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N E W S

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Direct-To-Consumer Advertising—Education or Emotion Promotion?

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During the past two decades, there has been an irreversible change in the nature of the doctor-patient relationship. Patients are seeking much more medical information and are actively participating in decisions affecting their health. Intruding into this trend has been the rise of direct-to-consumer promotion, which, in its initial thrust, bypasses primary care doctors and other physicians. Although increased access by patients to accurate, objective information about

tests to diagnose and drugs to treat illnesses is an important advance, confusion arises when commercially driven promotional information is represented as educational. Two articles in this issue of the *Journal* address the direct-to-consumer promotion of medical products and services. Rosenthal et al. describe the resources allocated to direct-to-consumer advertising of prescription drugs, as compared with other forms of promotion. Lee and Brennan examine issues arising from the direct-to-consumer marketing of high technology medical screening tests. These articles raise several questions. Is direct-to-consumer advertising educational or emotional? How often is it misleading? Is enforcement by the

Food and Drug Administration (FDA) of advertising regulations adequate? What can be done to neutralize the negative effect of this type of advertising?

In an excellent review of direct-to-consumer promotion, Mintzes stated that “the question is not whether consumers should obtain information about treatment options; the question is whether drug promotion—whose aim is to sell a product—can provide the type of information consumers need.”

Addressing the issue of pharmaceutical advertising more generally 30 years ago in the *Journal*, Ingelfinger argued that “advertisements should be overtly recognized for what they are—an unabashed

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attempt to get someone to buy something, although some useful information may be provided in the process.” He suggested that such advertising should be divested of its “pseudo-educational character.”

Serious deficiencies have been documented in the educational value of advertising for prescription drugs. In a survey of 1872 viewers of television advertisements, 70 percent thought they had learned little or nothing more about the health condition requiring treatment, and 59 percent thought they knew little or nothing more about the drug being advertised. Another study found that whereas many advertisements provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, the necessary duration of use, alternative treatments (including behavioral changes) that could improve their health, or misconceptions about the disease to be treated. The average number of “educational codes” (i.e., specific learning points relating to a medical condition or a treatment) present in the advertisements was only 3.2 out of a possible 11.

None of these deficiencies should be surprising in the light of the characterization of advertising by the Canadian economist Stephen Leacock as “the science of arresting the human intelligence long enough to get money from it.” Leacock also thought that, for the purpose of selling, advertising “is superior to reality.” An advertisement, aimed at the marketers of pharmaceutical products, from an agency that creates drug advertisements, provides some revealing insights about how the process works. The promotional material describes the hippocampus as the “prescription-writing center of the brain”—the part that “processes information by connecting new concepts with the

parts of the brain where gut instincts are formed, areas that influence emotional behavior and form memories.” The advertising agency asserts that its “communications are focused on making the hippocampus respond positively to your product...[by demonstrating] how your product is superior and unique.” An executive of a company that focuses on direct-to-consumer

The FDA should crack down harder on misleading ads.

advertising commented that “consumers react emotionally, so you want to know how they feel about your message and what emotional triggers will get them to act....We want to identify the emotions we can tap into to get that customer to take the desired course of action.” Another article, describing problems the drug industry has had in adapting to direct-to-consumer marketing, said that companies “are overly focused on communicating rational attributes to customers. But consumers often choose a product on [the basis of] emotional attributes....How an emotional appeal fits into fair balance in advertising prescription drugs under the requirements and approval process of the FDA is not clear.”

Patients have dangerous misperceptions about direct-to-consumer advertising. According to one study, a substantial proportion of people incorrectly believed that only the safest and most effective drugs could be advertised directly to consumers and that the FDA required that it be allowed to review advertisements before they were

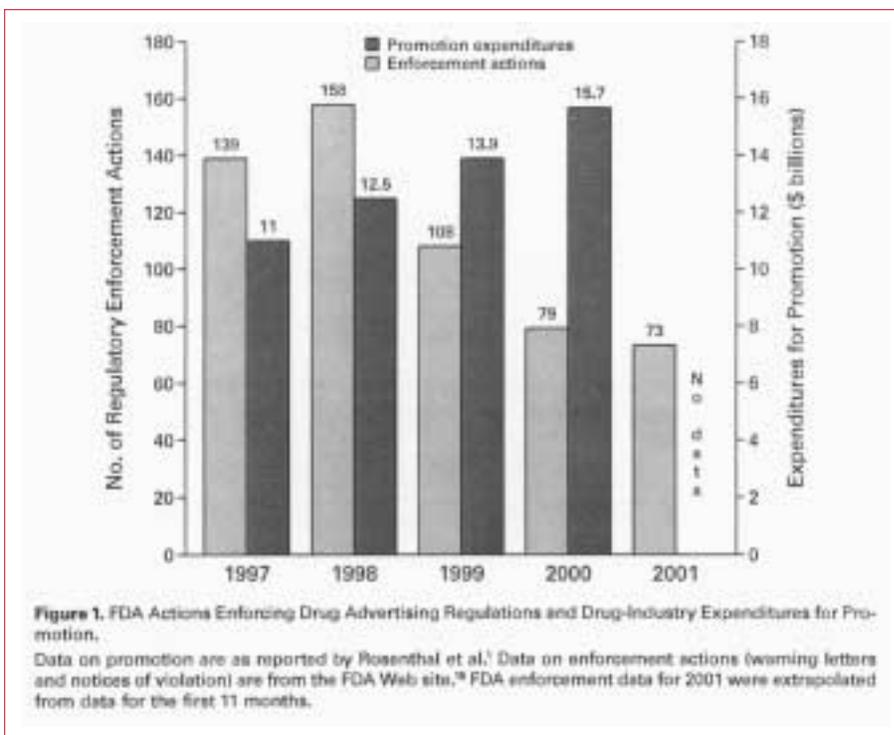
published. According to another study, consumers rated the safety and appeal of drugs described with an incomplete statement of risks more positively than similar drugs described with a more complete statement of risks.

Defenses of direct-to-consumer advertising by the pharmaceutical industry inevitably mention that the real gatekeeper is the doctor, since only the doctor can write a prescription. Even Rosenthal et al. state that doctors will only write a prescription for a drug when they are “familiar with it and comfortable prescribing it.” Although it is beyond the scope of this editorial, it is important to examine studies assessing the accuracy of sources of information that physicians use to learn about new drugs or devices. There is evidence that many drug advertisements are not balanced or accurate, and duped gatekeepers may not adequately resist patients’ exhortations to write a prescription.

Since a ban on the advertising of pharmaceutical agents is incompatible with the First Amendment, much stricter control by the FDA of misleading advertising is necessary. Although expenditures for the promotion of drugs increased from \$11 billion in 1997 to \$15.7 billion in 2000 (see Figure 1, next page), there is a significant decrease in the number of actions taken by the FDA to enforce advertising regulations—from 139 letters of warning to companies or notices of violation in 1997 to 79 in 2000 and an estimated 73 in 2001. The FDA is grossly understaffed for this important oversight function: the entire Division of Drug Marketing, Advertising, and Communications (DDMAC) has had only 28 to 30 employees since 1997. A further handicap for the FDA is that it lacks the legal authority to impose civil monetary penalties on companies even when they repeatedly violate the law. An editorial in a December

2001 issue of *Business Week* commented that “pharmaceutical company advertising on TV promotes high-priced new drugs with marginal improvement over cheaper generic versions. The FDA should crack down harder on misleading ads.” In the realm of screening computed tomographic CT scans analyzed by Lee and Brennan, enforcement is beginning to occur. FDA recently sent a notice of violation to a company, CATscan2000, for illegally promoting screening for heart disease in asymptomatic people: this form of technology has not been approved for use in such screening.

Beyond increased enforcement by the FDA, the issue of better information for patients must be addressed. The irritation felt by many physicians when patients approach them after seeing a direct-to-consumer advertisement may derive from the fact that such advertisements, with their powerful, emotion-arousing images and frequently unbalanced information on safety and effectiveness, mislead patients into believing that drugs are better than they actually are. There is a hollow ring to the statement by Pharmaceutical Research and Manufacturers of America President Alan Holmer



that “direct-to-consumer advertising is an excellent way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments.”

The education of patients—or physicians—is too important to be left to the pharmaceutical industry, with its pseudo educational campaigns designed, first and foremost,

to promote drugs. Public Health Service agencies such as the National Institutes of Health and the FDA, along with medical educators in schools and residency programs, must move much more forcefully to replace tainted drug company “education” with scientifically based, useful information that will stimulate better conversations between doctors and patients and lead to true empowerment.

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The Antihistamine Desloratadine (CLARINEX)— Son of Loratadine (CLARITIN)

By the time you read this, desloratadine (CLARINEX)—the Schering-Plough Corporation's replacement for their \$3 billion a year antihistamine loratadine (CLARITIN)—will be on pharmacy shelves. An army of sales people will be bribing your doctor with expensive meals, gifts, and vacations to switch your prescription from loratadine to desloratadine. Executives of your managed care organization or insurance company, depending on their concept of medical ethics, will be huddled in a back room with Schering-Plough representatives negotiating for kickbacks, deep discounts or other favors, to make desloratadine the preferred antihistamine on their drug formularies.

Desloratadine is only technically a new drug. Patients who have been taking loratadine since it was approved in 1994 actually have been getting a dose of desloratadine because loratadine is broken down, or metabolized, to desloratadine in the body. Desloratadine is thereby produced as an active metabolite of loratadine.

Loratadine is due to lose its patent protection in December 2002 and Schering-Plough's purpose in developing desloratadine can only be to protect its share of the brand name antihistamine market. It was certainly not to produce a safer or more effective antihistamine. The market for this drug alone accounts for about one-third of the company's worldwide sales.

The market share protection scheme works like this. Loratadine has been Schering-Plough's golden goose for years racking up tens of billions in sales, but loratadine is

soon going to lose its patent protection. The question for the company was: how to protect loratadine's market share to keep potential investors interested and current stock holders happy?

Schering-Plough used a simultaneous two pronged attack. First, they hired an army of Washington lobbyists spending millions trying to buy a three year patent extension for loratadine. When that failed, the company abused the intent of our patent laws to reward ingenuity and originality to get desloratadine, the metabolite of loratadine, protected and then got desloratadine past the Food and Drug Administration's (FDA) outmoded 40 year old legal standard for marketing drugs, which does not require new drugs to be better than older ones.

Schering-Plough now has two antihistamines protected by patents—loratadine and desloratadine—that are inherently the same. With only 10 months left on loratadine's patent, the goal is to switch as many patients as possible to the "new" desloratadine with its longer patent protection. This effectively extends Schering-Plough's brand name monopoly in the antihistamine market for the life of the desloratadine patent and the company prays it will blunt generic competition to loratadine.

However, Schering-Plough has run into one very large hitch. There are no studies or data to show that loratadine and desloratadine are clinically different. And ethical managed care organizations and insurance companies are waking up to the fact that new drugs making it through the FDA's drug approval process may be no more effective

and can be less safe than drugs already on the market. Without evidence from head-to-head clinical trials testing a new drug against an old drug, ethical managed care organizations realize they would be buying a "pig in a poke."

So, how does Schering-Plough plan to sell desloratadine when less expensive generic loratadine will be on the market in 10 months? Yet another tactic, other than those mentioned in the first paragraph of this article, is to offer desloratadine at a discount compared to loratadine. The wholesale list price for desloratadine has been announced at \$1.83 per tablet, compared to \$2.22 for loratadine, a difference of \$0.39 per tablet.

A Wall Street analyst hit the nail on the head when he said "While the steep discount will mean less revenue growth for Schering in the short term, it will be beneficial over the longer term because it will speed up recruitment of Claritin [loratadine] users to Clarinex [desloratadine]." Put another way, in the long term consumers will have their pockets picked by Schering-Plough if they start using desloratadine.

Alas, the anarchy of the American "health care" system.

What You Can Do

There is no medical reason for you to be switched from loratadine to desloratadine. However, if you use desloratadine in the short term before generic loratadine is available you will save money. If you use desloratadine after generic loratadine is marketed you will be ripped-off.

Ephedra Dietary Supplements Laced with Synthetic Stimulants

A strongly worded letter from the Health Research Group, dated January 31, 2002, admonished Department of Health and Human Services secretary Tommy Thompson that his "... Department has been grossly negligent in protecting Americans from what is clearly the most dangerous drug that masquerades as a food supplement, Ephedra. At least 10 products made by nine dietary supplement producers are now being sold on the Internet—products that illegally contain dangerous synthetic derivatives of ephedra." Secretary Thompson was specifically asked to order the seizure of these illegally marketed products.

A list of these producers and their products appear in the box on this page. The text of the letter is available on our web site at www.citizen.org/publications/release.cfm?ID=7146. A hard copy of this document can be obtained by writing to us at 1600 20th Street, NW, Washington, DC 20009.

Ephedra is an herb that contains a number of substances that are chemically similar to the amphetamines ("speed" like substances) such as ephedrine and norephedrine (also known as phenylpropanolamine or PPA). Data from the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition's Special Nutritionals Adverse Event Monitoring System shows that dietary supplements containing these chemicals are associated with more reports of death, heart attack, heart rhythm disturbances, high blood pressure, stroke and seizure than all other dietary supplements combined.

The Health Research Group petitioned the FDA on September 5, 2001 to ban the production and sale

PRODUCT	PRODUCER
ADIPOKINETIX	Syntrax Innovations, Inc. PO Box 1593 Cape Girardeau, MO 63702
ADRENALIN	Genapharm, PO Box 2558 Ceder Park, TX 78641
ALPHADRINE	Pro-Muscle Address not available
EPHEDRINE 25	Scientifically Advanced Nutrition Corporation 4230 Del Rey Ave. # 458 Marina Del Rey, CA 90292
EPHEDROL	Thermal Plus 900 Greenbank Rd. Suite 522 Nepean, Ontario K2J-4P6
HOLLYWOOD CUTS	Scientifically Advanced Nutrition Corporation 4230 Del Rey Ave. # 458 Marina Del Rey, CA 90292
LIPODRYL II	Thermolife 720 El Camino Real #101 Belmont, CA 94002
META-BURN EXTREME	Metabolic Response Modifiers 236 Calle Pinteroesco San Clemente, CA 92673
OVERDRIVE	7th Millennium Nutrition P.O. Box 2206 Stow, OH 44224
PHENYLKINETICS	21st Century Nutritionals / Synergy Nutritionals 745 Hollywood Blvd. N.W., Ft. Walton Beach FL 32548

of dietary supplements containing ephedra and the chemicals derived from this herb. Prior to this, on October 19, 2000, we had also petitioned the FDA to ban all over-the-counter (OTC) uses of PPA. The FDA is now in the process of formally removing PPA from all prescription and OTC products.

On January 9, 2002, Canadian regulatory authorities announced the initiation of a voluntary recall of certain products containing Ephedra and ephedrine. This decision was

reached after a risk assessment concluded that these products pose a serious health risk. Secretary Thompson should look north for guidance.

U.S. law is very clear on adding synthetic compounds to dietary supplements. The Food, Drug and Cosmetic Act expressly limits dietary supplements to ingredients that are concentrates, metabolites (breakdown products), constituents, or extracts of dietary substances.

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Do Not Use!

The Pain Drug Tramadol (ULTRAM/ULTRACET) and Serotonin Syndrome

Australian drug regulatory authorities have received 171 reports of suspected adverse reactions with the pain drugs tramadol (ULTRAM) or tramadol in combination with acetaminophen (ULTRACET) since Ultram began being marketed in Australia in late 1998. In six of these reports, a very serious adverse reaction known as the serotonin syndrome was listed as the adverse reaction. Tramadol is a drug that increases serotonin levels by blocking the storage of the chemical in nerve cells. A summary of these reports was published in the December 2001 issue of the *Australian Adverse Drug Reactions Bulletin*.

The box on this page lists the features of the serotonin syndrome. To establish the existence of this condition in a patient at least 3 of

the 10 clinical features listed. These must occur following either the addition of a new drug that increases serotonin levels or an increase in the dose of a drug that raises serotonin levels.

Four of the six reports of serotonin syndrome to the Australian authorities described the use of tramadol in patients who were also taking antidepressants known to increase the concentration of serotonin in the brain. These included the selective serotonin reuptake inhibitors (SSRIs) sertraline (ZOLOFT) and citalopram (CELEXA), the selective monoamine oxidase inhibitor (MAOI) moclobemide (a drug not available in the U.S. that releases serotonin from nerve cells), and a combination of the tricyclic antidepressants amitriptyline (ELAVIL) and clomipramine (ANAFRANIL), both of which block the storage of serotonin in cells.

Lists of currently marketed SSRIs and MAOIs appear on the box on this page.

Another of the six reports involved a person who was taking the dietary supplement St. John's Wort, also believed to increase serotonin levels. The final report described the use of a relatively high daily dose of tramadol, 400 milligrams, in an elderly man. Four of the six patients recovered after treatment while one patient required admission to the intensive care unit and had not recovered at the time the *Australian Adverse Drug Reactions Bulletin* summary was published. The outcome was unknown in another patient.

Tramadol was approved for use
continued on page 23

Features of Serotonin Syndrome published in the *American Journal of Psychiatry* 1991.

- mental status changes (confusion, mild degree of mania)
- agitation
- myoclonus (spasm or twitching)
- hyperreflexia (reflexes are exaggerated)
- sweating
- shivering
- tremor
- diarrhea
- incoordination
- fever

EPHEDRA, from page 21

Our letter concludes by informing Secretary Thompson that "Failure to act swiftly and decisively in this matter as required by law and to ban all ephedra alkaloids will result in a continuation of the harm and injury of dietary supplement consumers nationwide and will emphasize how fraudulent your concerns about food safety are."

What You Can Do

You should not use any dietary supplements other than vitamins and minerals. Even supplement producers who do not lace their products with synthetic substances are not required to show that what they are selling is either safe or effective for any purpose.

SSRI Drugs

citalopram (CELEXA)

fluoxetine (PROZAC)

fluvoxamine (LUVOX)

paroxetine (PAXIL)

sertraline (ZOLOFT)

Fluoxetine is also marketed for premenstrual dysphoric disorder as SARAFEM.

MAOI Antidepressants

isocarboxazid (MARPLAN)

phenelzine (NARDIL)

tranylcypromine (PARNATE)

Do Not Use Until 2007!

Cefditoren (SPECTRACEF)—Old Japanese Antibiotic Debuts In U.S.

Cefditoren (SPECTRACEF) was approved for sale by the Food and Drug Administration (FDA) in November 2001 making it the 23rd member of the cephalosporin family of antibiotics (semisynthetic relations of penicillin) and the 11th member of the subgroup known as third generation cephalosporins. The drug has been available in Japan since 1994.

We have invoked our *Do Not Use Until Five Years After Release* rule with this drug. The Five Year Rule is described in the box on pg. 24.

The drug is being sold by TAP Pharmaceuticals Inc., a joint venture between Abbott Laboratories of Illinois and the Japanese firm Takeda Chemical Industries.

Cefditoren is approved only for use in adults and adolescents 12 years of age or older for the treatment of acute worsening of chronic bronchitis, sore throat or tonsillitis, and uncomplicated skin and skin

Cefditoren can interact with antacids containing magnesium and aluminum hydroxides

structure infections caused by bacteria that will be killed by cefditoren. Company press releases indicate that TAP asked the FDA for approval for the treatment of sinus infection (acute bacterial sinusitis) as an approved use. But, the

company failed to prove that cefditoren was of value in the treatment of sinus infection.

The drug's professional product labeling or "package insert" contains two unusual contraindications for using cefditoren. First, the drug should not be used in patients with carnitine deficiency or congenital errors of normal metabolism that may result in a clinically significant carnitine deficiency. Cefditoren can cause a decrease in blood levels of carnitine of 39 percent to 63 percent depending on the dose of the drug. Progressive muscle weakness and breakdown of muscle (rhabdomyolysis) are associated with severe carnitine deficiency. However, neither of these adverse effects has been reported with the use of cefditoren at this time.

The second contraindication to using cefditoren is in patients who are truly allergic to milk products

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SEROTONIN SYNDROME, *from page 22*

in this country by the Food and Drug Administration (FDA) in March 1995. We listed the drug as *Do Not Use* in the 1999 edition of *Worst Pills, Best Pills* because it appears to be no more and sometimes less effective than the combination of codeine with acetaminophen. In addition, shortly after the drug was approved safety warnings had to be added to its professional product labeling, or "package insert," about the risk of seizure or convulsion with its use and its ability to cause dependence. The newly marketed combination of

tramadol with acetaminophen (ULTRACET) was listed as *Do Not Use* in the October 2001 issue of *Worst Pills, Best Pills News* for the same reasons tramadol was listed as *Do Not Use*.

Both ULTRAM and ULTRACET carry the same warning about using either product with MAO inhibitors or SSRI antidepressants and serotonin syndrome.

Use with MAO Inhibitors and Serotonin Re-uptake Inhibitors
Use ULTRAM with great caution in patients taking monoamine oxidase inhibitors. Animal studies have shown increased

deaths with combined administration. Concomitant use of ULTRAM with MAO inhibitors or SSRIs increases the risk of adverse events, including seizure and serotonin syndrome.

What You Can Do

You should not be using tramadol either in the form of ULTRAM or ULTRACET if you are taking an MAO inhibitor or SSRI antidepressant.

If you develop the symptoms of serotonin syndrome while taking tramadol, immediately discontinue the tramadol and contact your doctor.

CEFDITOREN, from page 23

(not lactose intolerance which is an inability to breakdown lactose) because the drug contains sodium caseinate, a milk protein.

Cefditoren can interact with antacids containing magnesium and aluminum hydroxides such as MAALOX to reduce the amount of cefditoren in the blood. It is recommended that cefditoren not be taken with the histamine-2 blocker drugs commonly used for heartburn. Using these drugs with cefditoren at the same time will also reduce the blood levels of cefditoren. The histamine-2 blockers include cimetidine (TAGAMET) and ranitidine (ZANTAC).

The Medical Letter On Drugs and Therapeutics reviewed cefditoren in their January 21, 2002 issue. *The Medical Letter* editors concluded:

It offers no clinical advantage over cefdinir (OMNICEF) or cefpodoxime (VANTIN), but it costs less. Older drugs that have narrower spectrums of activity are as effective as cefditoren for the approved indications, and are less likely to promote emergence of resistance. Cephalexin (KEFLEX, and others), for example, would be a better choice for skin and soft tissue infection, and cefuroxime (CEFTIN) for bronchitis. Penicillin remains the drug of choice of streptococcal pharyngitis or tonsillitis.

The Health Research Group's Five Year Rule

You should wait at least five years from the date of release to take any new drug unless it is one of those rare "breakthrough" drugs that offers you a documented therapeutic advantage over older proven drugs. New drugs are tested in a relatively small number of people before being released, and serious adverse effects or life-threatening drug interactions may not be detected until the new drug has been taken by hundreds of thousands of people. A number of new drugs have been withdrawn within their first five years after approval. Also, warnings about serious new adverse reactions have been added to the labeling of a number of drugs, or new drug interactions have been detected, usually within the first five years after a drug's release.

*This drug offers
no documented
advantage over
numerous other
antibiotics*

The third generation cephalosporin sub-group of antibiotics is a mature market segment. Many of the drugs in this sub-group have been on the market for years and are available as lower cost generics. Since generic manufacturers do not

advertise directly to physicians or consumers the promotion of a new brand name drug like cefditoren is essentially unopposed. Drug companies know if they can get a drug through the FDA's outdated 40 year old standard for marketing drugs (not requiring new drugs to be better than old ones) they can make a financial killing on the strength of their advertising campaign.

What You Can Do

You should not take cefditoren for at least five years, until 2007. This drug offers no documented advantage over numerous other antibiotics that are equally or more effective than older antibiotics approved for the same uses.

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