Health-pediatric drugs

PEDIATRIC LABELING FOR DRUGS

BACKGROUND

Children suffer from most of the same diseases as adults, and by necessity, are treated with many of the same drugs as adults. Manufacturers of drugs are not currently required to study and label their products for use in children, even where they can anticipate that the products will be prescribed for children. Although pediatric studies are conducted for some drug classes and by some manufacturers, the majority of drugs and biological products that pediatricians use have not been tested by their manufacturers in pediatric populations. As a result, product labeling frequently fails to provide directions for safe and effective use in children. The absence of pediatric labeling information poses a serious risk of inappropriate dosing and unexpected adverse effects in children. It also may result in failure to provide children with optimal treatment in cases where physicians are reluctant to prescribe potentially toxic drugs to children before the drugs have undergone pediatric testing.

Despite these risks, pediatricians often have no choice and the use of drugs that have not been adequately labeled is widespread. An FDA survey of drugs prescribed during 1994 identified the ten drugs prescribed most frequently to children without adequate labeling. Together, these ten drugs were prescribed to children more than 5,000,000 times in one year (see Tab 1). The pediatric physician community has therefore urged FDA to take steps to ensure that drug labels provide information on the safe and effective use of the drugs in children.

In recent years, FDA has undertaken several initiatives to encourage the voluntary addition of pediatric use information to drug labels. FDA implemented a "Pediatric Plan" designed to focus attention on, and encourage, voluntary development of pediatric data during drug development. As part of the Plan, FDA staff meets with manufacturers at several stages of drug development and encourages them to conduct pediatric studies of their drugs. FDA has also identified the top ten drugs used in children without adequate labeling instructions, and has written the manufacturers of these drugs requesting that they submit supplemental applications to add pediatric use information to their drug labels. In 1994, FDA issued a new rule that allowed pediatric use information to appear on labels on the basis of substantially less data than required before. The rule also required manufacturers to survey existing data to determine whether there was sufficient information to support pediatric use information on the drug's label.

These voluntary efforts to increase the amount of pediatric use information on labeling have not resulted in significant gains. The response to the 1994 rule has not been encouraging. Moreover, efforts to date have not increased the number of new drugs entering the marketplace with adequate pediatric labeling. As shown in the chart below, a comparison of new molecular entities (NME's) approved in 1991 through 1996 shows no improvement in the percentage approved with adequate pediatric labeling. While approximately 56% of the drugs approved in 1991 with potential use in children had some pediatric labeling, 37% of those approved in 1996 with potential use in children had pediatric labeling. The data also suggest that commitments by manufacturers to conduct pediatric studies after approval frequently do not result in pediatric labeling.

FDA estimates that pediatric studies are needed for approximately 10-15 products per year that would not otherwise have been studied in children. This figure includes an estimated 10-13 new drugs and biological products and two already marketed products.

Status of pediatric labeling/studies for NME's approved in 1991-1996	1991	1992	1993	1994	1995	1996	Total
Total number of NME's approved	30	25	25	22	28	53	183
Those with potential use in children (pediatric studies needed)	16	14	14	15	14	40	113
Label included some pediatric use information or pediatric studies complete at time of approval (as a percent of NME's needing pediatric studies)	9 (56%)	4 (29%)	5[1] (36%)	6[1] (40%)	5 (36%)	15 (37%)	44 (39%)
Post-approval pediatric studies promised or requested	7	10	10[2]	10[2,3]	10[2]	17	64
Pediatric labeling added after approval	1	0	1	0	0	0	2

REGULATORY STRATEGY

The absence of adequate pediatric labeling continues to pose a significant public health issue. New approaches to the problem are needed. Financial incentives may be successful in generating pediatric labeling for some drugs, but there is no assurance that such incentives will work since they would leave it up to the manufacturer's discretion to conduct the studies. In addition, FDA's experience shows that a significant minority of manufacturers conduct needed pediatric testing without financial incentives. Providing exclusive marketing rights to companies that would have conducted pediatric studies without incentives may impose

[1] In one case, pediatric use information provided for one of two approved indications.

[2] In one case, pediatric data requested for second of two approved indications.

[3] In one case, pediatric data requested for additional age groups.

unnecessary costs on prescription drug consumers, and on governmental and third party payers in the form of more expensive drugs.

The adequacy of pediatric labeling can be substantially improved by imposing a limited pediatric study requirement applicable only to the drugs and biological products needed most urgently by children. Pediatric studies would be required for certain innovative new drugs and never-before approved biological products if they (1) provide a meaningful therapeutic advance to children over existing treatments, or (2) are likely to be widely used in pediatric patients. The requirement could be deferred until after approval if, or example, it was appropriate to delay pediatric studies until sufficient data were collected in adults, or if imposition of the requirement would delay the availability of an important new therapy. Where deferral was permitted, a deadline for submission of the studies could be established. The study requirement could be waived altogether if among other things, the product was likely to be unsafe or ineffective in pediatric patients, pediatric studies were impossible or highly impractical, or reasonable efforts to develop a pediatric formulation had failed. } OIRA advised

The pediatric study requirement would also, in compelling circumstances, apply to manufacturers of already marketed drugs and biological products to support pediatric use labeling for already approved indications. Appropriate circumstances would be (1) where the marketed product is widely used in children and the absence of pediatric labeling presents significant risks to children, and (2) where the product offers a meaningful therapeutic benefit over existing therapies, but additional dosing or safety information is needed to permit safe and effective use in children.

In the event that a manufacturer failed to carry out a required pediatric study, the drug would not be disapproved or withdrawn, because such an action would deprive adult patients of important therapies. Instead, an order from a Federal court requiring the manufacturer to conduct or fund the needed studies would be sought. authorities to enforce

Fib-Health - Pediatric drug Testing

CLOSE HOLD NOT FOR DISTRIBUTION DRAFT

IMPACT OF PEDIATRIC STUDY REQUIREMENT

FDA has made a very preliminary assessment of the impact of the proposed pediatric study requirement. This assessment is based on the assumption that the requirement would apply to drugs classified as "new molecular entities" and biological products that either (a) represent a significant therapeutic advance or (b) would be prescribed to children more than 100,000 times per year.

- FDA estimates that it approves 5-10 drugs and biological products per year that would require new studies under this rule that would not otherwise have been conducted.

  (In making this estimate, FDA analyzed product approvals between 1991 and 1995, looking at 4 factors: (1) the number of products approved with potential use in children; (2) the number of products that the manufacturers voluntarily studied in children; (3) based on (1) and (2), the number of products that were not studied in children, but should have been; (4) of the latter category, the number that represented a significant therapeutic advance or that were prescribed to children more than 100,000/year.)

- The cost of conducting studies that adequately assess pediatric safety and effectiveness could vary from approximately $200,000 for a pharmacokinetic comparison of adults and children to $3-5,000,000 for a full-scale clinical trial.

  - The cost of a study is calculated based on a rough estimate of $5,000 per subject enrolled in the study. Pharmacokinetic studies require very few patients (40-50, in most cases), while controlled clinical trials may require several hundred patients.

Elena -
FDA estimates its draft proposal would affect 5-10 drugs per year at a cost of $200,000 - $5 m per drug.
- Pauline

stimate in advance which kinds of
ed for specific future drugs. The total
s per year is therefore likely to be
nd $25,000,000.

Health - Pediatric Drug Labeling

File - Health - Pediatric drug testing

Pediatric Drug Labeling Background Materials

CLOSE HOLD

1. Internal FDA fact sheet on the issue and a draft FDA proposal

2. Top 10 drugs used off label on kids (without pediatric safety and dosing information on the label)

3. Information on FDA's 1994 actions which have failed to encourage drug manufacturers to voluntarily provide pediatric information on labels.

4. Wall Street Journal article on the issue.

Health — Pediatric Drug Labeling

PROPOSAL TO ADDRESS THE LACK OF PEDIATRIC LABELING FOR DRUGS

BACKGROUND

Children suffer from most of the same diseases as adults, and, by necessity, are treated with most of the same drugs as adults. The majority of new drugs and biological products, however, have not been tested in pediatric populations. As a result, product labeling frequently fails to provide directions for safe and effective use in children, despite widespread use. An FDA survey of drugs prescribed during 1994 identified the 10 drugs prescribed most frequently to children without adequate labeling. Together, these 10 drugs were prescribed more than 5,000,000 times. Because of differences in size and ability to metabolize drugs, children require different doses than adults and may be subject to different adverse reactions. The absence of pediatric labeling information thus poses a serious risk of inappropriate dosing and unexpected adverse effects in children. It may also result in failure to provide children with optimal treatment in cases where physicians are reluctant to prescribe potentially toxic drugs to children before they have undergone pediatric testing. For example, a survey by the Pediatric AIDS Foundation found that fewer than 10% of children with AIDS were receiving protease inhibitors, the newest and most promising AIDS drugs.

In recent years, FDA has undertaken several initiatives to encourage the voluntary addition of pediatric use information to drug labels. FDA has implemented a "Pediatric Plan" designed to focus attention on and encourage voluntary development of pediatric data during drug development. FDA has also identified the top 10 drugs used in children without adequate labeling instructions, and has written the manufacturers of these drugs requesting that they submit supplemental applications to add pediatric use information to their drug labels. In 1994, FDA issued a new rule that allowed pediatric use information to appear on label on the basis of substantially less data than before, and that required manufacturers to survey existing data to determine whether there was sufficient information to support pediatric use information in the drug's label.

These voluntary efforts to increase the amount of pediatric use information in labeling have not resulted in significant gains, particularly with respect to new drugs entering the marketplace. A comparison of drugs approved in 1991 and 1996 showed that approximately 47% of the drugs approved in 1991 with potential use in children had pediatric labeling, while 37% of those approved in 1996 with potential use in children had pediatric labeling.

Year	total NMEs approved	potential use in children	pediatric labeling at approval	post-approval study promised	pediatric labeling later submitted
1991	26	15	7	7	1
1996	53	40	15	17	?

PROPOSAL

FDA is considering proposing new regulations to address the lack of pediatric use information by requiring, for the first time, that applications for certain new drug and biological products contain pediatric data. The purpose of the proposed rule would be to ensure that important new drugs and biological products carry adequate pediatric labeling at the time of, or soon after, approval. The pediatric study requirement would be limited to a small group of new drugs and biologics: new molecular entities (the most innovative drugs) and biological products that (1) would provide a significant therapeutic advantage to children suffering from the disease or (2) would be expected to be used in a substantial proportion of children. Pediatric studies could be deferred until after approval if FDA found that it was appropriate to delay pediatric studies until sufficient data were collected in adults. The requirement could also be waived altogether under certain circumstances.

The proposed rule might also codify FDA's authority to require in compelling circumstances that manufacturers of already marketed drugs and biological products conduct studies to support pediatric use labeling. The circumstances in which FDA might require pediatric studies of a marketed drug would be: (1) where the drug is widely used in children and the lack of adequate labeling poses significant risks to children, or (2) where the drug offers a significant therapeutic advantage to children but additional information is needed to permit safe and effective use.

The absence of workable penalties has historically hampered FDA's ability to require pediatric studies. It is inappropriate from a public health standpoint to prevent the marketing of a drug that offers a clinical benefit to adults simply because the manufacturer has failed to study the drug in another subgroup of the population. FDA is therefore considering a different type of penalty for failure to conduct a pediatric study. FDA would take the manufacturer to court and obtain an injunction requiring the

study to be completed. Violation of the injunction would be punishable by contempt or fines.

Pediatric Corner

Center IDs Top 10 Drugs Used Off-Label in Out-Patient Setting

By L. Miriam Pina, M.D.

After the Final Pediatric Rule was published in December 1994, the Pediatric Use Survey Working Group of the Pediatric Subcommittee was formed. The group's first charge was to identify the drugs most widely used in pediatrics on an out-patient basis for which there was inadequate use information.

Results of the survey disclosed that most drugs that are indicated for diseases occurring in both adults and children have very little information about pediatric use in the labeling. Some age groups have less information available to them than others. The population of less than 2 years of age, for instance, has virtually no pediatric use information on drug products in several class categories. In general, drugs used to treat diseases like asthma, and seasonal and perennial rhinitis, so common in children, present very little information about pediatric drug use. For other therapeutic areas, such as infectious diseases, the pediatric information is, in contrast, quite good.

The working group analyzed survey data from IMS America, Ltd., to provide estimates for pediatric use for 1994. The IMS database is an ongoing pharmaceutical marketing research survey describing drugs mentioned during patient contacts by a nationwide panel of office-based physicians randomly selected from the American Medical Association and the American Osteopathic Association (more than 2,940 physicians representing 27 specialties).

Data collected from the panel are projected nationally by multiplying the raw number of mentions in each stratum, defined by region and specialty, by a corresponding projection factor.

The table displays the drugs that were most widely used off-label in the pediatric population in 1994, according to the IMS database. The drugs are presented in order of frequency of mentions per year and reflect neither the severity of the diseases being treated nor the adverse events reported. Also, for drugs used to treat chronic conditions, the number of mentions may not correlate well with the number of patients being treated. In the chronic use of the Schedule II drug Ritalin, for example, the physician is required to prescribe it with no refills under close surveillance (the prescribing requirements vary from state to state). Thus, in this case, the number of appearances will be overestimated when compared with other drugs used chronically. Nonetheless, in every case, the physician had to make a decision to use the drug with inappropriate pediatric use information.

Members of the Pediatric Use Survey Working Group are: L. Miriam Pina, M.D., chairperson, Division of Pulmonary Drug Products, Kimberly Struble, Division of Anti-Viral Drug Products; Linda Hu, Division of Over the Counter Drug Products; Jones Bell, M.D., Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products; Cazimiro Martin, Division of Over the Counter Drug Products; Frank Rosa, recently retired from the Division of Pharmacovigilance and Epidemiology; and Charles Maynard, Division of Pharmacovigilance and Epidemiology. The December *Pike* lists representatives from each of the Center's review divisions who can assist you with Pediatric Rule issues. The working group plans on publishing in-patient data in a future issue.

L. Miriam Pina, M.D., is a visiting scientist in the Division of Pulmonary Drug Products.

Product	Indication(s)	Label Statement	Off-Label Prescribing Frequency	Prescriber's Specialty (percentage)
Albuterol inhalation solution for nebulization (albuterol sulfate, 0.083 mg/ml)	Prevention and relief of bronchospasm.	Safety and effectiveness (S&E) have not been established in children below 12 years of age.	1,626,000 to children <12 years old.	Pediatricians (62%) Family practitioners and allergists (20%)
Phenergan (promethazine HCl)	Relief of diverse allergic reactions.	Should not be used in children below 2 years of age.	663,000 to children <2 years old.	Pediatricians (82%)
Ampicillin sodium for intravenous or intramuscular injections.	Infections due to susceptible organisms.	S&E have not been established in infants and children under the age of 12.	639,000 to children <12 years old.	Pediatricians (88%) Most common indication: perinatal infections

Product	Indication(s)	Label Statement	Off-Label Prescribing Frequency	Prescriber's Specialty (percentage)
Auralgan otic solution	Prompt relief of pain of acute otitis media and to facilitate the removal of excessive or impacted cerumen.	No instructions for pediatric use at any age.	600,000 to children <16 years old.	Pediatricians (62%) Family practitioners (23%)
Cortisone cream (clotrimazol 1%, betamethasone dipropionate 0.05%)	Topical treatment of particular dermal, fungal infections.	S&E in children below the age of 12 have not been established.	325,000 to children <12 years old.	Pediatricians (51%) Family practitioners (24%)
Prozac (fluoxetin HCl.) pulvules and liquid	Depression and obsessive compulsive disorders.	S&E in children have not been established.	349,000 to children <16 years old. Note: was mentioned to 3,000 infants <1 year of age were in 1994.	Psychiatrists (81%) Most common indication: depressive disorders
Intal (cromolyn sodium).	Prophylactic agent in the management of bronchial asthma.	For inhalation (nebulization) solution, S&E below the age of 2 have not been established. For inhalation aerosol solution (MDI), S&E have not been established below the age of 5.	Intal inhalation solution was prescribed 109,000 times to infants <2 years of age. Intal inhalation aerosol (MDI), 399,000 times to children < 5 years.	Pediatricians (71%)
Zoloft (sertraline HCl)	Depression.	S&E have not been established in children.	248,000 for children <16 years.	Psychiatrists (72%)
Ritalin tablets and sustained-release tablets (methylphenidate HCl) (Schedule II drug)	Treatment of attention deficit disorders and narcolepsy.	S&E have not been established in children <6 years of age.	226,000 to children <6 years old.	Pediatricians (47%) Psychiatrists (26%)
Alupent Syrup (metaproterenol fate).	Bronchodilator for bronchial asthma and for reversible bronchospasms.	Clinical trial experience in children under the age of 6 is limited.	184,000 to children <6 years old.	Pediatricians (59%) Family practitioners (23%)
Beclomethasone dipropionate nasal sprays (includes Beconase AQ and Vancenase AQ nasal sprays).	Relief of symptoms of seasonal and perennial rhinitis and for the prevention of recurrence of nasal polyps following surgical removal.	S&E in children below the age of 6 have not been established.	174,000 to children <6 years old.	Pediatricians (46%)

PEDIATRIC LABELING Qs and As

Q: WHY ARE YOU DOING THIS REGULATION NOW?

A: Despite efforts to increase the number of studies on pediatric populations, still too many children take prescription drugs that have not been tested on children. Over 80 percent of drugs manufactured in the United States have not been tested on children and over 50 percent of drugs that are known to be widely tested in children have not been tested.

As a result, some physicians are reluctant to prescribe much-needed therapies to children. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk.

In some cases, guessing can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children have had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: CAN'T YOU ACHIEVE THE SAME EFFECT THROUGH VOLUNTARY COMPLIANCE?

A: FDA has already implemented reforms to encourage voluntary compliance. However, as 80 percent of drugs manufactured in the United States and over 50 percent of drugs widely used in children still do not have a adequate pediatric labeling, FDA has concluded that this new rule is necessary to ensure that children get the protection they need.

Q: GIVEN THAT THE DRAFT FDA REFORM LEGISLATION, PENDING IN CONGRESS, CONTAINS FINANCIAL INCENTIVES TO ENCOURAGE VOLUNTARY COMPLIANCE, WHY IS THIS RULE NECESSARY?

A: The Congressional approach, while thoughtful and worthy of serious consideration, would not assure that most or all of prescription drugs used by children are tested and labeled appropriately. We believe that the Dodd/Dewine legislation has the potential to complement the regulation the President is unveiling today, but it is not a replacement for it.

Q: DO YOU SUPPORT THE DODD LEGISLATION AS CURRENTLY DRAFTED AS A COMPONENT OF THIS EFFORT?

A: We are reviewing this legislation to determine if it can be designed to compliment and bolster our efforts today. We believe that it has great potential to compliment the legislation but we are not prepared to accept it as currently drafted before we consider all of the ramifications of overlaying the important regulation the President is announcing today.

Q: HAVE CHILDREN BEEN AT RISK IN THE PAST?

A: Yes. In some cases physicians do not prescribe drugs because they determine that it is simply not worth taking the risk of prescribing drugs that have not been tested in children.

In other cases, physicians choose to prescribe treatment, because it is the only means to cure a child's nagging illness or even a life threatening disease. Those physicians are left to make their best guess at the appropriate doses -- rather than rely on the through studies and information that the rest of us take for granted.

In some cases, however, guessing can be devastating. One example of the potential for harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: HOW MANY PRODUCTS WILL BE AFFECTED BY THE RULE?

A: FDA anticipates that this will impact about 12 new drugs each year. The agency will also review drugs already on the market to determine which ones should have pediatric studies. FDA will work as quickly as possible to ensure that in a few years the drugs most important to children will have directions for use in kids on their labels.

Q: WHAT KINDS OF DRUGS ARE COMMONLY MISSING THIS PEDIATRIC DATA?

A: Drugs such as anti-asthmatics, steroids, drugs to treat gastrointestinal problems, strong pain medications, antidepressants, and antihypertensives commonly lack appropriate pediatric labeling.

Q: WHAT DO DOCTORS DO WHEN THEY DON'T HAVE THIS INFORMATION?

A: In some cases they choose not to prescribe the drugs at all. In other cases, they take their best guess -- without the assistance of information that we rely on for adult medications. Sometime, however, guessing can have dangerous consequences, such as seizures, heart problems, or even death.

Q: WHEN CAN PARENTS EXPECT THAT INFORMATION TO SUPPORT SAFE AND EFFECTIVE USE OF PRODUCTS IN CHILDREN WILL BECOME AVAILABLE?

A: We believe that, in some cases, the information already exists and the drug companies merely need to analyze and compile it. In these cases, the information can be made available on the labeling of the products fairly quickly. In other cases, studies need to be conducted. Under the requirements of FDA's 1994 regulation, where the effects of the product and the disease for which it is indicated are sufficiently similar in both adults and children, these studies can be done within one year.

Q: HOW MUCH WILL THIS COST DRUG MANUFACTURERS?

A: FDA estimates that the costs of pediatric studies will be less than 1% of the total costs of developing a drug.

Q: WILL DRUG PRICES INCREASE AS A RESULT OF THIS REGULATION?

A: Because the cost of pediatric studies to manufacturers is expected to be small, it is anticipated that there will be little or no price increases to patients.

Q: WILL THIS REQUIREMENT HOLD UP DRUG APPROVALS?

A: Clearly we will provide every incentive to complete the study before the drug is approved. However, the rule explicitly ensures that a drug's entrance into the market is not held up even if all studies on pediatric populations have not yet begun. We will rely on other legal and financial remedies to ensure that companies comply as soon as possible.

Q: WHEN WILL THIS REGULATION GO INTO EFFECT?

A: There is a 90 day period for comment on the proposed rule after which the agency will evaluate and respond to the comments and publish a final rule. The final rule will take effect 3 months after issuance. At that time, for drugs already on the market, FDA, in compelling circumstances, may request that pediatric studies be initiated. Manufacturers of new drug and biologic products, under review at the agency, will have 2 years to comply with the pediatric study requirement. Manufacturers of new products, not yet submitted for review, will have 18 months to comply with the requirement. Drugs already on the marketplace will have 3 months to comply.

Q: WHAT IS THE ENFORCEMENT MECHANISM FDA WILL TAKE TO FORCE COMPANIES TO PROVIDE THIS DATA ON APPROVED DRUGS?

A: FDA can go to court and ask the court to order the company to comply with the regulations. If the company does not comply, the court can impose penalties.

U.S. FOOD AND DRUG ADMINISTRATION
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Date: 3/5/99

To: Chris Jennings

Fax Number:

From: **Bill Hubbard**

Pages (w/o cover): 2 ROFN

Comments:

Chris,
You asked for information on why the OTC relabeling was important. Does this help?

Every year Americans purchase five billion over-the-counter drugs for a wide variety of ailments--from aches and pains to skin rashes and acne to cough and colds. These are drugs that don't need a doctor's prescription and require the consumer to make their own judgements about what drug to take, how to take it, and whether to give it to their children. In such cases having the necessary information to make the right choice is not just important, it's critical.

Until now, information on the 100,000 OTC drug labels--about directions for use, warnings, advice on when to consult a doctor or pharmacist-- has usually been in small type, run together and hard to read and understand.

Today we are changing that. The new regulations that are being published this week will reinvent the OTC drug label by giving consumers a clear, orderly, understandable set of information that will give them the information they need to make the right choices for their health care.

Why is this necessary? First, although OTC drugs are generally very safe, each year 170,000 Americans are admitted to the hospital because they have been injured by misuse of an OTC drug. The health care cost alone of this is three-quarters of a billion dollars. We know that many, many of these injuries could have been avoided if the consumers had been given the proper information on how to take the drug and warnings about possible risks from that product.

Second, many of our elderly citizens cannot easily read the small, run-together type in the current label. This new label will remedy that by ensuring larger, better spaced information

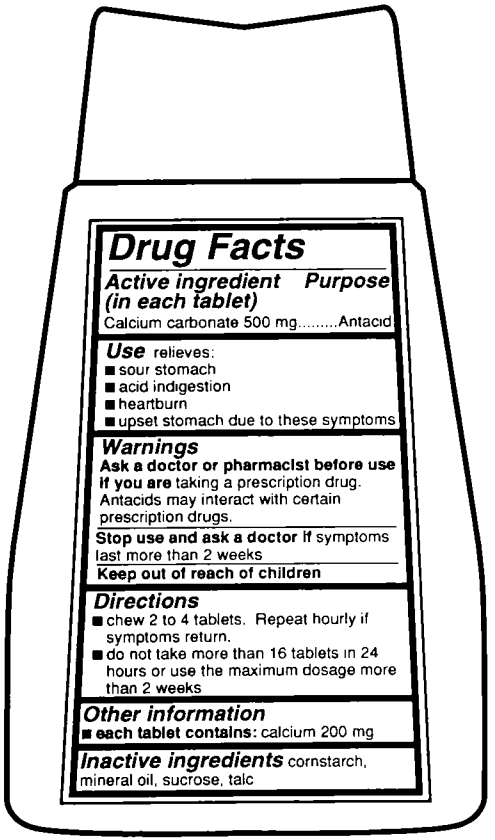
Third, it's important that people pick the right product for their condition. With this label, consumers will better recognize which drug will treat their ailment, make the right choice, and receive the benefit the want and the drug is intended for.

And lastly, no longer will we as consumers be left standing forever in the drug stores or supermarket line trying to wade through the jumble of data that is in the current label. Graphic design experts have donated their time and talent to help us design a label that will contain the best principles of modern design. Consumers will see information laid out in the most readable form, and it will always be in the same place. As this label become more familiar, we will be able to travel through it faster and with greater comprehension.

This label will deal with real problems that Americans confront every day, sometimes tragically. For example, a few months ago ABC News ran a story about 14 month old Sophie Regosin-Hodges, whose parents gave her a "children's" pain reliever. Sophie's parents didn't know that the "children's" product was different from the "infant" version, and Sophie was injured to the point that she has had to undergo a partial liver transplant. Our new label will make it easier to identify subtle differences like this.

Now, we're doing this for the clear and compelling public health reasons I've stated. But we're also trying to make government and its activities more transparent to the public that pays the freight and uses the services. This label will cut through the gobbledygook and give our citizens a clear, readable translation of information that can often be confusing. You may recall that we did this for the food label early in this Administratrion, and that label has since been recognized as a major advance in consumer understanding of how to build a better diet.

New Standard Labeling Format



Drug Facts

Active ingredient (in each tablet) — **Purpose**
Calcium carbonate 500 mg.....Antacid

Use relieves:
- sour stomach
- acid indigestion
- heartburn
- upset stomach due to these symptoms

Warnings
Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

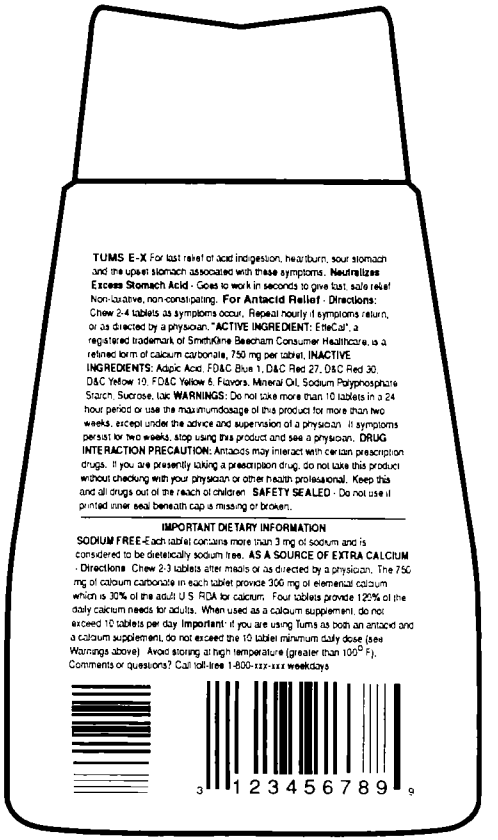
Keep out of reach of children

Directions
- chew 2 to 4 tablets. Repeat hourly if symptoms return.
- do not take more than 16 tablets in 24 hours or use the maximum dosage more than 2 weeks

Other information
- **each tablet contains:** calcium 200 mg

Inactive ingredients cornstarch, mineral oil, sucrose, talc

Existing Label



TUMS E-X For fast relief of acid indigestion, heartburn, sour stomach and the upset stomach associated with these symptoms. **Neutralizes Excess Stomach Acid** - Goes to work in seconds to give fast, safe relief. Non-laxative, non-constipating. **For Antacid Relief** - **Directions:** Chew 2-4 tablets as symptoms occur. Repeat hourly if symptoms return, or as directed by a physician. **"ACTIVE INGREDIENT:** EtteCal®, a registered trademark of SmithKline Beecham Consumer Healthcare, is a refined form of calcium carbonate, 750 mg per tablet. **INACTIVE INGREDIENTS:** Adipic Acid, FD&C Blue 1, D&C Red 27, D&C Red 30, D&C Yellow 10, FD&C Yellow 6, Flavors, Mineral Oil, Sodium Polyphosphate Starch, Sucrose, talc **WARNINGS:** Do not take more than 16 tablets in a 24 hour period or use the maximum dosage of this product for more than two weeks, except under the advice and supervision of a physician. If symptoms persist for two weeks, stop using this product and see a physician. **DRUG INTERACTION PRECAUTION:** Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional. Keep this and all drugs out of the reach of children. **SAFETY SEALED** - Do not use if printed inner seal beneath cap is missing or broken.

IMPORTANT DIETARY INFORMATION

SODIUM FREE-Each tablet contains more than 3 mg of sodium and is considered to be dietetically sodium free. **AS A SOURCE OF EXTRA CALCIUM** - **Directions:** Chew 2-3 tablets after meals or as directed by a physician. The 750 mg of calcium carbonate in each tablet provide 300 mg of elemental calcium which is 30% of the adult U.S. RDA for calcium. Four tablets provide 120% of the daily calcium needs for adults. When used as a calcium supplement, do not exceed 10 tablets per day. **Important**- if you are using Tums as both an antacid and a calcium supplement, do not exceed the 10 tablet minimum daily dose (see Warnings above). Avoid storing at high temperature (greater than 100° F). Comments or questions? Call toll-free 1-800-xxx-xxx weekdays

3 1 2 3 4 5 6 7 8 9 9

OTC Drug Companies

Nonprescripiton Drug Manufacturers Association (NDMA)	James D. Cope (Pres.)	(202) 429-9260
Warner Lambert	Hans F. Knapp	(201) 540-2000
Bausch & Lomb	Kim S. DeVitto	(716) 338-6000
Procter & Gamble*	Christine H. Moorman	(Mason, OH)
Novartis	Vincent De Stefano	(908) 598-7706
Schering-Plough	Ronald J. Garutti (VP)	(908) 604-1640
Merck	Edwin L. Hemwall (VP)	(West Point, PA)
Private Label Manufacturers Assn.	Brian Sharoff (Pres)	(212) 972-3131
Pfizer	Stephen Cristo	(212) 573-7827
Bayer	John Tomaszewski	(201) 254-5000

* P&G also raised serious concerns with the cosmetic requirements

Cosmetics

Cosmetic, Toiletry, and Fragrance Assn.	Thomas J. Donegan (VP)	(202) 331-1770
Helene Curtis	Bruce V. Varner	(312) 661-0222
Estee Lauder (represented by Arent Fox)		

General

American Medical Association	P. John Seward	(312) 464-5000
American Dental Association	Gary Rainwater (Pres)	(312) 440-2871
Association of Food and Drug Officials	Dan S. Smyly (Pres)	(717) 757-2888

Consumer

National Consumers League	Linda Golodner (Pres)	(202) 835-3323
National Women's Health Resource Center	Amy Niles	(202) 293-6045
Consumer Helath Information Corp.	Dorothy L. Smith (Pres)	(703) 734-0650

Kids

American Academy of Pediatrics	Robert E. Hannemann (Pres)	(202) 347-8600

Elderly

AARP	Martin A. Corry	(202) 434-2277

Pharmacists

American Pharmaceutical Assn.	John A. Gans (Exec. VP)	(202) 628-4410
National Community Pharmacists Assn.	Calvin Anthony (Exec. VP)	(703) 683-8200
National Assn. of Chain Drug Stores	S. Lawrence Kocot	(703) 549-3001

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FOR IMMEDIATE RELEASE
March XX, 1999

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6242
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Consumer Inquiries: 888-Info-FDA

NONPRESCRIPTION DRUGS TO GET NEW, EASY-TO-UNDERSTAND LABELS

To help consumers make informed decisions about the medications they use and give their families, Vice President Al Gore and Health and Human Services Secretary Donna E. Shalala announced today a final FDA regulation to provide new, easy-to-understand labeling on nonprescription drugs.

The regulation calls for a standardized format that will improve the labeling on drugs Americans use most--nonprescription, or over-the-counter (OTC) drugs. By clearly showing a drug's ingredients, dose and warnings, the new labeling will make it easier for consumers to understand information about a drug's benefits and risks and about the proper use of the drug.

"When a sick child needs an over-the-counter medicine in the middle of the night, parents shouldn't have to struggle to decipher the label," said Secretary Shalala. "Written in plain language and presented in a user-friendly format, the new label conveys essential information for patients and consumers."

FDA proposed its OTC labeling regulation in February 1997. It developed the new label format based on almost 2,000 comments from the proposed regulation and through several years of agency work with consumer and industry groups. The rule has been developed so that all OTC drugs have labeling that is easy-to-read and understand. The new labeling will also provide

consumers with better information for selecting the most appropriate OTC medication and understanding its benefits and risks.

"All medicines have benefits and side effects," said Jane E. Henney, M.D., Commissioner of Food and Drugs. "The improved label will make it easier for patients and consumers to select the appropriate over-the-counter product, and it will help them use that product more effectively."

Titled "Drug Facts," the new labeling makes it easier for consumers to identify active ingredients, which will be listed at the top, followed by uses, warnings, directions and inactive ingredients. FDA recommends that drug manufacturers include a phone number for consumers to call for more information or for answers to their questions. The requirement for listing inactive ingredients will allow consumers to select products that do not contain ingredients to which they are allergic. The rule also sets minimum type sizes and other graphic features for the standardized format, including options for modifying the format for various package sizes and shapes.

FDA has developed a public education campaign to help consumers understand how the new labels can be used to learn more about OTC medications. This educational campaign will include print and radio public service announcements, consumer brochures, point-of-purchase posters and other exhibit materials. FDA will also work in partnership with national health and professional organizations such as the Nonprescription Drug Manufacturers Association to disseminate this information across a wide range

of education networks.

In many cases, OTC drugs with the new labeling will begin appearing on the shelves within the next two years. All OTC drugs will be required to adopt the new labeling within the next six years.

####

FOR INTERNAL USE ONLY

OTC Labeling
Qs & As

1. What is FDA announcing today?
FDA has finalized its regulation to require nonprescription drugs to carry clear, simple and readable labeling. This action also will make it easier for consumers to understand information about products' benefits and risks and how the drugs should be used most effectively. It will also help ensure that consumers select the right product to meet their needs. The new format will enable consumers to readily and easily determine whether a product contains ingredients that they need or do not need or should not take. It will also make it easier for consumers to compare similar products to determine which product contains the ingredients that are right for them based on their symptoms and personal health situation.

2. When will consumers start to see the new labels?
For many products, the new labeling will appear on products within the next 2 years. OTC drug products that have sales of less than $25,000 per year will receive a special one-year extension. Certain OTC drug products are not required to use the new format for 6 years, although manufacturers of these products are encouraged to adopt the new labeling sooner.

3. Is this the final iteration of the new labeling design or will FDA change its mind and require a different format in five years?
FDA has spent the past 10 years developing the best approach to clear, simple, readable OTC drug labeling--a goal we believe will be achieved through this regulation. This approach was developed with substantial input from consumers, industry, health professionals, and others. However, while FDA believes this regulation is comprehensive, we would not ignore suggestions from industry, health professionals, or consumer groups that offer improvement to the regulation.

4. Why didn't FDA require a larger type size on labeling?
FDA researched this issue very carefully, balancing the need for the required information to fit on various package sizes and the need to ensure that the required information is prominent and readable. FDA considered the comments received on the proposal and reviewed literature studies that demonstrated how important type size is in evaluating readability. Six-point type size for the text is considered the minimum acceptable given other labeling graphical features. Manufacturers can use a larger type size and are encouraged to do so.

5. What about the elderly? Will they be able to read the new labeling?
It's quite true that the elderly have had difficulty reading OTC drug labeling in the past. FDA reviewed several studies that included elderly consumers. One study showed that a 4.5-point minimum type size is not readable, and another study presented information that 6.7-point is a readability threshold for persons over age 60 years. Recognizing that factors other than type size can also enhance readability and that there are space constraints for labeling on drug packages, the agency chose to require a minimum type size of 6 point along with other graphic labeling features designed to enhance readability.

6. Can manufacturers be exempted from this rule if their packages are very small?
While an exemption process is available for unusual circumstances, FDA believes it has developed a rule that takes into account the needs of the variety of marketed OTC drug products and that it will be quite rare for a product to be unable to comply with the various modifications allowed in this regulation.

7. How much will this cost industry?
The agency has calculated that this final rule will cost industry about $58 million. This cost estimate takes into account the two-year phase-in period and the additional one year extension for OTC drug products having sales of less than $25,000 per year. Some manufacturers may have to modify the labeling or packaging to accommodate the new format.

8. Will consumers see an increased cost of OTC drugs as a result of this final rule?
Because most OTC drug product labeling is routinely updated and reprinted every few years, the two year implementation period (with one year extension for low volume products) substantially reduces the overall cost impact. So, FDA does not expect this initiative to affect retail drug prices. However, FDA also does not regulate OTC drug product pricing.

9. Did consumers and industry assist FDA in developing this final rule?
FDA received substantial input from consumers, industry, health professionals, and other experts in developing the format and the provisions in this rule. The agency received over 1,800 comments to the proposed rule, held several public meetings, conducted consumer research, and met with many interested parties to obtain their input in this initiative.

10. Does the final rule include cosmetic products that contain drug ingredients, such as sunscreens?
"Drug-cosmetic" OTC products are included in the final rule. These products contain drug ingredients and are marketed for both drug and cosmetic uses. Drug-cosmetic products have specific warnings and/or directions that consumers need to know so they

can use these products effectively and with less risk.

11. How will FDA evaluate the success of this new initiative?
At this time, FDA does not have a formal plan for evaluating the success of this initiative. It has, however, planned a comprehensive public information campaign as consumers begin to see the new labeling appear on products. FDA routinely interacts with industry and consumer groups such that it can informally assess how well the new labeling is working and how industry is responding to this initiative. If, from that interaction, FDA saw the need to use more formal evaluative tools, it would do so.

12. Will drug companies need FDA approval of their new labeling prior to marketing?
In most cases no prior approval will be necessary. The final rule provides for simplified, interchangeable terms so the required information can fit into the new format. Manufacturers will be permitted to drop certain words or phrases without prior approval as long as such changes do not alter the meaning of the information. If there is a question, manufacturers are encouraged to discuss it with the agency.

13. What does industry think of this reg?
FDA cannot speak for the pharmaceutical industry, but we can say that we have appreciated their contributions and support in finalizing this initiative. We also note that the comments we received on the proposed rule were positive and on balance very supportive of the agency?s effort to adopt a standardized, easy-to-read format for OTC drug labeling. The industry should provide its own reaction to this final rule, however.

14. How is FDA going to enforce this new final rule?
A drug that requires, yet lacks, this new labeling after its required implementation period would be considered misbranded and subject to the same enforcement approach that FDA can take with other misbranded drugs, including warnings, product seizures, and injunctions. FDA, however, expects to work closely with the industry to ensure a cooperative, broad-based transition to the new labeling format.

15. Aren't some drug companies already improving their labeling? Why couldn't this be a voluntary effort? It would seem that manufacturers would be forced by the marketplace to improve their labeling on their own because the trend has already started.
For several years the agency has encouraged manufacturers to voluntarily make their OTC drug labeling easier to read. Although some progress has been made, most of the product labeling on the shelves still is difficult to read and uses type sizes that are barely legible. This initiative also facilitates easier to understand language, which manufacturers could not have done on there own without a change in the regulations.

16. How does this final rule affect homeopathic drugs and dietary supplements since they also are sold over the counter?

Homeopathic drug products are subject to the same labeling provisions of the Food, Drug, and Cosmetic Act as other drug products. However, if these products are labeled in accordance with the existing Compliance Policy Guide for homeopathic products, ordinarily, they will not be recommended for regulatory action. Dietary supplements must be labeled in accordance with the dietary supplement regulation in 21 CFR Part 101.

17. How many drugs will be affected by this new regulation?
It is estimated that about 100,000 OTC drug products are on the market today. All OTC drug products are covered by this final rule.

18. Was the new format tested with real consumers? How do you know that the new labeling will be effective?
The agency did conduct research on the revised format compared to existing labeling and on various graphical features of OTC labeling formats. This research focused on consumer comprehension of the information from the revised format, compared to existing labeling, and examined consumer preferences. The new labeling is more effective because it was found to be greatly preferred by, and more easily understood by consumers in these study groups.

19. Specifically, in simple terms what will the new format look like?
The new format will have standardized headings and subheadings using terms that will be more familiar to consumers. For example, the new labeling will refer to "uses" instead of "indications"and it will no longer use the terms "precautions" or "contraindications". It will also require the information to appear in a standardized order, described below:

"**Drug Facts**" - title
"**Active ingredient(s)**" - including amount in each dosage unit
"**Purpose**" - pharmacologic class or action
"**Use(s)**" - indications
"**Warnings**"
"**Do not use**" - absolute contraindications, when the product should not be used under any circumstances
"**Ask a doctor before use if you have**" - warnings for persons with certain preexisting conditions and for persons experiencing certain symptoms
"**Ask a doctor or pharmacist before use if you are**" - drug/drug and drug/food interactions
"**When using this product**" - side effects that could occur and substances or activities to avoid
"**Stop use and ask a doctor if**" - signs of toxicity and other serious reactions that would require consumers to stop using the product immediately.
Pregnancy/breast-feeding warning
Keep out of reach of children/Accidental overdose warnings

"Directions"
"Other information"
"Inactive ingredients"
"Questions?" (optional)- followed by telephone number

The final rule also requires certain graphical features including:

- **Minimum type size**
  - Title = at least 14 point or 6 point larger than headings
  - Headings = at least 8 pt or 2 points larger than text
  - Text and subheadings = at least 6 pt
- **Easy-to-read sans serif type style**
- **Left justified text**
- **Leading** - at least o pt (minimum space between lines)
- **Kerning** - letters cannot touch
- **Clearly marked sections with hairlines between sections**
- **Bold line surrounding "Drug Facts" information**
- **Upper and lower case letters only** - no all caps
- **Bullets** - square, 5 pt type
- **Directions table** - if three or more categories
- **Other graphical highlights** - contrast, white space, etc.

- There are also special provisions which allow modifications when the information does not fit on small or unusually shaped packages:
- These exemptions may be used if 60% of available labeling space is insufficient to bear required labeling information.
- "Drug Facts" may be in a type size larger than all other print on the Drug Facts panel, instead of minimum 14 pt.
- If more than one bulleted statement is on a line, the second bullet may start on one line and continue to the next line.
- Uses shall be minimum required uses in the monograph.
- Any single, clear, sans serif, easy-to-read, 6-point type style no more than 39 characters per inch may be used for the text.
- Surrounding box may be omitted if information is offset using color contrast.

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Record 1 from database: **MEDLINE**

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Title
Informational and symbolic content of over-the-counter drug advertising on television.

Author
Tsao JC

Address
Department of Journalism, University of Wisconsin-Oshkosh 54901, USA.

Source
J Drug Educ, 1997, 27:2, 173-97

Abstract
The informational and symbolic content of 150 over-the-counter drug commercials on television are empirically analyzed in this study. Results on the informational content suggest that over-the-counter drug ads tend to focus on the concern of what the drug will do for the consumer, rather than on the reasons why the drug should be ingested. Accordingly, advertising strategy is centered on consumer awareness of the product as the primary goal. Educational commitment, however, did not seem to be blended into the promotional efforts for over-the-counter drugs. Findings on the symbolic content of over-the-counter drug ads reveal that drug images have been distorted. Performance of most drugs has been portrayed to be simple resolutions to relieve the symptom. Moreover, a casual attitude toward drug usage is encouraged in the commercials, while time lapse of drug effects is overlooked.

Language of Publication
English

Unique Identifier
97416120

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MeSH Heading (Major)
Advertising|*; Drugs, Non-Prescription|*; Television|*

MeSH Heading
Drug Labeling; Health Education; Human; Knowledge, Attitudes,

Practice; Social Responsibility; Support, Non-U.S. Gov't; United States

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JOURNAL ARTICLE
ISSN
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UNITED STATES

Research Tools
Aging
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Record 1 from database: **MEDLINE**

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Title

Use of food nutrition labels is associated with lower fat intake.

Author

Neuhouser ML; Kristal AR; Patterson RE

Address

Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center, Seattle, WA 98109-1024, USA.

Source

J Am Diet Assoc, 1999 Jan, 99:1, 45-53

Abstract

OBJECTIVE: The Nutrition Labeling and Education Act of 1990 mandated that standardized nutrition information appear on almost all packaged foods manufactured after May 1994. This study describes the demographic and diet-related psychosocial correlates of nutrition label use, and examines the relationship between label use and diet. DESIGN/SUBJECTS: Data are from a random-digit-dial telephone survey of 1,450 adult residents of Washington State. The questionnaire assessed nutrition label use, fat-related diet habits, fruit and vegetable consumption, diet-related psychosocial factors, health behavior, and demographic characteristics. STATISTICAL ANALYSES: Analyses examined associations of demographic characteristics with nutrition label use; diet-related psychosocial factors and health behavior with nutrition label use, controlled for demographic characteristics; and nutrition label use with fat and fruit and vegetable intake, controlled for demographic characteristics and psychosocial factors. RESULTS: Nutrition label use was significantly higher among women, residents younger than 35 years, and residents with more than a high school education. When controlled for demographic characteristics, the strongest predictors of label use were believing in the importance of eating a low-fat diet, believing in an association between diet and cancer, and being in the maintenance stage of change for adopting a low-fat diet. Label use was significantly associated with lower fat intake and, after controlling for all demographic, psychosocial, and behavioral variables, explained 6% of the variance in fat intake ($P < .001$). Label use was not associated with fruit and vegetable consumption. APPLICATIONS/CONCLUSION: Persons successfully limiting their fat intake use nutrition labels, suggesting that the new nutrition

labels are helpful. Dietetics professionals can use the results of this study to emphasize to their clients the importance of reading nutrition labels in maintaining a low-fat diet.

Language of Publication
English

Unique Identifier
99116256

MeSH Heading (Major)
Dietary Fats|*AD; Feeding Behavior|*; Food Labeling|*/SN

MeSH Heading
Adult; Age Factors; Cross-Sectional Studies|CROSS SECTIONAL STUDIES; Educational Status; Female; Health Behavior; Health Status; Human; Knowledge, Attitudes, Practice; Male; Middle Age; Nutrition Surveys; Questionnaires; Regression Analysis; Sex Factors; Support, U.S. Gov't, P.H.S.; Telephone; Washington

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Publication Type
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UNITED STATES

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Research Tools
Aging
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Biomedical
-MEDLINE
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Record 1 from database: **MEDLINE**

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Title
Prescription to over-the-counter drug reclassification.

Author
Jacobs LR

Address
Medicine Shoppe, Chardon, Ohio, USA.

Source
Am Fam Physician, 1998 May, 57:9, 2209-14

Abstract
Self-care is becoming increasingly popular among health care consumers. The availability of over-the-counter medications makes it possible for consumers to treat numerous ailments without the supervision of a health care professional. Many of the medications now available without a prescription were previously classified as prescription-only products. The U.S. Food and Drug Administration has procedures in place that allow prescription products to be reclassified as over-the-counter medications if certain criteria are met. Reclassified products have had clinical and economic effects on the U.S. health care system and have led to concerns among health care professionals. Patient education and counseling are particularly important to promote safe and effective use of over-the-counter products.

Language of Publication
English

Unique Identifier
98269155

Order full text for this document

MeSH Heading (Major)
Drugs, Non-Prescription|*ST

MeSH Heading
Human; Patient Education; United States; United States Food and Drug Administration

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ISSN
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Country of Publication
UNITED STATES

NLM database Document

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Order full text for this document

Title

Over-the-counter medication use in an older rural community: the MoVIES Project.

Author

Stoehr GP; Ganguli M; Seaberg EC; Echement DA; Belle S

Address

School of Pharmacy, Department of Psychiatry, University of Pittsburgh, PA 15261, USA.

Source

J Am Geriatr Soc, 1997 Feb, 45:2, 158-65

Abstract

OBJECTIVE: To examine the self-reported use of over-the-counter (OTC) medications and the factors associated with OTC use in a rural older population. DESIGN: A cross-sectional study of an age-stratified random community sample. SETTING: The mid-Monongahela Valley, a rural area of Southwestern Pennsylvania. PARTICIPANTS: A total of 1059 older individuals with a mean age of 74.5 (+/- 5.5) years, 96.9% of whom were white and 57.3% of whom were women. MEASUREMENTS: Self-reported over-the-counter drug use and demographic information, and information about prescription drug use and recent use of health services. RESULTS: The majority (87.0%) of the sample were taking at least one OTC medication; 5.7% reported taking five or more OTCs. Women took significantly more OTCs than did men (P < .001). Individuals with more education took significantly more OTCs than those who had less (P = .018). The OTC category used most commonly was analgesics (66.3% overall), followed by vitamin and mineral supplements (38.1%), antacids (27.9%), and laxatives (9.7%). The use of analgesics decreased significantly (P = .018) with increasing age, whereas the use of laxatives increased significantly (P < .001). Women were more likely than men to be using each of these four major OTC groups. Unlike the associations with prescription drug use we reported previously in the same population, there were no significant associations for overall OTC use with age or with the use of health services. However, although vitamin use (as an example of an OTC drug taken for "preventive" purposes) was not associated with health services use, the use of laxatives (as an example of a "curative" OTC) was significantly associated (P < or =

.002) with a greater number of physician visits, emergency room visits, hospitalizations during the past 6 months, home health care service utilization, and number of prescription medications. CONCLUSIONS: A substantial proportion of our older sample reported using a variety of over-the-counter drugs. Analgesics and vitamin/mineral supplements were the most frequently used categories. Women and those with more education were taking more OTC drugs. OTC use was not related to age, but the use of analgesics decreased with age while laxative use increased with age. Unlike prescription drug use, overall OTC drug use was not associated with health services utilization.

Language of Publication
English

Unique Identifier
97185832

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Drugs, Non-Prescription|*/TU; Rural Population|*SN

MeSH Heading
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