Blurring the Boundaries: Promotion Targeting Consumers

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Direct-to-consumer (DTC) advertising of prescription drugs is allowed in the US,[(26)] where it has become increasingly common during the late 1980s and the 1990s, but not in other industrialized countries. How important is this form of advertising? In 1996 in the United States, expenditures for DTC printed advertisements for prescription drugs grew to more than US$700 million, and in both 1995 and 1996 the US pharmaceutical industry spent more money on printed advertisements for prescription-only products to consumers than on printed advertisements aimed at doctors and other health professionals.[(27)] About three quarters of this spending was on advertisements in consumer magazines. The entire expenditure on promotion was much greater – estimated at US$12.3 billion in 1996 [(28)] – with the largest proportion spent on the salaries of sales forces which still mainly target doctors.

Wyeth-Ayerst's prominent 1996 newspaper campaign for its antidepressant venlafaxine (Effexor), used three ads promising that life will get better for children and other family members too if a depressed parent or spouse seeks treatment — by implication with Effexor — with the statements "I got my mommy back" and "I got my marriage back". These statements promote magic solutions, the idea of a "pill for every ill", even when that ill may consist of complex emotional, family and relationship problems. These advertisements also failed to add that this antidepressant has not been found to be any more effective than less expensive alternatives. A US magazine advertisement by SmithKline Beecham linked to its web site, "cafe herpes", played on consumers' emotions with a picture of a young woman saying: "I'll tell you about the shame, the pain, and a hundred broken dates – that's what genital herpes did to me before I found Famvir."[(29)] Again, a drug solution is recommended for a social problem: social stigma — particularly for women who have contracted a sexually transmitted disease.

One consistent theme in direct-to-consumer advertisements in the US is that consumers need to be anxious — that serious illness is lurking around the corner — and that drug treatment is needed to allay this anxiety.

According to Astra Merck: "people who have heartburn two or more times a week probably do not have ordinary heartburn, but the 'potentially serious condition' of gastro-oesophageal reflux disease. They are encouraged to ask their doctors about an Astra Merck product, Prilosec, and call a toll-free number for a free brochure and a symptom questionnaire to give to their doctor.[(30)] In an advertisement promoting use of misoprostol (Cytotec) with

NSAIDs, Searle tells Canadian arthritis patients that they may have ulcers but not know it: "And you may not feel anything in your stomach, because arthritis medication hides the pain." Ominously, the advertisement adds, "It's the thorns you don't see that may hurt you."[31]

Merck & Co played on women's fears of disability with a 1997 US advertisement for alendronate (Fosamax) stating that "Thanks to Fosamax and its power to rebuild bone Susan Brenner is still paddling her own canoe after 50."[32] The advertisement shows a healthy-looking woman of about 50 in front of a lake at sunset. The implication, further developed in the advertising text, is that all menopausal women may have osteoporosis and can break a bone at any time. In fact, most osteoporotic fractures occur after age 75 and the effects of alendronate use around age 50 on fracture risk 20 to 25 years later remain unknown. Long-term studies of estrogen, which is also used to increase post-menopausal bone mass and prevent fractures, indicate that the effect is rapidly reversed after discontinuing use, with no long-term gain if women use estrogen for less than 10-15 years.[33] [34]

Most healthy 50 year-old women who know how to paddle a canoe are likely to find it easy without drug treatment. Ironically, regular exercise is one of the major ways to prevent osteoporosis.

Alendronate has been associated with severe oesophagal adverse reactions[35], is much more expensive than other drug treatments used to prevent osteoporosis[36] and was less effective in increasing bone mass in a comparative trial with estrogen-progestin products.[37] A letter to the editor in the *New England Journal of Medicine* states that, "evidence that bisphosphonates [the class of drug alendronate and etidronate belong to] should be widely used in women with postmenopausal osteoporosis is meager, and we think it is too early for drug committees in local hospitals with shrinking budgets to recommend them even if the drugs have been approved by the regulatory authorities."[38]

In August 1997, Eli Lilly began a US$15-$20 million print advertising campaign in major magazines for fluoxetine (Prozac) its best-selling antidepressant. An advertising company used to selling cereals, hamburgers and automobiles, Leo Burnett Co., was hired for the job. According to an article in the *International Herald Tribune*, the aim of the campaign is not to wean users of other antidepressants onto fluoxetine but to "stimulate demand for Prozac by urging people who are not being helped for depression — or receiving less strong medicine than they may need — to seek treatment."[39]

The advertising text deliberately plays on negative public perceptions of benzodiazepine tranquilizers while reassuring readers that this mood-altering drug is more innocuous, "It's not a tranquilizer. It won't take away your personality. Depression can do that, but Prozac can't." The campaign slogan "Welcome back" further develops a theme equating use of fluoxetine with achieving a normal state. Non-drug treatments are presented as a secondary measure doctors may recommend after a patient has begun to respond to fluoxetine, rather than as a genuine alternative.[40] Sidney Wolfe, director of the US Public Citizen's Health Research Group, calls this campaign an "appalling statement about how desperate a drug

company is to expand its market share."[41]

A theme which was conspicuously absent from an advertisement for an antifugal, itraconazole (Sporanox), appearing in *Newsweek*, *Sports Illustrated*, *Better Homes & Gardens* and other US magazines was that drugs don't always work as intended. The advertisement featured before and after photos of feet with and without a toenail fungus infection. It did not mention that the oral antifungul, which must be taken for three months, only cured toenail fungus about half the time in pre-marketing clinical trials or that another 20% of those who are cured suffer relapses.[42]

The first widespread prescription-drug advertising to consumers in the US took place in the early 1980s. Soon after disaster struck. Eli Lilly launched its new anti-arthritic drug benoxaprofen (Oraflex) in May 1982 with an aggressive promotional campaign aimed at the public as well as to health professionals.[43] Claims that the drug could prevent disease progression helped to quickly generate drug sales. The number of prescriptions rose quickly from 2,000 to 55,000 per week and benoxaprofen began to generate more than US$1 million a week in sales. However, within five months Lilly removed the drug from the market because of severe adverse reactions, primarily in the elderly, including deaths. The US FDA declared a moratorium on DTC advertising of prescription drugs soon after, in February 1983, which was lifted in September 1985 after two years of consultation and review.[44]

In August 1997, the US FDA announced new guidelines for radio and television advertisements of prescription drugs which would remove a major barrier to broadcast advertising. Previously, manufacturers had been required to include product labeling information (what the FDA calls the "brief summary" of prescribing information, usually printed in fine print on the back of advertisements) with all advertisements which included both the product's name and health claims. As a result few manufacturers had chosen to broadcast full advertisements, usually stopping at reminder ads which mentioned only the product's name but not why it is used, or disease-oriented ads which did not include the product name. The FDA's 1997 guidelines say that manufacturers can include health claims if they also include information on major side effects and provide consumers with a free phone number or Internet site to obtain additional information. This effectively opens television and radio to prescription drug DTC advertising. The first violation of FDA standards occurred only two weeks after publication of the new guidelines, when Schering-Plough was told to halt a television advertising campaign.[45]

Of special relevance to these US campaigns is one of the principles mentioned in the WHO *Ethical Criteria* on advertisements in all forms to the general public: "While they should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health."[46] A second principle in the *Ethical Criteria* which appears to be honoured mainly in the breach is that: "Language which brings about fear or distress should not be used."[47]

Is DTC advertising likely to lead to better health?

US FDA Associate Commissioner for policy, William Hubbard, defends the agency's policies

on DTC advertising as, “part of a coordinated effort to empower people, to help them take charge of their health care, make them better patients and better consumers.”[48]

In a speech to drug regulators at the 4th IDRAC Conference of Medicines Agency in The Hague in April 1997, Patrick Deboyser, speaking on behalf of the pharmaceutical unit of the European Commission’s industry directorate, said that he would support the idea of reconsidering the European Union’s ban on direct-to-consumer advertising of prescription medicines.[49] In Canada, similar announcements led Dr Joel Lexchin, Secretary/Treasurer of the Medical Lobby for Appropriate Marketing (MaLAM) to examine whether Canadian consumers are likely to obtain more appropriate treatment if DTC advertisements are allowed.[50] He argues that this regulatory change is justified only if it can be shown to be likely to lead to improved health outcomes.

As Lexchin notes, a prerequisite for any improvement in treatment and health outcomes is accurate information. In order to predict potential accuracy — since DTC ads are not allowed in Canada — he looked first at nonprescription drug advertising to consumers, then at prescription drug advertising to doctors. A 1993 survey of 15 Canadian magazines found that 24% of advertisements for OTC drugs contained “minor errors” such as stating that there were no side effects or exaggerating a product’s merits; 39% had major violations such as unapproved claims or misrepresentation.[51] Advertising aimed at doctors was no more accurate; a 1991 survey of 111 ads in 14 Canadian journals found that risks were mentioned only 53% of the time, and that this was almost always in the context of a statement about lack of side effects. In contrast, benefits were discussed in 91% of the ads.[52]

In other words, the information on risks and benefits was skewed towards a misleadingly positive representation of the product and a lack of attention to warning both health professionals and consumers about potential risks. A similar bias was found in a 1995 US *Consumer Reports* evaluation of 28 DTC advertisements for prescription drugs. The advertisements were submitted to a panel of 32 medical specialists who evaluated ads for products related to their specialty. The reviewers found that one-third contained factual inaccuracies or assertions that were not scientifically supported; only half conveyed important information on side effects in the main promotional text; fewer than half presented the drug’s effectiveness, potential benefits and risks fairly; and 11 ads — nearly 40%– were considered more harmful than helpful by at least one reviewer.[53]

The *Consumer Reports* review also highlighted several themes in the advertisements which contribute little to rational use:

- implied 100% effectiveness (four anti-allergy products);
- failure to mention age groups in which the product is more or less effective (minoxidil, Rogaine)
- an appeal to maternal guilt (DDAVP nasal spray for bedwetting);
- romantic scenes used to sell the drug (an anti-psoriasis drug and menopausal hormones).

Studies in Belgium, The Netherlands, the UK and the US over more than 20 years have shown that doctors who rely heavily on commercial sources of information are less likely to prescribe appropriately,[54] as judged by whether they use medicines in the correct dose and for the appropriate duration, their restricted use of drugs with serious side effects, use of non-drug treatments when they are most appropriate, better knowledge of drug therapy, and using the least costly of equivalent alternatives.

If reliance on promotion is associated with negative effects on prescribing, what of consumer demand? Does DTC promotion create a demand from consumers which results in pressure on doctors to prescribe? After all, consumers need to convince their doctors to prescribe a drug they see advertised. A US marketing firm, Scott-Levin Associates compared results of surveys in 1987 and 1992, a period of rapid growth of DTC promotion in the US. They found that 18% of patients asked their doctors about specific drugs in 1987, as compared to 54% in 1992.[55] According to a 1989 survey of 3,600 US doctors, over half of patients mention advertised drugs. Eighty-four percent of the doctors said they would consider prescribing a drug if a patient requested it and 16% said they were very likely to prescribe the drug.[56] A second study of misprescribing in the US found that the most common reason doctors cited for prescribing inappropriately was perceived patient demand.[57]

Advertisement on a cash register receipt in a large Washington DC supermarket, 1997
Are you experiencing signs of persistent anxiety? Do you worry excessively? Call 1-800-4-RELIEF EXT 4 Call today for your free information on persistent anxiety. A service provided by Bristol-Myers Squibb Co. You may be one of over 10 million Americans suffering from persistent anxiety. Persistent anxiety involves persistent worry for at least 6 months, as well as other physical and psychological symptoms that significantly affect your ability to function. Only your doctor can diagnose persistent anxiety and recommend treatment options. [Within a few days after calling the toll free number, the consumer received a personalized letter and advertising material for buspirone (BuSpar) from Bristol-Myers Squibb.] Source: Personal correspondence with L. Sasitch, Public Citizen.

Recent promotion of the nonsteroidal anti-inflammatory drug (NSAID) nabumetone (Relafen) in the US showed that it was possible to sell US$400 million of a product “that has not been shown to be any more effective than any of more than a dozen competing drugs in the same family, some of which are much less expensive,” according to Larry Sasich of the US Public Citizen’s Health Research Group.[58] How was this accomplished? In addition to heavy promotion to doctors, including distribution of reprints of journal articles that “slant the science, and promote the drug to doctors who do not carefully read the medical literature or know how to interpret it,” an added sales boost was advertisements to consumers, “who are not given enough information to make a valid judgment about the drug’s safety or effectiveness,” according to the Health Research Group. Of particular concern was the statement in consumer advertising that Relafen was found to have a low potential for ulcers. Studies of the gastrointestinal toxicity of NSAIDs show that ibuprofen has the least toxic effects, ketoprofen and piroxicam the most toxicity, and that drugs like nabumetone fall in between. The statement that the drug has a low potential for ulcers is

“false, unethical, dangerous to the public health, and criminal,” states Sasich.[59]

A 1997 promotional violation in Pharmacia & Upjohn’s user guide for alprostadil for injection (Caverject) highlights the problem of systematic bias in information provision. Although the company is legally required to give equal prominence to information on effectiveness and safety, the FDA found not only that potential benefits were more prominently displayed than potential risks but that the design of the guide discouraged patients from reading the safety information on the last page.[60]

In Pakistan in 1996, Eli Lilly gave GPs a patient information brochure on fluoxetine (Prozac) to place in their waiting rooms. The brochure contained a questionnaire to help consumers diagnose themselves with depression and a statement encouraging patients with depression to take “one capsule of Prozac every day,”[61] implying that self-medication with fluoxetine is appropriate. In Pakistan, as in many other developing countries, prescription-only regulations are not enforced, enabling consumers reading this booklet to buy the drug directly from a drugstore. The questionnaire was loosely adapted from the American DSM III (psychiatric illness classification system) and contained such vague symptoms as “sleeping too little or too much”. A Pakistani non-governmental organization whose members are mainly doctors, The Association for Rational Use of Medication in Pakistan (ARUMP), is unlikely to agree with the company’s self-congratulatory slogan in the brochure, “Lilly, a step ahead in public health”. They called this DTC promotion “simply deplorable” and urged the company to stop.[62]

A study of retail pharmacy sales in urban and rural areas showed an increase in the proportion of direct-to-consumer sales of prescription medicines in India in the 1990s as compared to the mid-1980s. In 1994 about 50% of medicines were sold without a doctor’s prescription, up from 38% in 1986.[63] The large majority of these drugs were officially classified as prescription-only and about one-fifth were antibiotics. The consumption of broad spectrum antibiotics had almost doubled from 1986 to 1994, replacing conventional antibiotics. This trend towards newer, more expensive products is worrying not only because of the money wasted, but also because it leads to unnecessary antibiotic resistance. These newer antibiotics are also more heavily promoted. Whether or not this trend reflects promotion directly to consumers or to health professionals and drug sellers is unknown; however it does raise concerns about the potential negative effects of DTC promotion in developing countries, where consumers often buy prescription drugs directly without consulting a doctor. The same study also found that in rural areas only 40% of the drugs bought were on the WHO essential drugs list.

No direct-to-consumer promotion of prescription drugs?

In Australia, where prescription drugs cannot legally be advertised to consumers, Roche used graphic hints linking promotion for consumers and doctors. An ad in the May 24, 1997 issue of *Good Weekend Sydney Morning Herald Magazine* advises patients taking antidepressants and experiencing sexual problems to speak to their doctors**.** The advertisement does not explicitly mention that the solution offered is to switch to a specific product and neither the name of the product nor the advertiser are mentioned. However,

the graphics used in the ad refer without any ambiguity to a simultaneous campaign in medical journals for moclobemide (Aurorix) by Roche which claims to improve sexual function.[(64)]

The box below describes a similarly unambiguous advertising campaign in Canada.

Fragrant or flagrant? Searle's thorny rose In Canada in 1996, Searle used the image of a rose to sell its product Cytotec (misoprostol) to doctors and consumers. An advertisement in medical journals told doctors that Searle was sending a rose to their patients. The campaign aimed to get NSAID users to request misoprostol from their doctors. The company used word association techniques to hint at the product's name without breaking the law. The text speaks of "cytoprotection" throughout with phrases like "cytoprotection can help"and "cytoprotection is another word for stomach protection". Literally the latter is not true; cytoprotection means cell protection. However, the similarity between the term "cytoprotection" and the name of the "unnamed" drug being advertised, Cytotec, is hard to miss. The advice most likely to reduce harm from NSAID use is conspicuously absent: avoiding unnecessary or excessive use and choosing the least risky alternative available.

Mark Wright, vice president of consumer and professional communications for a Canadian marketing firm, describes the situation in a trade magazine: "Because current government regulations prevent branded consumer advertising of prescription products, pharmaceutical companies must settle for advertising about disease conditions and options available through their physicians. Then, once the patient sees the doctor, the company's product will be prescribed."[(65)] He recommends that companies use toll free telephone numbers (1-800 numbers) to build a profile of consumers, develop customized brochures and "help prepare the consumer for a consultation with the doctor by providing him or her with appropriate information" as well as serving, "to heighten trust and improve the profitability of companies and their products."

Although DTC promotion is not allowed in Canada, it flows easily across the country's southern border via television, radio and magazines and reaches a considerable proportion of the English-speaking public. When injectable medroxyprogesterone acetate (Depo Provera) was approved as a contraceptive in 1997 in Canada, commentators mentioned that many doctors had already been prescribing this product for birth control since its 1992 US approval. Three earlier applications for approval of contraceptive use in Canada–in 1989, 1992 and 1993–had been rejected by the Canadian drug regulatory agency. Ironically, US women's magazines sold in Canada carried advertisements for the contraceptive throughout the mid-1990s, although these ads would have been forbidden on two counts in publications originating in Canada: promotion of an unapproved indication and DTC prescription drug promotion.

DISEASE-ORIENTED CAMPAIGNS

A series of booklets on diseases such as HIV/AIDS, Alzheimer's, cancer and depression, produced by the US industry association, PhRMA, were bound into issues of *Time, Reader's Digest* and *Newsweek* and more than 19 million copies of each were distributed in the US. They look like glossy health education brochures although each page has "Special

Informational Advertisement" as a fine print heading. [66]

The booklet on depression[67] is instructive not only for what it says, but for what it leaves out: nowhere is it stated or even implied that depression might occur in response to grief, loss or other personal or social problems. Only once is a life event mentioned — an unhappy childhood — and this is dismissed as an obsolete theory implying blame: "It [depression] was thought to be the 'fault'of the individual — due to a weakness in character, lack of self-control, or an unhappy childhood." The modern scientific explanation is then provided: "Too much or too little of these chemicals [neurotransmitters] may result in depression, anxiety or other emotional or physical disorders."[68] Few if any experts would dismiss all social and psychological causes of depression. This booklet neither mentions that it presents an extreme and controversial view nor that any differing scientific explanations for depression exist.

Information on Disease Prevention
Seven easy steps to avoid misleading the public
Disease-oriented promotional campaigns often present alarming figures on disease risks: one in four women die of heart disease; one in nine of breast cancer. These figures can be both accurate and misleading. They are misleading because of what they leave out: how old people are when they die; who is at highest risk. We all have to die of something, after all. Most people are unlikely to take steps to prevent a disease which will strike them down at 95; if they can prevent the same disease at age 45, they may think differently. Dismissals of "small increases" in risk for fatal diseases are also common. These may sound unimportant, but they translate into serious concerns if the disease is common or occurs at a young age. These are a few suggestions for presenting and judging information on risks.
1. Information about disease, how often diseases occur, death rates and other measures of illness and disability should be presented in an age-specific manner. If possible, this should allow a person of a specific age to guess her chances of developing the disease within a time period. For example, how likely is a 50-year-old woman to develop breast cancer within the next 10 years? It should also mention whether risks are similar for everyone or differ by ethnic background, race, gender or other factors.
2. How accurate and specific is the definition of disease? For example, if "one in four people is depressed" does this include someone who just failed an exam or did not get a much-wanted raise as well as someone with serious long-term clinical depression?
3. Information on preventative drug therapies and other interventions should include "numbers needed to treat". This is a measure of how many people need to take a drug to prevent one case of disease or death. For example, to prevent one hip fracture in a post-menopausal woman, an estimated 250 women would need to take estrogen therapy for 10 years.[69]
4. If the same drug or other intervention **causes** serious disease or death, a "numbers needed to harm" estimate can show how many people need to take the drug for a certain time period for one extra person to develop a disease or to die. For example, if 167 women take estrogen for 10 years, one extra woman is expected to develop breast cancer.[70]
5. If a preventative treatment can cut people's risk of developing a disease by one-half, this looks impressive. However, it could as easily mean that one in 10,000 people develops the disease versus two in 10,000, or 25% versus 50%. In other words, it doesn't tell us whether the treatment makes a small or big difference to people's likelihood of developing a disease. The 50% is a relative risk reduction. It is useful information to know but only **together** with information about absolute risks: what proportion of people in a certain group would develop the disease with or without treatment.
6. How scientifically sound were the studies which showed that a drug or other intervention could prevent disease? Did other well-designed studies fail to show this effect?
7. If other strategies for disease prevention can lower the risk as much or more than preventative use of a medicine, this information should be included. For example, does quitting smoking prevent more heart disease than preventative medicine use?

USING THE MEDIA TO SPREAD A QUESTIONABLE MESSAGE

In Poland, a clip on the evening news presented a new antidepressant, fluoxetine (Prozac), as an "antidote to unhappiness," without informing the public that the source of the information was commercial.[71] In the US, the same manufacturer, Eli Lilly, "orchestrated an edition of the Oprah Winfrey Show in which participants spoke glowingly of Prozac (fluoxetine)," says Frank Van Meerendonk, a former Dutch teacher who runs the Benelux Prozac Survivors Support Group. He says, "What they didn't reveal was that Lilly's PR company, Burson-Marsteller, was behind the programme, hand-picking members of the audience and flying them around the country."[72]

A recent event in Latvia highlights the potential dangers of media promotion of prescription drugs. In April 1997, a weekly health column in the main Latvian daily newspaper, *Diena,* carried an article on treatment of fungus nail and skin infections. The author, who relied on information provided by pharmaceutical companies, recommended systemic treatment with specific brand-name products, including ketoconazole, (Nizoral), for more than eight weeks, although in Latvia ketoconazole's labeling states that it should only be used for two weeks. The article contained no information on risks associated with the use of antifungal drugs. Although these products are officially available only on prescription, in practice consumers can buy them from any private pharmacy without a prescription. In July 1997, a 52-year-old woman was diagnosed with drug-induced liver failure and was admitted to hospital, where she died two weeks later. She had read the newspaper article and had taken ketoconazole for ten weeks to treat a nail infection.[73]

In the UK an independent committee monitoring a large scale study of paclitaxel (Taxol) as a treatment for advanced ovarian cancer announced in June 1997, after looking at the results of the trial thus far and reviewing other evidence about the drug, that "there is major uncertainty over the use of paclitaxel as a first-line therapy in epithelial ovarian cancer."[74] They were concerned that previous studies were unreliable because they had been so small in scale. Had their mid-trial results shown a clear advantage in the group using paclitaxel-based treatment, they would have decided to end the trial early on ethical grounds so all participants could use the drug. A public meeting was held to announce that this was not the case.

Bristol-Meyers Squibb, paclitaxel's manufacturers, had been arguing that the trial should be stopped early, and that "the first-line treatment with Taxol-based regimens should now be the standard of care for all advanced ovarian cancer patients". The health page of a UK daily newspaper had boldly reported that "Taxol works".[75]

An editorial by the UK medical journal *The Lancet* raises strong concerns about the company's role in this message: "drug companies must set aside the temptation, via the press, to hijack patients' lobbying powers, for that way the patient can only lose."[76]

A June 1997 *Time Magazine* article included pre-launch promotion for a new anti-migraine drug developed by Glaxo. A Glaxo press release had announced that the new drug, "lasts longer than Imitrex (sumatripan) and is less likely to trigger unpleasant side effects,"[77] and

that the FDA was considering approval. No evidence is presented in the *Time* article to back these claims.

Playing on consumer fears to fight generic substitution

In Mexico, the industry association, AMIF (*Asociacion Mexicana de Industriales Farmaceuticos*) published a series of large newspaper advertisements in late 1996 asking consumers to insist that the medicines on their prescription are not changed (*Exija que no cambien los medicamentos de su receta*). Readers are told that substitutions can "compromise the results of your treatment and well-being". In one advertisement, a pregnant woman is pictured and quoted as saying that she has confidence in her doctor and that for her health and her future child's health, she follows all of her doctor's recommendations.[(78)]

The implication is that generic substitution could be harmful during pregnancy. Nowhere is the reader informed that generic substitutes contain the same active ingredients as the equivalent brand name drug, in other words that they are in fact the same medicines. Neither are they told that certain of these medicines — regardless of whether they are brand name or generic products — have been found to be harmful during pregnancy, others not. In this case, health concerns and fears of injury are misused to obtain consumer support for higher priced brand name drugs.

Criteria for Quality Consumer Health Information
Informs patients about their clinical conditions and includes information about all available treatments or management options, including non-intervention provides comprehensive and unbiased information about outcomes (risks and benefits) based on systematic review of research evidence outlines uncertainties and gaps in scientific knowledge language and design is simple, attractive and easily understood caters for a variety of users, including black people, non-English speakers, people with disabilities, etc. is regularly reviewed and updated is integrated into a planned programme for shared clinical decision-making involves users and professionals in the development and evaluation of the materials
Source: Promoting Patient Choice, The King's Fund, London

Should DTC promotion be allowed?

Consumers need better access to independent information in order to make informed choices about both drug and non-drug treatments. Funding for this is scarce and in many countries consumers have little access to the information they need to truly participate in treatment decisions. Industry groups are arguing that DTC promotion provides much needed information to consumers.[(79)] These arguments obscure the fundamental difference between promotion, which aims to sell a product, and the type of information needed to choose how best to treat a health problem. Given the industry's track record on drug promotion to health professionals, and its DTC track record in the US, there is no reason to believe that DTC drug promotion will lead to any improvement in prescribing or use of medicines. On the contrary, existing evidence points to a likely increase in irrational prescribing and use.

RECOMMENDATIONS: Direct to consumer promotion of prescription drugs

1. Direct-to-consumer advertisements of prescription-only drugs should not be allowed, given the lack of evidence of health benefits and the serious potential for harm.

2. Legislation controlling promotion should apply equally to promotional activities disguised as education about drugs or diseases, including prohibition of direct-to-consumer prescription drug promotion where this applies. This will require clear definitions of promotional versus non-promotional information based on criteria such as:

- whether a manufacturer is the direct or indirect source of the information,
- whether information on a disease is linked to recommendations for drug treatment,
- whether disease risks are presented in a manner which could be construed as inciting the public to seek drug treatment,
- whether use of specific drugs are recommended,
- whether diagnostic testing is recommended which may lead to drug treatment,
- and whether all available drug and non-drug treatment options are discussed in a fair and balanced manner.

3. Regulatory authorities may wish to consider a tax on pharmaceutical sales which could be used to set up a blind trust to fund independent drug information for both health professionals and consumers, as well as patient groups and other non-profit and charitable health organizations. Gilbert and Chetley recently recommended a similar model for the UK as a means to ensure the quality of information reaching consumers.[(80)] Such a trust should be administered by an independent board with full provisions for transparency, public representation and accountability.

OVER-THE-COUNTER (OTC) DRUG PROMOTION

Regulatory standards for promotion of the drugs which can be legally purchased directly by consumers, OTC drugs, are generally lower than for prescription-only drugs. Advertisements with slogans such as “clinically proven”, “prescription strength”, “extra strength”, “maximum strength”, “24 hour relief”, or “nothing is stronger” are common. The idea that medicines may be harmful as well as beneficial is simply missing. Over-the-counter drugs are not risk-free, regardless of the impression left by this advertising. They also do not always work as expected, and much needed information on limits to effectiveness is also conspicuously absent.

Dr Reinstein of the World Self-Medication Industry, which represents manufacturers of OTC drugs, argued against the need for information on risks in advertising at the 1994 World Health Assembly: “Detailed information in advertising simply reduced the effectiveness of the main message which was: the name of the product, what it could be used for and an express invitation to read the label or leaflet as appropriate.”[(81)]

He fails to mention that consumers generally have to buy the medicine before they can open a box and read the leaflet. A 1994 study by the International Organisation of Consumers’

Unions (now Consumers International) looked at 238 ads for OTC products in 11 industrialized countries. They found that most did not comply with standards set out by the WHO *Ethical Criteria* and about three-quarters did not mention contraindications, side effects and warnings.[82] Unlike Dr Reinstein, the authors of this study recommended full provision of information on risks and benefits in advertisements of OTC drugs.

Consumer organizations have also stressed the principle of the public's right to full information on which to base treatment options. The European OTC market is currently valued at nearly US$13 billion,[83] with one-third of the market held by the top 10 companies. The market is expected to continue to grow, with many products moving from prescription-only to OTC status. In an article on the consumer movement in drug policy, Mintzes and Hodgkin comment that as a result of the increasing number of OTC switches, "consumer organizations have begun to pay more attention to advertising standards for OTC products and the availability of independent information about these products."[84]

An advertisement for minoxidil (Rogaine) which has recently gained OTC status in the US, highlights the promotional problems following the switch to OTC status. It is presented with shampoos and conditioners under the heading, "Hair care you need…right now". The only hint the consumer has that this is a medicine comes in the promotional claims on the package, visible only with effort, "medically proven to regrow hair" and "full prescription strength". No adverse effects, warnings or contraindications are visible in this advertisement. The promotional message not only misrepresents the product as only having beneficial effects, consumers might be excused for being unsure whether they were buying a medicine or a beauty product.

RECOMMENDATIONS: OTC promotion:

1. Promotion of over-the-counter medicines should be subject to as strict controls as prescription-only drugs, as these products are often bought and used without the advice of a health professional.

2. This information should be presented in a balanced manner, bringing the reader's attention equally to claims about benefits and warnings about risks.

3. All promotional claims about health effects must include validated up-to-date scientific evidence to back those claims.

4. All advertising for OTC drugs should include the following information, presented legibly or audibly. Information should be presented in everyday language and at a low enough literacy level for consumers to understand, and include explanatory graphics where appropriate:

– the name of the active ingredient(s), INN or approved generic name

– the brand name

– the amount of active ingredient(s) per dosage form or regimen

– name of other ingredients known to cause problems

– approved therapeutic uses

– dosage form or regimen

– side effects and major adverse drug reactions

– precautions, contraindications and warnings

– major interactions

– documented degree of effectiveness (difference in treatment success between those taking the medicine and those not using it in placebo-controlled clinical trials)

– name and address of manufacturer or distributer

– reference to scientific literature to back promotional claims.

5. Presently, consumers can obtain information only on expected benefits of OTC drugs before purchasing them; information on risks is generally included only in package inserts which they see after buying a drug. Consumers need pre-purchase access to full, comparative information.

HERBAL AND NATURAL REMEDIES

In a Malaysian daily newspaper in 1995, a "Tea of Longevity" was advertised as being: "Suitable and beneficial to many ailments including migraine, weak heart, hernia, menstrual pain, kidney stones, rheumatism, sexual stress, impotence, frostbite, internal and external cancer and infection."[(85)] A 150 mg pack of this tea costs the equivalent of 10 days wages for an unskilled Malaysian worker. In the US, a natural supplement named Cholestin is advertised as reducing the type of cholesterol linked to heart disease.

In Mexico, Bio Research Institute recommended consumers use DHEA, a natural supplement, from age 40 onwards, claiming that this product slows ageing, reduces obesity, prevents heart attacks, prevents and controls osteoporosis and — among several additional wide-ranging claims — has anti-cancer properties.[(86)] The same company promoted a herbal product, "Natu-sex" to increase potency and sexual desire in men and women, with claims that "many studies in the US and Europe have demonstrated an increase in blood testosterone levels in 75% of users." No references are included to back this claim, or the conflicting statement that the product has no adverse effects (if blood testosterone was increased significantly, adverse as well as beneficial effects would be expected.)[(87)]

In each of these cases, the manufacturers can make health claims without having carried out studies to show that their product has the promised effect because these products are not classified as drugs. Dr Balasubramaniam, pharmaceuticals advisor for Consumers' International and Asian coordinator of HAI, argues that there is a need for strict regulation

of the promotional health claims made for herbal remedies, as well as the manufacturing process, safety monitoring, and provision by qualified practitioners. He points out the lack of information available to consumers: "at present there are no authoritative sources from which pharmacists can obtain relevant information on herbal remedies to advise consumers and other health professionals."[88] To a large extent this is because the studies have simply not been done. Given that according to recent WHO estimates 80% of the world's population depend on traditional medicine for health care, Dr Balasubramaniam argues for research into the efficacy and safety of traditional remedies which maintains the holistic framework within which these medicines are provided and used.

The whole area of herbal remedies, dietary supplements and traditional medicines is one which is largely ignored by drug regulatory authorities and national legislation. For the consumer on the one hand there is the problem of misinformation and misleading, unsupported health claims, on the other that information on effective, appropriate remedies is often lacking.

RECOMMENDATIONS: Promotion of herbal remedies and dietary supplements:

1. Health claims should only be made if evidence exists to back them, with up-to-date scientifically validated documentation provided to back all claims.

2. Where there is traditional experience with a natural remedy but no validated evidence to support its use, a warning message stating this should be mandatory.

3. If health claims are made for a product, information requirements should follow the guidelines suggested under point four of the recommendations for OTC drug promotion.

4. Information on expected benefits and potential risks should be presented in a balanced manner and should be available to consumers before a product is purchased.

SPONSORSHIP OF PATIENT GROUPS, INSTITUTES AND FOUNDATIONS

Charitable donation or disguised promotion?

In the UK a patient booklet on infertility by Women's Health Concern, a non-profit society with pharmaceutical industry funding, includes information on clomiphene, a drug used to induce ovulation. [89] The booklet includes information on side effects. However, it reassures women that, "Most women do not experience any side effects. If they occur, none are serious but include hot flushes, mild headaches and occasional abdominal discomfort most pronounced at mid-cycle."

The UK Committee on Safety of Medicines, as quoted in the *British National Formulary*, is far less reassuring: "The CSM has recommended that clomiphene should not normally be used for longer than 6 cycles (possible increased risk of ovarian cancer in patients treated for longer than recommended)".[90]

Listed side effects include visual disturbances and ovarian hyperstimulation, both of which

require immediate drug withdrawal. Ovarian hyperstimulation is a potentially life-threatening condition requiring hospitalization. The Women's Health Concern booklet also includes no warnings about the higher likelihood of multiple births following ovulation induction with clomiphene. There is a higher risk of prematurity, stillbirth and infant mortality with multiple births. Few would argue that these are not serious risks.

Information and educational materials produced by patient groups are not subject to advertising regulations even when those groups receive pharmaceutical company funding. This funding may or may not be acknowledged in information materials produced by the organization. The booklet on infertility by Women's Health Concern mentioned above includes no disclosure of industry funding.

Company sponsored meetings and organisations – a regulatory loophole

Similarly, when a company sponsors a public lecture on a health issue the source of funding is not always apparent. As the manager responsible for symposia and public meetings for a multinational company in Western Canada remarked in a telephone conversation in May 1997, these events are linked to company products: "From a business point of view we would not be putting something on in opthamology as we do not have a product line in opthamology."[(91)]

When Glaxo Canada launched its new treatment for migraine, sumatripan (Imitrex), the company began giving substantial grants to the Canadian Migraine Foundation, a patient group which had been dormant for some time, according to John Martens, a pharmacist responsible for patient education in British Columbia at Glaxo. Public meetings were held in the Migraine Foundation's name but were in reality organized by Glaxo as part of a pre-launch promotional campaign. When the Foundation began to feel uncomfortable about the company's heavy-handed involvement and objected, Glaxo simply found another organization to fund, the Canadian Association of Neuroscience Nurses.[(92)]

"What companies would do and I was actually part of the process, is create a demand for a product before it was actually released," states Martens. "We went around to various communities and organized public health education seminars on migraines and that topic was really popular… seminars that we actually charged five dollars for, another marketing tactic that makes the patient think that this thing isn't being funded by a major pharmaceutical company. We held these seminars right across Canada."[(93)]

With global sales of US$600 million for sumatripan in 1995,[(94)] the financial rewards of intense promotion to "carve a niche in the migraine market" for this product were considerable.

Institutes and societies directly founded by drug companies

Sometimes links to companies are more direct. For example, one of the co-founders of the International Menopause Society was an executive of Organon, a Dutch pharmaceutical company which produces hormonal products. The 8th European Conference on Obesity,

held in Dublin on June 19, 1997, was the site for the launch of a new pan-European organization for the obese, their families and health professionals, Eurobesitas, which, "will receive funding from pharmaceutical companies involved in developing obesity drugs but says it will maintain its independence." according to a report in the pharmaceutical bulletin *Scrip*.[(95)]

Just how independent can it be? When the American Thyroid Association discovered in a media report that Boots/Knoll, which provided 60% of its funding, had prevented publication of an important study showing that the company's thyroid product, Synthroid, was no better than alternatives, the association debated whether to write to the company to ask it to allow publication, but the move was narrowly defeated. "An outsider is left with the sad impression that the ability of the association to influence these events by speaking with moral authority was weakened by its heavy dependence on money from Knoll," comments a *JAMA* editorial.[(96)]

Promoting a diagnostic test beyond its proven usefulness

The Bone Measurement Institute, financed by Merck & Co, manufacturers of alendronate (Fosamax) for osteoporosis treatment, has been working with suppliers of bone densitometry equipment to help finance a fourfold increase in bone mineral density testing sites in the US to 3,000 in 1997, up from 750 in 1995.[(97)] The Institute aims to increase testing even further to "identify at-risk women" and is trying to convince primary care physicians to have bone densitometry machines in their offices.

Is this a problem? Given the current state of knowledge about bone density testing, yes, it is. The International Network of Agencies for Health Technology Assessment (INAHTA) evaluated how effectively fractures would be prevented if all women underwent bone mineral density testing after menopause. They estimated that only between 1%-7% of all osteoporotic fractures would be prevented.[(98)] Only a small minority of women identified as having low bone density eventually go on to break a bone. The health impact of widespread testing remains controversial, given the lack of adequate evidence of effectiveness in preventing fractures and the large overlap in bone mineral densities among people who do and do not later experience a fracture; the value for Merck, however, is clear.

...Or promoting new disorders like shortness

The Foundation on Economic Trends, a US advocacy group, accused Genentech of using a private charity, the Human Growth Foundation, "to help 'recruit' thousands of healthy children of short stature for potential treatment with its human growth hormone (HGH) Protropin," according to a 1994 report in *Scrip*.[(99)] The charity, which included Genentech and Lilly officials on its Board of Directors and was mainly funded by these two companies, approached city educational authorities and offered height screening for all children. Tens of thousands were screened and if they were found to be in the bottom fifth percentile for their age group, their parents received a letter advising them to see their doctor and saying that if short stature resulted from a medical problem, treatment was available. According to the Foundation for Economic Trends, neither the schools nor parents were informed of the

financial ties between Genentech and Lilly and the Human Growth Foundation.

This campaign to medicalize shortness raises serious ethical concerns. In a height screening programme to identify the shortest 5% of children, the large majority of children identified have no health problems causing shortness, they are simply small because they have short parents. In France all children treated with growth hormone are entered into a national registry. A study of final adult height of all children treated between 1973 and 1993 reported that "Despite years of a demanding treatment, treated children remained short…" and treatment was much less effective than expected from short-term studies.[(100)] The effect on a small group of these children judged to be "normal short" because their parents were also very short was especially poor. Not only is this treatment expensive and unnecessarily risky if it is ineffective; it has a considerable effect on children's lives, who are labeled as having a disorder and must undergo five injections a week for years of their childhood.

In the US when Solvay and Upjohn were launching a new drug for treatment of obsessive-compulsive disorder in 1994, they set about "to make the disease better known and to make patients seek treatment," according to an Upjohn spokesperson. The *Wall Street Journal* comments that: "Most consumers have no idea that studies and public service messages actually are part of a plan to sell drugs. The drug companies typically leave few fingerprints, running their disease campaigns through PR [public relations] firms, patient groups, 'institutes' and other third parties."[(101)]

Marc Czarka, Directorof Pharmaceutical Affairs for Eli Lilly in the Benelux, said in 1997 that Lilly funds the American Psychiatric Association and that it sponsors and helped to create the Belgian League of Depression in 1995 together with other pharmaceutical companies. "It's useful for us because, unlike American law, European law does not allow us to talk directly to potential patients," says Czarka. "The league does it for us."[(102)]

Alan Sheppard, marketing director for Evans Medical, is quoted in *Pharmaceutical Marketing* magazine as saying that patient groups are helpful for marketing because they help companies to, "rapidly disseminate information about a product to patients."[(103)] Patient groups are also often asked to speak at press conferences launching a new drug.[(104)]

A UK sponsored patient group promotes a drug in Bolivia

Patient groups can also help a company advertise its product internationally. A 1996 advertisement for Climatrol, a combined estrogen-progestin product, by RI, Laboratorios Recalcine International, included a quote by the Director of the UK National Osteoporosis Society, a patient group which receives pharmaceutical industry funding, endorsing use of this type of product. Ironically, unlike many other patient groups with industry funding, the UK National Osteoporosis Society has developed guidelines to govern its interactions with the industry. These guidelines state that: "The Society is very careful when working with pharmaceutical companies and their agents that the independent, unbiased advice offered to the general public and professionals is not influenced in any way…"[(105)]

Why does the industry fund patient groups?

In an article in *Consumer Policy Review*, Gilbert and Chetley listed four reasons the industry seeks to fund patient groups:

1. Patient groups enable companies to spread awareness of new drugs at a pre-launch stage and help to prepare the market.

2. They provide a more credible endorsement of a product than could be achieved if the information was coming directly from the company

3. They can aid industry in arguing for fewer controls on drug licensing and pricing.

4. It enables companies to reach consumers directly.[(106)]

This analysis is echoed by Sean Milmo in an article in *Pharmaceutical Visions*, an industry magazine: "Because patient associations are so intent on gathering and passing on to their members information about drugs under development, they have become useful vehicles for pharmaceutical companies for disseminating information about new medicines at the pre-launch stage." [(107)]

He notes that Merck collaborated with the UK National Osteoporosis Society in pre-marketing of Fosamax (alendronate) and Zeneca worked closely with schizophrenia and respiratory disease groups, "on educational projects in preparation for the launch of its anti-asthma drug Accolate and its schizophrenia treatment Seroquel."[(108)]

Advocacy and support for people — or products?

Patient groups often begin as small-scale grassroots organizations formed by people with a disease who wish to get together with others in the same position and share experiences, emotional support and information. They frequently act as advocates for better health care and are typically voluntary organizations. Patient groups can provide a valuable lifeline of understanding and expertise in obtaining appropriate medical care. Many have no links to the pharmaceutical industry and rely on membership fees and/or public funding. Others, as noted above, may be founded by a company or subverted to promote a company product or policy.

The problem for the public is that industry links are often unclear and sponsorship may or may not be disclosed at public meetings or in information materials. Information produced by patient groups is not subject to the same regulations as that directly disseminated by a company. For example, a patient group can legally recommend an unapproved drug use or make claims about a product not yet on the market in a brochure whereas a company cannot.

Any patient group, charity or institute with financial links to the industry or a specific company which spreads awareness of a disease so that more people may seek drug treatment, endorses specific products, or presents positively biased drug information is helping to promote product sales. This is covered by the WHO *Ethical Criteria* definition of promotion: "all informational and persuasive activities by manufacturers and distributors,

the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."[109]

Many of the activities and information materials of sponsored patient groups violate two principles in the WHO *Ethical Criteria*, that "Promotional material should not be designed so as to disguise its real nature," and that "Scientific and educational activities should not be deliberately used for promotional purposes."[110]

As noted by Gilbert and Chetley in a consumer policy review on drug promotion in the UK, "The definition of non-promotional literature or information lacks clarity, and there is potential confusion with what constitutes balance in the presentation of information or education to consumers."[111]

NGO Guidelines for Sponsorship The European Public Health Alliance (EPHA), a Brussels-based coalition of health NGOs, has some members who are dependent on industry funding and others which are strongly opposed to it. As an organization frequently asked to represent patients in Europe in meetings organized by the industry, EPHA felt it had to clarify its position on sponsorship and held a consultation meeting with its membership in late 1995. EPHA's guidelines include questions NGOs should ask themselves when considering accepting industry sponsorship. For example, will the relationship with industry: – compromise the organization's ability to promote their aims and objectives responsibly and sincerely? – negatively influence colleagues, (members, colleagues in European institutions)? – be used by industry to negatively influence colleagues in the promotion of public health? EPHA also recommends against sponsorship of core activities and suggests formal contracts be negotiated for a sponsored project, including conditions such as full editorial control, no product endorsement, no exclusivity clause, and open acknowledgment of sources of financial support.[112] For a full copy of the guidelines, contact EPHA

Education or Promotion? Educating consumers to comply with prescribed drugs... **but not to recognize side effects** The American Pharmaceutical Association distributes training materials for pharmacists funded by Pfizer. The emphasis is enhancing consumer compliance with prescribed regimens. Benefits are emphasized and little or no information is provided on how pharmacists can communicate risk information. The effects on health of inappropriate compliance and lack of communication of risk information can be serious. A recent study published in the British Journal of Clinical Pharmacology found that people hospitalized for severe adverse reactions related to NSAID use had continued to take their medicines despite early signs of an adverse reaction because they did not know what to expect or what to do.[113] Similarly, an educational kit for French schoolchildren aged 9 to 11, "Le Bon Usage du Médicament" (Wise use of medicines), produced by SNIP, the French industry association, stresses compliance and omits any information on risks of drugs when used as prescribed.[114] The kit teaches children to expect a medicine every time they go to the doctor. Instead of asking the child, "Did the doctor prescribe a medicine?"after a visit, the question asked is: "What medicine did the doctor prescribe?"

RECOMMENDATIONS: Sponsorship of patient groups

Actions by patient and consumer groups:

1. Associations, alliances and networks of patient and consumer health groups as well as individual organizations should consider developing and disseminating ethical guidelines on industry sponsorship. These should include provisions for accountability to the organization's membership and the public, transparency, and exclusion of potential funding sources if conflict of interest is a problem, ie, if a funder's financial interests are linked to the organization's membership and/or activities.

2. Blind trusts could be considered as a way consumer groups could accept money from a variety of private sources, which might or might not include the pharmaceutical industry, without compromising their independence.

3. Consumer groups should list sources of funding in all publications and should have a written policy on quality assurance of information materials, including a procedure for peer review by individuals or organizations who are independent of the pharmaceutical industry.

Regulatory action by national governments:

1. Any informational and educational materials whose production is funded by the pharmaceutical industry should be subject to the same regulations governing drug promotion as materials directly produced by a company, including requirements for fair balance, accuracy, avoidance of false or misleading statements or promotion of unapproved uses, an adequate discussion of risks as well as benefits, and pre-screening where this is a legal requirement for pharmaceutical advertising.

2. Regulatory guidelines for sponsored symposia and other meetings targeting health professionals should also apply to public meetings and educational events.

Guidelines for sponsored public meetings and educational events WHO *Ethical Criteria* The current guidelines for sponsored meetings in the *Ethical Criteria* are weak. They state only that, "The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at the meeting and in any proceedings. Entertainment or other hospitality, and any gifts offered to members of the medical and allied professions, should be secondary to the main purpose of the meeting and should be kept at a modest level."[(115)] The US FDA has developed much more detailed guidelines for sponsored meetings, published in November 1997:[(116)] The content of the programme, planning, selection of speakers and moderators should be fully controlled by the provider, not the sponsoring company. Ideally it should be based on a written agreement between the provider and company stating that the provider is solely responsible for designing and conducting the meeting and that it will be educational, non-promotional and free from commercial bias. The company should not write scripts, target points for emphasis, otherwise influence the content, or suggest speakers actively involved in promoting the company's products. Presentations should not be misleading or biased in favour of the company's products. The focus should be on a single drug produced by the company or a competitor and all relevant treatment options should be discussed. There should be full disclosure of funding sources, including any financial relationships between presenters and the company and the provider and the company. The provider should not be financially dependent on the company in a way which allows the company to exert influence on the content, for example owned by the company; it should not be involved in sales and marketing; and should not have a history of failure to meet standards for independence, objectivity or scientific rigour. Repeated presentations are discouraged unless there is a public health rationale for them, for example if they are on an urgent public health topic. Audiences should not be selected on the basis of marketing goals, for example to reward high prescribers or influence "opinion leaders". The programme should include opportunities for discussion and questions. There should not be any promotional presentations by sales representatives or promotional exhibits in the meeting room.

DRUG PROMOTION ON THE INTERNET

Fountains of Youth? Or was it of Money? Internet Promotional claims for products sold as food supplements http//:www.smart-choice.simplenet.com/line.gif "Why take DHEA? Slows the aging process! Works as anti-cancer Agent! Depression helped in some patients! Helps weight problems! Reduce risk of mental function decline (Alzheimer's disease) with aging! Increase Sex drive! Lessen Symptoms of Menopause and PMS! Burns Fats – helps to build Muscle! Helps reduce diabetic symptoms! Aid to MS sufferers! Aid to Aids/HIV sufferers!" [*just what doesn't it do?]*
http//:www.smart-choice.simplenet.com/sominset.htm "Too many people are becoming sick and/or dying from heart disease, cancer, diabetes, etc. Many studies are now showing that much of this sickness, disease and even premature death is avoidable…" *[The solution? Vitamin and mineral supplements produced by this company, of course.]* "Insomnia exists when melatonin levels are low or when it is produced at the wrong time" *[ie the causes and solutions of insomnia are chemical*] "Some researchers believe the steady increase in the incidence of cancer is partially because of the extended time we are exposed to artificial lighting. This results in extended hours each day that melatonin production is suppressed when levels would have been higher longer." *[never mind the lack of documented cancer prevention]*

Will public health be a casualty of the information superhighway?

Anyone with access to the Internet or the "information superhighway" as it has been called, can look up a disease or medicine and find the latest information posted anywhere globally. Anyone with a medicine — or many medicines — to sell, can set up a web site and provide information, or links to others who make claims about the products which a manufacturer may not legally make.

The lack of controls extends not only to Internet drug promotion but also to direct mail order sales of products which should be prescription-only. In 1996 a distributor calling itself Quality Health, Inc, put 17 drugs for sale on the Internet. Claims for the products included "protecting oneself against age-related memory disorders", an "intelligence booster" and promoting "the flow of information between the right and left hemispheres of the brain."[(117)]

Manufacturers UCB and Zeneca stated they did not agree with their products being sold this way. However, many of the claims made by Quality Health are similar to those the companies have made in developing countries where regulation of promotion is inadequate. For example UCB promoted piracetam (Nootropil) in Peru in 1991 with claims that the product can improve memory and concentration, linking use of the product to better grades at school.[(118)] Quality Health called it an "intelligence booster".

The response from drug regulators has been inadequate, if the intent of drug regulation is to prevent consumers from being misled about the potential health effects of medicines. Regulators in Germany said they could do nothing about Quality Health's Internet promotion as it was posted from another country.[(119)] The UK was only able to prevent the company from mailing brochures to UK residents.[(120)]

A 1997 editorial in *The Lancet* raised concerns about the "unregulated supply of medicines of unknown quality direct to the public."[(121)] Consumers may buy a large range of drugs including growth hormones, insulin, vasopressin; claims about therapeutic effects are often unsupported.

As one commentator recently noted, "Australia is having difficulty in prosecuting Internet hucksters who claim–illegally in that country–that their products will cure cancer or AIDS."[(122)]

The problem, unfortunately, is not only one of a few hucksters or quacks providing misinformation, although as the box at the side attests, they do exist. Dr Louis Morris of the US FDA commented that, "One of the differences between searching through a medical journal and looking through the Internet is that when I'm searching through a medical journal and see an ad from Pfizer, it looks like an ad from Pfizer. When I click on the Internet, I don't know where I am – I could be anywhere."[(123)]

SmithKline Beecham's "café herpes" is a case in point. It is presented as an educational site, with friendly cartoons and very accessible information for people with herpes. It is easy to miss the company logo at the bottom of the home page if one clicks to one of the menu options before scrolling down sufficiently. Not until one chooses to click on "product information" does the educational style of the message begin to go astray: only a single drug treatment, famciclovir (Famvir) is presented.

What kind of national and international regulation is needed?

The unwieldy nature of the Internet — with over four million websites currently operating — and its disregard for national borders make regulation difficult. As some of the examples above demonstrate, unregulated commercial use of the Internet to sell medicines has the potential to cause harm as well as playing on people's fears of disease and disability to sell products without proven effectiveness.

The US FDA held a public meeting on Internet promotion in October 1996 because of concerns about the inadequacy of existing regulation.[(124)] Some of the concerns raised were that:

- the source of information material is often not obvious to the viewer
- it is difficult to distinguish between advertisements aimed at consumers and health professionals
- links exist between companies' home pages and other sites giving out information on unapproved uses of drugs, bypassing US regulations against a company promoting its drug for an unapproved use
- conditions of company sponsorship of "chat rooms" and "newsgroups" are unclear
- information is provided on products not approved in the US or with different approved labeling.

A 1993 US Congress Office of Technology Assessment report judged that the information US

companies provided with exported drugs in four developing countries could, in about half the cases, lead to "nontrivial harm to a substantial proportion of users and severe harm or death to some users."[(125)] Ironically through the Internet US consumers and prescribers can now have access to information of a similar low quality.

Heather Simmonds, head of the Association of the British Pharmaceutical Industry's (ABPI) Prescription Medicines Code of Practice Authority, suggested at the FDA meeting on Internet promotion that each country have jurisdiction over the information put on the Internet within its borders. This would clearly lead to inadequate regulation to ensure that the information the public receives meets national regulatory criteria, as all Internet users also receive information posted from other countries.

The solution offered by a GlaxoWellcome spokesperson Paul Vance, is that if Internet users don't like what a pharmaceutical company offers, they won't come back, "It's a good, self-regulating system with lots of information available".[(126)] Thomas Merchant, from Smith Kline Beecham, argued against disclosure of a company's name on every page of a web document, arguing that this would be impractical. Perhaps he was thinking of Smith Kline Beecham's "café herpes", described above.

In an article in *Scrip Magazine,* Tory Tanaka, an IMS marketing manager, warns that free access to an international audience on the Internet may backfire because of regulations against direct-to-consumer advertising and national differences in product approval and licensing: "So, to avoid the risk of hefty fines pharmaceutical marketers must be especially cautious about providing product information on the Internet."[(127)]

1997 World Health Assembly Resolution highlights the need for regulation

Out of concerns that sale of medicines through the Internet, "may present a hazard for the public health as well as a risk for the individual patient, particularly with regard to misleading or fraudulent product information and lack of individual counseling for consumers", the World Health Assembly passed a resolution on cross-border advertising, promotion and sale of medical products through the Internet in May 1997 [(128)]. This resolution called for a working group to meet and make recommendations.

The group met in September 1997. They discussed concerns about Internet promotion, stressed the vulnerability of those seeking information on the Internet and made recommendations for ways in which WHO, national drug regulators, the industry and consumers could act to improve the standard of information available on the Internet. The meeting stressed that both regulatory standards and voluntary codes should aim to ensure that all Internet promotional activities complied with the *WHO Ethical Criteria.* Some specific recommendations for the pharmaceutical industry included: disclosure of web site ownership or financial support; statements about who the intended audience is and the purpose of the information; provision of accurate; balanced information, including information on dangers and adverse effects; and careful selection of Internet linkages.[(129)]

Could the WHO *Ethical Criteria* for Medicinal Drug Promotion be applied to the

Internet?

The Internet is a new medium for drug promotion but the guiding principles for adequate regulation remain similar. There is a need for effective national legislation regulating all messages to health professionals and the public about medicines, ongoing monitoring, enforcement and effective sanctions.

The principles in the WHO *Ethical Criteria* apply equally to Internet promotion, including the need for "appropriate measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs".[(130)]

- Internet promotion is covered under the *Ethical Criteria* description of promotion as all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.
- more complex is the proviso that only drugs legally available in a country should be promoted there, as well as insistence that claims be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste,
- promotional materials should include no misleading and unverifiable statements, inducing medically unjustifiable drug use, and giving rise to undue risks.
- scientific and educational activities should not be deliberately used for promotional purposes
- The *Ethical Criteria* lists the type and balance of information that advertisements should contain
- The *Ethical Criteria* recommend against direct-to-consumer advertising of prescription drugs

In sum, much which contravenes WHO *Ethical Criteria* is currently on the Internet.

Balanced Information on Risks and Benefits? Internet Health Information from Novartis: Novartis' information on hormone replacement therapy, accessible from the company's home page, cannot be faulted for a lack of balance of negative and positive information. Both are present. There's only one small hitch: every negative statement is about menopause, every positive statement about Novartis' products. **An accurate depiction of an approved indication?** Following fairly standard information on "the most common symptoms", a set of "other menopausal symptoms" are said to "arise gradually after a period of estrogen deficiency and may at first be attributed to aging or to other causes." "The majority of these symptoms are caused by tissue changes that result from estrogen deficiency. These symptoms include loss of collagen in skin and ligaments and a reduction in blood flow. Other symptoms include loss of muscle strength and mass and a reduction in short term memory. Irritability, anxiousness, depression and loss of confidence may also occur." "Cardiovascular disease and osteoporosis are the most harmful long-term effects of menopause." [*sic*] **And of Novartis' hormonal drug treatments?** "HRT is remarkably effective in the treatment of menopausal symptoms…" [*Nowhere is the reader informed that these drugs are approved for the "most common symptoms" and not the more imaginative list of "other menopausal symptoms" , most of which are without documented links to menopausal status.*] "There is a consensus, based on epidemiology studies, that HRT is protective against ischaemic heart disease and leads to at least a 40-50% reduction in likely mortality rates in women with this disease." [*This is not an approved indication*] "Novartis produces the most widely used range of HRT products in transdermal patch form for the treatment of menopausal symptoms and prevention of post-menopausal osteoporosis." *[Any risks, side effects, contraindications or negative information on these products? Not on Novartis' patch of the "information superhighway".]* www.novartis.com/healthcare/ph_frame.html (July 1997)

RECOMMENDATIONS: Internet promotion

Users and prescribers of medicines need accurate, balanced and up-to-date information on which to base treatment choices. Health priorities should define the guiding principles for regulation of drug promotion on the Internet.

The medium may be new; the content of the message is not. National drug regulatory authorities have the mandate to regulate information provided by manufacturers and distributors in order to sell their products. There is an overwhelming public health interest in ensuring that Internet information on drugs is of no lower a standard than that allowed from other information sources in a country. As information on the Internet is available in all countries, this can only be achieved through a "highest common denominator" approach to information provision. Additionally, commercial information should not be disguised as health education, whether it is published on the Internet or elsewhere.

1. International agreements are needed to regulate product promotion and sales on the Internet as this form of promotion crosses national borders. International harmonization procedures for drug regulation should include agreements covering drug promotion based on guidelines in line with the WHO *Ethical Criteria*. This would create a forum for regulation of cross border promotion, including Internet promotion.

2. Commercial or educational information originating from a commercial source should be required to have the company's name clearly and prominently stated on each screen, whether a company has directly provided the information or paid another party to do so.

3. Direct links from a company's home page should be regulated as if they originated from the company.

4. Advertisements posted internationally on the Internet need to be considered to be DTC advertisements as they reach the general public. An on-screen proviso that information is "for US viewers only" or "for health professionals only" is inadequate unless companies wish to add some sort of password mechanism to limit viewing to those to whom it can legally advertise. All posted advertisements should be required to meet similar regulatory standards for content as advertisements in other media, including the need for balanced information on risks and benefits, backing of claims with validated scientific evidence, etc.

5. Educational information provided by pharmaceutical companies on the Internet and in other media about health conditions their products treat should be subject to the same requirements for balance, disclosure of risks as well as benefits, and backing with validated scientific evidence as direct product advertising. In other words claims about the need for treatment should be subject to similar regulation as other forms of drug promotion.

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