable indication to said patient of changes to medication dosage levels from a package which comprises a plurality pills, capsule, and/or tablets of medication according to a set of criteria inputted to said computer by said patient's medical professional, wherein said patient inputs responses to medical questions to said computer and said computer processes said responses according to said criteria and generates an audible or visual indication or instruction to the patient.

13. The method of claim 12 wherein said audible or visual indication or instruction is communicated by said remote computer to said package.
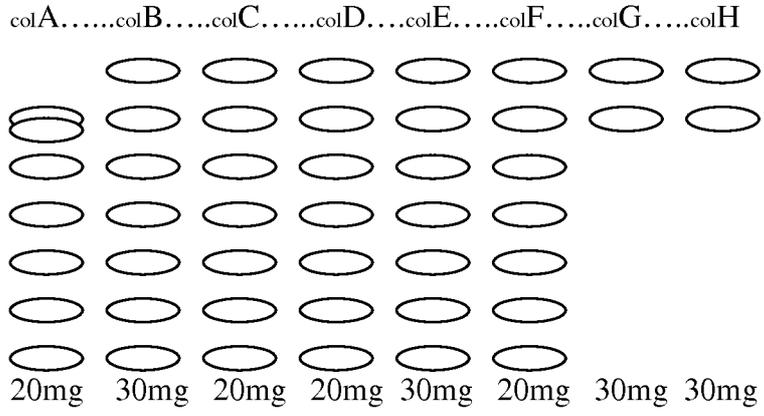
colA......colB.....colC......colD....colE.....colF.....colG.....colH

20mg   30mg   20mg   20mg   30mg   20mg   30mg   30mg

Fig. 1

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colA	colB	colC	colD	colE	colF	colG	colH
A1	B1	C1	D1	E1	F1	G1	H1
A2	B2	C2	D2	E2	F2	G2	H2
A3	B3	C3	D3	E3	F3		
A4	B4	C4	D4	E4	F4		
A5	B5	C5	D5	E5	F5		
A6	B6	C6	D6	E6	F6		
A7	B7	C7	D7	E7	F7		
20mg	30mg	20mg	20mg	30mg	20mg	30mg	30mg

Fig. 2

colA…...colB…...colC…...colD….colE…...colF…...colG…...colH…...colI…...colJ…... colK

30 mg   30mg   30mg   20mg   20mg   30mg   20mg   20mg   30mg   20mg   20 mg

Fig. 3

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colA......colB.....colC......colD....colE.....colF.....colG.....colH......colI......colJ

Fig. 4

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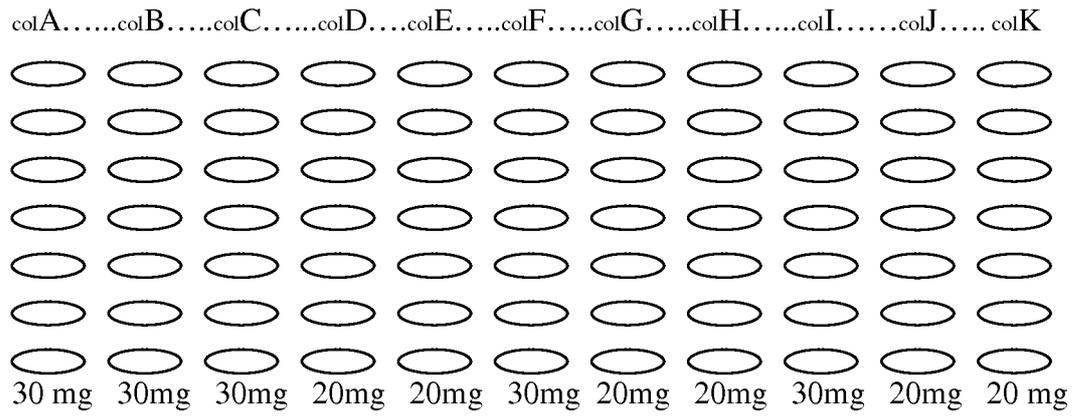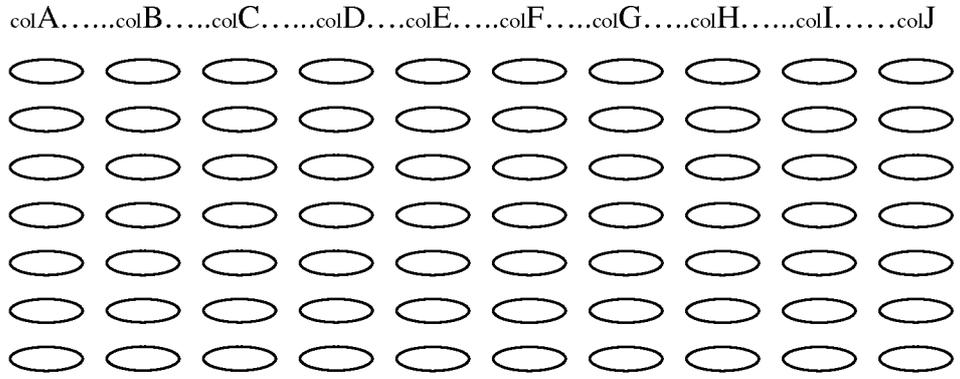| Patient Questionaire		Pre-Test	Day 7	Day 14	Day 21	Day 28
How often in the last 3 days did the following statements apply to you: Never or Rarely = 0 Sometimes = 1 Often = 2 Very Often = 3						
1	Careless mistakes were made or failed to give attention to details					
2	Attention could not be sustained					
3	Necessary things were lost, scattered or damaged					
4	Trouble listening to others when spoken to directly					
5	Failed to finish work or failed to follow instructions					
6	Organizing tasks was difficult					
7	Concentration-requiring tasks were avoided					
8	Usual and daily activities were forgotten					
9	Sounds, sights and smells were distracting					
10	Difficulty awaiting turn					
11	On the go or driven by a motor					
12	Interrupted or intruded on others					
13	Fidgeted with hands or feet or squirmed in seat					
14	Impulsively blurted out answers					
15	Difficulty playing or engaging in leisure activities quietly					
16	Getting out of seat when it was expected to remain seated					
17	Excessive restlessness or excessive running and climbing					
18	Talking excessively					
	Total Score:					

Fig. 5

Instructions:

♦ (If you have not yet taken the rating scale, go to www.ADHDdosing.com or use the rating scale on the inside panel of this ADHDjustableStarterPack™)

♦ **Take one pill of Vyvanse® from Column A this morning and then take one pill from this column every morning, every day, for seven days straight.**

♦ **At the end of the week take the rating scale again to measure your ADHD symptoms.** To do this, go back to the website www.ADHDdosing.com and register again using the identification number below. You will then be instructed by your doctor directly or by an email as to which column or columns of pills to take for the next seven days. (If you used the rating scale on the inside panel of this ADHDjustableStarterPack™, then take the test again on this pack, record your score and contact your doctor with your scores.)

♦ **Repeat this procedure every week you are using this starter pack.**

Your identification number is: XXXXXXXXXXX