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Health Action International HAI-Europe Jacob van Lennepkade 334 T 1053 NJ Amsterdam The Netherlands tel: + 31 (0) 20 683 36 84 fax: + 31 (0) 20 685 50 02 tlx: (+ 402) 6105915 gma lu E-mail: (GE02:) HAI-Europe

Under strict embargo until 15 September 1993

Worldwide consumer campaign on problem drugs

Today, Health Action International (HAI), an international network of consumer, development and health organisations, is launching *Problem Drugs*, a new information pack on medicines.

Problem Drugs, written by Andrew Chetley, covers 10 categories of medicines: antibiotics, antidiarrhoeals, analgesics, cough & cold remedies, growth stimulants, drugs in pregnancy, contraceptives, hormone replacement therapy and psychotropics. It contains detailed information on the "problem drugs" currently being marketed, recommendations for rational drug treatments, and priorities for action which will be taken up in campaigns by HAI groups in over 70 countries worldwide.

Overall, this information pack documents an excessive waste of resources:

- 4 out of every 5 antidiarhoeal products on the market are of no value in the treatment of acute diarrhoea;
- more than 4 out of every 5 cough and cold products contain ineffective ingredients, while more than 1 out of every 2 contains ingredients liable to cause harmful adverse reactions;
- * 1 out of every 3 analgesics is a combination product, and 1 out of every 5 contains a potentially harmful ingredient;
 - more than 1 out of every 3 non-steroidal anti-inflammatory drugs (NSAIDs) should be removed because of a poor safety record, lack of significant therapeutic advantage over safer preparations, and, in most cases, much higher cost;
 - more than 4 out of every 5 vitamins cannot be recommended; nearly 3 out of every 5 are promoted for unproven indications; more than 2 out of every 5 contain non-essential or ineffective ingredients; more than 1 out of every 2 is irrationally formulated; and nearly 1 out of every 2 contains excessive dosages.

Obsolete and dangerous drugs continue to be marketed. The pain killer dipyrone has been banned or severely restricted in twenty-three countries because it has caused deaths, yet it is widely promoted in Latin America, Africa and Eastern Europe for indications like fever and pain.

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HEALTH ACTION INTERNATION IS AN INFORMAL NETWORK OF SOME 100 CONSUMER, HEALTH, DEVELOPMENT ACTION AND OTHER PUBLIC INTEREST GROUPS INVOLVED IN HEALTH AND PHARMACEUTICAL ISSUES IN 60 COUNTRIES AROUND THE WORLD, HAI ACTIVELY PROMOTES A MORE RATIONAL USE OF DRUGS. ALL DRUGS MARKETED SHOULD MEET REAL MEDICAL NEEDS, HAVE THERAPEUTIC ADVANTAGES, BE ACCEPTABLYSAFE AND OFFER VALUE FOR MONEY. Other coordinating IIAI offices:

HAI Clearinghouse/Action for Rational Drug for Asia (ARDA), c/o IOCU, PO Box 1045, 10830 Penang, Malaysia tel: + (604) 371396 fax: + (604) 366506 telex: MA 40164 apiocu AIS Latin America, c/o Acción para la Salud, Avda. Palermo 531, Dpto. 104, Lima 13, Peru, tel: +(5114) 712320 fax: +(5114) 712320

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"People may not be aware that the drug they buy at their pharmacy or that doctors prescribe to them has been banned for safety reasons in another country," says HAI-Europe coordinator Catherine Hodgkin. "We want to make this information known and to clearly recommend the steps needed to protect public health."

The problem, however, is not restricted to a few "bad apples". It is an inevitable result of the way the pharmaceutical industry puts profits above health. Lack of adequate regulatory controls and overpromotion exacerbate this situation. "The company with the best marketing strategy often succeeds, even if its products offer no advantage," says author Andrew Chetley.

HAI makes clear recommendations for change in *Problem Drugs*, pointing out the responsibilities of users, prescribers, government and industry. To list a few:

- Products which have been withdrawn for safety reasons in one country should be withdrawn in all countries;
- Governments should review the drugs on the market and remove products which are obsolete, ineffective, or harmful;
- * Stronger controls are needed on promotion;
- * Prescribers and consumers should have access to independent drug information;
- * Uniform labelling should be adopted for drugs in pregnancy;

Above all, drugs should only be marketed if they meet a real medical need, are acceptably safe and effective, and offer satisfactory value for money.

These recommendations, and many more, will form the basis for campaigns for better national and international drug policy by HAI groups all over the world.

* Review copies available on request *

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Chetley A., *Problem Drugs*, Amsterdam, Health Action International, 1993 208 pages, indexed by subject, company and drug. ISBN 90-74006-X

Problem Drugs was first published in 1986 and has been used by thousands of health workers, educators, journalists, students and activists around the world. It has been translated into Spanish, French, Arabic, Bangla and Indonesian. The revised edition will also be translated into Spanish, French and Russian in 1994.

Price: Dfl 30 + Dfl 5 for postage and handling Payments in Dutch guilders only by Eurocheque, Postal Order or credit card (VISA, Mastercard or American Express)

For further information, please contact:
Barbara Mintzes, Press Office, HAI Europe
Jacob van Lennepkade 334 T, 1053 NJ Amsterdam, The Netherlands
Tel: (31 20) 683 36 84; Fax: (31 20) 685 50 02
Andrew Chetley (author)
24 Speedwell Close, Cambridge CB1 4YZ, UK
Tel and Fax: (44 223) 41 36 67

Take your medicine and you'll get better. Right? Well, not necessarily...

Tens of thousands of drugs are on sale all over the world. Most are either unsafe, ineffective or a waste of money. Many are used unnecessarily or inappropriately.

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Comments on the first edition of Problem Drugs:

"Very useful...gives us the information which cannot be ob from manufacturers." – Tanzanian Bureau of Standards

"The recommendations are generally clear, entirely according obviously necessary." – The Lancet

"Its findings, particularly with respect to the developin countries, are disquieting." – British Medical Journal

"Health educators love it."- Health educator, Nigeri

"Essential and thought provoking reading" - Nurs

A new campaign and information pack for a more rational use of drugs by Health Action International

revised and updated in 1993 by Andrew Chetley

Chetley, A. Problem Drugs, Amsterdam, Health Action International 1993 208 pages, indexed by subject, company and drug ISBN 90 74006 06 X Problem Drugs was first published in 1986 and has been used by thousands of health workers, educators, pharmacists, journalists. students and activists. around the world. It has been translated into Spanish. French, Arabic, Bangla and Indonesian. This revised edition will also be translated. into Spanish, French and Russian in 1994.

problem

- contains well-documented and up-to-date information sheets on many types of drugs, including antidiarrhoeals, antibiotics, analgesics, growth stimulants, cough & cold remedies, drugs in pregnancy, contraceptives, hormone replacement therapy and psychotropic drugs
- has special sections on drugs and children, women and the elderly
- highlights examples of unethical marketing, double standards and failure to meet real health needs
- is international in scope
- · gives clear recommendations for action

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September 15, 1993

Children and drugs: starting the habit of a lifetime

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In 1986, the US-based company, Merck Sharp and Dohme (MSD) told a UK public interest group, Social Audit, that it would no longer promote its antihistamine drug, Periactin (cyproheptadine), as an appetite stimulant. A year later, the company began a string of six successive years as the recipient of *Fortune magazine*'s "most admired corporation" award. Among the attributes that were assessed to make up the award were community and environmental responsibility. In 1991, MSD's Indian subsidiary, Merind, was still promoting cyproheptadine as an appetite stimulant for children. The product was also on the market in Pakistan and throughout Africa — including in countries where famine conditions existed.

"This is one of the most disturbing examples of pharmaceutical industry marketing of inappropriate and unnecessary products for children", says Andrew Chetley, author of Health Action International's latest publication, *Problem Drugs*. "As long ago as 1971, independent sources in the USA were telling companies like Merck Sharp and Dohme that promoting cyproheptadine as an appetite stimulant for children would do more harm than good. Twenty years later, this company still does not seem to have heard the message."

The World Health Organization (WHO) has stated that there is no evidence that the products being promoted as appetite stimulants have any effect on appetite, and says these preparations "should not be used".

However, they are not the only drugs that children should not use. According to WHO, two-thirds of all drugs used by children may have little or no value. At least \$1 billion is wasted every year on inappropriate antidiarrhoeal drugs and cough and cold remedies for children. Many of these preparations are useless and some are potentially dangerous. Ineffective products such as antidiarrhoeals and appetite stimulants can detract attention from effective therapies or from efforts to identify and treat the real causes of poor growth and development among children.

The use of "brain tonics" and other substances to improve children's performance at school is another area where money is wasted and unnecessary products are consumed. In Peru in 1991, the Belgian company, UCB, advertised that its piracetam product, Nootropil, would help children with "school difficulties" such as "memory problems, difficulty learning, lack of concentration, intellectual tiredness, poor

performance, agitation and irritability". There is no evidence that piracetam can perform any of these miracles. The product was licensed in 1993 in the UK, but only for the treatment of a rare condition that results from brain damage, cortical myoclonus. During 1992, in the UK, three vitamin manufacturers were successfully prosecuted for claiming that their

Common examples of drug misuse in children

- antibacterials for viral upper respiratory
 infections
- decongestants for colds, resulting in unacceptable adverse effects
- drugs in diarrhoea
- oral anti-emetics for vomiting
- antipyretic agents for fever
- tricyclic antidepressants for bed-wetting sedatives for sleepless children or those
- labelled hyperactive
- spasmolytics in abdominal pain
- appetite stimulants

vitamin products could increase children's intelligence.

Aside from the waste of resources, the excessive use of drugs by children has its own health consequences. Adverse reactions to the drugs is one such consequence. In Mexico, for example, 12% of paediatric hospitalisations were due to adverse effects of medication. Because infants and children react to drugs in a different way from adults, they usually need lower dosages. The exact way children respond to a particular drug can only be determined through research and experience; however, most drugs do not have established doses for infants and children. About three-quarters of the drugs on the market in the USA are either contraindicated or contain strong precautions for use in children, and 9 out of every 10 contain warnings against use by infants and toddlers.

A long-term consequence of excessive and inappropriate drug use in children is that they may grow up believing that drugs are the only solution to many of life's problems. HAI is calling on health workers and governments to take action to ensure that children do not get started on a lifetime habit of taking unnecessary medicines. It also is calling for the removal of paediatric medicines that are hazardous or ineffective and is urging stronger controls over the promotion of medicines for children.

- ends (680 words) -

Note to editors

This feature is based upon the information contained in sections 1B (Drugs and children), 5A (Cough and cold preparations), 6A (Growth stimulants), 6B (Brain tonics) and 6C (Vitamins) of *Problem Drugs*. Publication details are as follows:

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For further information, please contact:

Barbara Mintzes, Press Office, HAI Europe

J. van Lennepkade 334-T, 1053 NJ Amsterdam, The Netherlands Tel: (31 20) 683 36 84; Fax: (31 20) 685 50 02

Andrew Chetley (author)

24 Speedwell Close, Cambridge CB1 4YZ, UK Tel and Fax: (44 223) 41 36 67 🛇 FEATURE 🛇

problem



September 15, 1993

Antidiarrhoeals: dying for lack of a drink

Executives from the US-based Johnson & Johnson company watched a British television documentary in 1990 in stunned silence as, before their eyes, a child in Pakistan died. The child died as a result of paralysis of the intestinal muscle, caused by the world's leading antidiarrhoeal drug. The drug, loperamide (Imodium), manufactured by Johnson & Johnson's subsidiary, Janssen, should never be used in young children.

Loperamide is only one of the many antidiarrhoeal products that should not be given to children, says *Problem Drugs*, the latest publication from Health Action International (HAI). It found that more than 8 out of every 10 antidiarrhoeal products on the market in developing countries in Asia, Africa and Latin America were unsafe or ineffective. As the World Health Organisation (WHO) puts it, "most medicines for diarrhoea are either useless or harmful".

Yet four million children die each year from diarrhoea. Most of those deaths could be prevented through better infant and young child feeding practices, better hygiene and sanitation, and by treating the dehydration caused by diarrhoea.

It is this dehydration that causes most deaths from diarrhoea. The solution is an inexpensive and easy to prepare drink of water, salt and sugar that helps restore children's fluid and mineral balance. This oral rehydration therapy (ORT) costs little more than 50 cents a child.

"The continued production and promotion of antidiarrhoeal products that detract from effective and affordable therapy is one of today's biggest public health scandals," says *Problem Drugs* author, Andrew Chetley. "It's time action was taken to stop this waste of resources and this loss of lives."

HAI is calling on governments to review the antidiarrhoeal products on national markets with a view to removing all those that are ineffective and introducing bans on products that contain hazardous ingredients.

Drugs that are singled out for removal because of safety risks include a number of products containing hydroxyquinolines. These first came to public attention in Japan in 1970 when an epidemic of subacute myelo-optic neuropathy (SMON) — a disease

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that could cause total paralysis and blindness — swept through the country. Clioquinol was the drug that caused the disease, but similar concerns were raised about the adverse neurological effects of its close relatives — iodoquinol and broxyquinoline. Lack of proven efficacy of these products in the treatment of diarrhoea makes their use even more foolhardy. According to WHO, "there is no rationale for their continued production and sale".

Loperamide preparations for children and paediatric preparations of a similar drug, diphenoxylate (sold as Lomotil by G.D. Searle) are also products that are overdue for a ban, according to *Problem Drugs*. In both cases, WHO has said "there is no rationale for the production and sale of liquid and syrup formulations for paediatric use". Following the international publicity surrounding the child deaths in Pakistan, Janssen withdrew oral and liquid formulations of Imodium (loperamide) in many countries; however, not all manufacturers have done the same, and several governments are now considering bans.

The inclusion of antibiotics in antidiarrhoeal products is another dangerous practice that *Problem Drugs* has highlighted. It found that one out of every two antidiarrhoeal products around the world contained an antibiotic, while in Latin America, it was two out of every three.

The indiscriminate use of antibiotics encourages the development of resistant micro-organisms, alters the normal bacterial content of the gut which can lead to possible fungal infections and the overgrowth of resistant bacteria, can increase the risk of relapse, prolong the period when the patient with an infection can pass on the disease, and can also interfere with subsequent bacteriological diagnosis. However, in India in 1991, G.D. Searle produced a regular magazine, *Diarrhoea Update*, that told doctors that the combination of diphenoxylate and an antibiotic was an "advantage" in fighting diarrhoea.

Products containing neomycin, streptomycin or dihydrostreptomycin, chloramphenicol, and/or one of the many sulphonamides are of particular concern. According to WHO, there is no evidence that these antibiotics are effective in the treatment of any type of diarrhoea. It says that "the production and sale of these products cannot be justified".

The firm conclusion is that the vast majority of antidiarrhoeal drugs on the market worldwide are, at best, unnecessary and, at worst, ineffective and sometimes dangerous.

- ends (700 words) -

See next page for note to editors

Note to editors

This feature is based upon the information in the five sections of Problem Drugs dealing with antidiarrhoeal drugs: 2A (Antidiarrhoeals); 2B (Antidiarrhoeals containing antibiotics); 2C (Hydroxyquinolines); 2D (Diphenoxylate); and 2E (Loperamide). Publication details are as follows:

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Andrew Chetley (author)

24 Speedwell Close, Cambridge CB1 4YZ, UK Tel. and Fax: (44 223) 41 36 67

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September 15, 1993

Antibiotics: wasting a valuable resource

Australian microbiologist Dr Ken Harvey is worried that the global misuse of antibiotics in humans and animals may leave us defenseless against severe infections.

"We may look back at the antibiotic era as just a passing phase in the history of medicine, an era in which a great natural resource was squandered and where the bugs proved smarter than the scientist," says Dr Harvey.

His concern, and that of many other experts in infectious disease control, is outlined in *Problem Drugs*, a new publication from Health Action International. It points out that the indiscriminate use of antibiotics has led to the development of bacteria that are resistant to the standard, effective and inexpensive drugs normally used to treat common diseases. This is described by a Dutch specialist in paediatric infections, Ronald de Groot, as "a global problem with a major impact on health care in developed and developing countries".

The inability to treat infections with the usual antibiotic of choice (or any other drug) can be disastrous. In recent years, resistant strains of bacteria have triggered severe outbreaks of gonorrhoea, dysentery, pneumonia, meningitis and deadly hospital infections in many countries. Infections caused by resistant bacteria are more likely to cause prolonged illness, frequent and prolonged hospitalisation and a higher death rate. This human suffering is accompanied by financial burdens as well. In the USA alone, the cost of antibiotic resistance has been estimated at more than \$100 million a year.

There is no shortage of evidence about the misuse of antibiotics. Studies from the USA, the UK, Canada, Italy, Australia, New Zealand, Uruguay, Nigeria, the Middle East and Brazil confirm the indiscriminate and often unjustified use of antibiotics. Anywhere from one-third to two-thirds of antibiotics prescribed in settings as diverse as the USA, New Zealand and Nigeria are inappropriate.

In developing countries, more of the national health budget and personal income is spent on antibiotics than on any other class of drug. In industrialised countries, too, sales are high, which all contributes towards a global market of some US\$22 billion. By the turn of the century, the global antibiotic market is expected to top \$40 billion.

sales are high, which all contributes towards a global market of some US\$22 billion. By the turn of the century, the global antibiotic market is expected to top \$40 billion.

| Country/Region | Year | Sales of antibiotics as | Total sales of antibiotics |
|----------------|------|-------------------------|-------------------------------|
| | | % of total market | US\$ million |
| ran | 1990 | 31 | |
| Middle East | 1989 | 29 | 71 |
| ndonesia | 1989 | 25 | 100 |
| Philippines | 1989 | 23 | 98.9 |
| Mexico | 1990 | 15 | 300 |
| Argentina | 1990 | 12 | 177.5 |

In some countries, a large percentage of the antibiotics produced are given to animals. In the USA, for example, about half of all antibiotics produced are used to prevent or treat animal disease, or as growth promoters in feed stock. One consequence of this extensive use of antibiotics has been the spread of antibioticresistant salmonella infection from animals to humans.

Whether antibiotics are used for human or animal consumption, the pharmaceutical industry invests heavily in promoting their use. Almost two-thirds of the antibiotic market is dominated by sales of three types of drugs: penicillins, cephalosporins and the newer quinolones. Misleading promotion abounds for these products; much of it encourages doctors to prescribe the latest — and most expensive — antibiotic as first-line therapy for a broad spectrum of infections. In most cases, independent advice from bodies such as the American Medical Association, the *British National Formulary*, or Australia's *Antibiotic Guidelines* is that these newer antibiotics should be used only for well-defined indications or as second or third line therapy when other drugs have failed due to resistance.

The World Health Organization suggested in 1990 that governments establish such a "reserve list" of antibiotics that would include many of the newer cephalosporins and quinolones. It said that although such antibiotics were effective in a wide range of infections, they were inappropriate for unrestricted use because of the need to reduce the risk of resistance to them or because of their high cost.

In the same year, UK-based Glaxo was promoting its cephalosporin antibiotic, Ceporex (cephalexin), in Pakistan with the picture of the hands of a baby and an elderly person linked together and the headline: "from early days, till autumn years, an indications that read like a who's who of epidemiology - everything from skin, ear and eye infections to respiratory, intestinal and reproductive tract infections.

"Antibiotics are too valuable a public health tool to waste simply because the pharmaceutical industry wants to recoup its investments a little faster," says Andrew Chetley, author of *Problem Drugs*. If we want to avoid future epidemics of infections that are difficult or impossible to control, we have to start using antibiotics more wisely, right now."

Health Action International is calling on governments to develop strict antibiotic policies as part of their national health and drug policies. Such policies should include developing a limited list of antibiotics, including the reserve list suggested by WHO; producing and regularly reviewing a set of therapeutic guidelines for antibiotic use; and studying the use of antibiotics with a view to introducing education programmes to encourage more rational use where necessary. HAI also recommends that governments introduce stronger controls to prevent misleading promotion of antibiotics.

- ends (880 words) -

Note to editors

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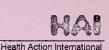
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Barbara Mintzes, Press Office, HAI Europe J. van Lennepkade 334-T, 1053 NJ Amsterdam, The Netherlands Tel: (31 20) 683 36 84; Fax: (31 20) 685 50 02 Andrew Chetley (author) 24 Speedwell Close, Cambridge CB1 4YZ, UK Tel. and Fax: (44 223) 41 36 67 ♦ FEATURE ♦

problem



September 15, 1993

Dipyrone: a drug no one needs

In the early 1980s, 94 people died in Germany after taking a pain killer that contained dipyrone. As a result, the German drug registration authority (BGA) restricted the indications for the drug to severe pain after surgery or accident, as a result of cancer, or because of intestinal colic. Combination products containing dipyrone were withdrawn from the market. In 1990, the BGA re-emphasised that it considered dipyrone a drug of last resort, primarily for cancer pain.

The world's leading manufacturer of dipyrone is the German company, Hoechst. The restrictions on dipyrone in its home country have not stopped Hoechst from promoting its dipyrone products widely in other countries, says Health Action International's (HAI) latest publication, *Problem Drugs*. In 1992, Hoechst was advertising dipyrone's "ample safety margin" in Latin America and recommending the product for all types of fever and pain.

Promotion such as this ensured high sales. Globally, dipyrone contributes more than 2% to the company's overall pharmaceutical sales. In countries such as Pakistan or the Philippines, dipyrone brings in anywhere from one-quarter to one-third of the company's national turnover.

Besides Hoechst, many local companies manufacture dipyrone-containing products. At least one out of every seven pain killers in markets in Pakistan, the Middle East, Africa and the Caribbean during 1990 contained dipyrone.

In 1977, the American Medical Association described dipyrone as "obsolete" and the US Food and Drug Administration withdrew approval of the drug because of the availability of safer alternatives. Ten years later; the German Medical Association said that even a small risk of a life-threatening condition was "an unacceptable price to pay for pain relief, especially since it cannot be maintained that alternatives are not available".

Dipyrone can cause two life-threatening conditions: agranulocytosis (severe loss of white blood cells due to bone marrow damage), and anaphylactic shock (a severe allergic reaction). In both cases, it is impossible to predict who is likely to be at risk from these conditions. In the mid-1980s Hoechst helped to pay for an international study which the company hoped would show that dipyrone was not a significant factor in causing agranulocytosis. Instead, the study found that one out of every four cases of drug-induced agranulocytosis in the participating countries occured as a result of taking dipyrone. Subsequent examination of the data in the study suggest that there could be as many as 7,000 cases of

Dipyrone is an analgesic (pain killer) with anti-inflammatory and antipyretic (feverreducing) properties. It is the sodium sulphonate derivative of amidopyrine or aminopyrine and, like propyphenazone and phenylbutazone, it is a member of the pyrazolone group of chemicals. The drug was first introduced by the German manufacturer, Hoechst, in 1922.

Dipyrone is known by many names: analgin, analginum, metamizol, aminopyrine-sulphonate sodium, sodium noramidopyrine methanesulphonate, sulpyrine, methampyrone, novamidazofen, natrium, novaminsulfonicum, noramidazophenum, and noraminophenazonum.

dipyrone-induced agranulocytosis worldwide each year — up to 2,000 of which could be fatal.

"The purpose of an analgesic is to kill pain, not people," says Andrew Chetley, author of *Problem Drugs*. "Dipyrone is a drug that no one needs. It is a disgrace that Hoechst and other companies have refused to take it off the market."

HAI is very clear about what needs to be done: ban dipyrone immediately.

- ends (545 words) -

Note to editors

This feature is based upon the information contained in sections 4A (Analgesics) and 4B (Dipyrone) of *Problem Drugs*. Publication details are as follows:

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Tel and Fax: (44 223) 41 36 67

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September 15, 1993

Norplant: contraceptive freedom or coercion?

It took 24 years to develop, test and approve the implantable contraceptive Norplant. It took less than two weeks for Norplant to be billed as a new method of coercion. Within days of licensing in the USA, a Philadelphia newspaper published a racist editorial recommending Norplant in the fight against black poverty; a judge in California included compulsory use of Norplant in the sentence of a woman found guilty of child abuse; and the state legislature in Kansas held hearings on a bill to encourage mothers receiving state welfare benefits to get the implant.

This new contraceptive consists of six silicone rods filled with the hormone levonorgestrel which are inserted under the skin of a woman's upper arm. Norplant has one of the longest periods of effectiveness for any contraceptive, five years. Specialised minor surgery is needed for insertion and removal.

A disturbing feature of Norplant's design is that women cannot just stop using it when they wish, says Health Action International's (HAI) latest publication, *Problem Drugs*. They need to find a specially trained health worker who agrees to remove the implants. This is not always easy. "Women are sometimes pressured into continuing to use the method when they don't want to," says *Problem Drugs* author Andrew Chetley.

In Thailand, women are routinely told that Norplant will not be removed for minor side effects. Reports from the Dominican Republic, Egypt, and Indonesia also found that "removal on demand" did not occur to the satisfaction of the users.

Norplant has been approved for use in at least 26 countries and more than 1.5 million women have used it. The developers believe that — despite its high cost — more than 30 million women could be using it by the end of the decade, most of them in developing countries.

National promotional campaigns are being used to help meet those targets. In Zimbabwe in 1992, posters proclaimed that Norplant was a "five-year insurance plan" with "no surprises", a convenient slogan that ignored the lack of knowledge of longterm effects of this contraceptive. Immediate effects are better known: at least twothirds of all women using Norplant experience irregular menstrual bleeding. In one

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Overall, women need to have a greater voice in setting the policies and practices that will determine not only how contraceptives — but all drugs — are researched, developed, produced, marketed, used and provided. "Women make up the majority of health care consumers and health care workers and should have a major voice in determining health and medical care policy," says Yvonne Bogaarts.

- ends (850 words) -

Note to editors

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This feature is based upon the information contained in sections 1C (Women and drugs), 8A (Contraceptives) and 8E (Implants) of *Problem Drugs*. Publication details are as follows:

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Andrew Cherley (author)

24 Speedwell Close, Cambridge CB1 4YZ, UK Tel. and Fax: (44 223) 41 36 67 study, more than one-third of all users had these problems during the full five-year period of use.

Another concern is that if pregnancy does occur while the method is used, there is a 20 to 30% chance that it will be ectopic. Ectopic pregnancies —- when the fertilised egg begins to develop in the Fallopian tube rather than in the uterus —- can be fatal for the mother if they are not terminated quickly. At least three to four out of every hundred Norplant users become pregnant during the five-year period of use.

If a woman keeps the implants for more than five years, the amount of hormone released gradually diminishes, increasing the likelihood of pregnancy. This may lead to more ectopic pregnancies and to a higher risk of birth defects in children exposed to the hormone levonorgestrel before birth.

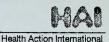
Five years is a long time to follow women up to notify them to have the implants removed. "This is expensive and time-consuming," says Yvonne Bogaarts, coordinator of Women's Health Action Foundation. "Most health services in developing countries simply aren't equipped for it."

It is clear that removal after five years does not always happen. In Brazil, 14 of 52 women followed up after a trial of Norplant had the implants in place for more than five years. The clinical trial they were taking part in had been stopped, the doctors had left, and other doctors did not know how to remove the implants.

Like other long-acting, highly effective contraceptive methods, Norplant has been developed to be used in family planning programmes in developing countries which aim to reduce population growth. Indonesia was the first country to use Norplant on a large scale, with more than 886,000 women having received the implants between 1987 and 1990. Problems arose when Norplant was included in the so-called "safari" programme - a programme where health workers visit a village for a day to recruit as many women as possible to use contraception. Individual counselling and information about side effects "tended to be minimal". Implants were inserted improperly by poorly trained health workers, using equipment that was not properly sterilised, leading to infections and later difficulties with removal. Some women had Norplant inserted when they were already pregnant, but did not yet know it.

HAI recommends against promoting implants as "first choice" contraceptives and says that they should only be used where they can be provided safely and respectfully and with a woman's fully informed consent. HAI is calling for research efforts to be directed at improving the availability and convenience of existing usercontrolled methods of contraception. ◊ FEATURE ◊ FEATURE ◊ FEATURE ◊ FEATURE ◊ FEATURE ◊ FEATURE ◊

problem



September 15, 1993

Tranquillisers: a tale of dependence

A British woman, Tess Higham, went to her doctor suffering from exhaustion and anxiety. The doctor prescribed antidepressants and sleeping tablets. This prescription began a dependency on psychotropic drugs that lasted 21 years. She described them as "lost years" and said the experience was like a "chemical lobotomy".

Her experience is not unique. According to Health Action International's (HAI) latest publication, *Problem Drugs*, the benzodiazepine drugs used to treat anxiety and sleep disorders follow in a long tradition of drugs that were introduced as being safer and less likely to cause dependence than their predecessors. But it was to be a false promise.

Between 15 and 44% of long-term users become dependent on benzodiazepines. Although they are among the most frequently prescribed drugs worldwide, benzodiazepines do not cure any anxiety disorders; they suppress symptoms that may return once the drug is stopped.

| World Market for Psychotropic Drugs | | | |
|-------------------------------------|--------------------------------|--|--|
| Therapeutic type | World Sales 1991 \$ Million | | |
| Hypnotics | 406 | | |
| Anti-anxiety drugs | 1,200 | | |
| Antidepressants | 1,500 | | |
| Antipsychotics* | 1,244 | | |
| Total | 4,350 | | |

* includes anti-epileptics and drugs to treat Parkinson's disease

Nonetheless, used wisely and for a limited amount of time, benzodiazepines can provide valuable breathing space when an emotional crisis becomes intolerable. Expert advice, such as that given by the UK Committee on Safety of Medicines (CSM), is that benzodiazepines should only be used for the short-term (two to four weeks) treatment of anxiety that is severe, disabling or causes extreme or unacceptable distress. The CSM says that their use for "mild" anxiety is inappropriate and unsuitable.

Unfortunately, misuse through overprescribing is common. *Problem Drugs* reports on studies in the UK, France, Spain, Canada and South Africa that found widespread overprescribing, often for long periods of time. In one UK study, at least one out of every three people taking tranquillisers had done so for periods of more than four months.

One cause of poor prescribing is the promotional effort of the pharmaceutical industry. In Peru in 1991, Multifarma promoted alprazolam (Alpaz) as a treatment for virtually every condition of daily life. It promised relief for:

- the "syndrome of the modern woman" who suffers from increased worries about work, and an increased workload, emotional worries and stress;
- the "syndrome of today's man" who worries about the future, his increased responsibilities, frustrations at not reaching his goals, financial problems and stress;
- the "syndrome of the housewife" who worries about the children's education, having too much work, financial problems, fear of domestic accidents and a fear of the house being burgled; and
- the "syndrome of the elderly" who fear being lonely, worry about their health and future, have limited finances, and lack affection.

In 1992, also in Peru, Upjohn used a similar theme for its brand of alprazolam (Xanax), indicating it for "a large variety of patients with anxiety", including a business executive who is under pressure, a housewife coping with family conflicts, a lonely elderly woman worried about her health, and a cardiac patient with digestive problems and fears of another heart attack.

"This medicalisation of life may help the pharmaceutical industry sell more drugs," says Andrew Chetley, author of *Problem Drugs*, "but it bears no resemblance to appropriate health care."

Women and the elderly are particular targets for benzodiazepines, antidepressants and other psychotropic drugs. In most industrialised countries women are two to three times more likely than men to be using tranquillisers or antidepressants. For example, a study in the Netherlands found that doctors were two times more likely to prescribe benzodiazepines for women than men when neither the symptoms nor the diagnosis warranted the drug. In developing countries, too, promotional materials clearly identify women as needing powerful drugs to cope with daily life. In India, for example, Sandoz recommends giving women suffering from anxiety an antipsychotic drug, thioridazine (Melleril-10), usually reserved for the treatment of severe psychoses such as schizophrenia. The Indian subsidiary of Merck Sharp and Dohme suggests that women undergoing the menopause would benefit from a combined tranquilliser and antidepressant (Libotrop). Menopause is not a valid indication for either drug; together, they make an irrational combination drug which should not be used to treat any condition.

In the USA, the elderly, who make up one-sixth of the total population, are prescribed one-third of all tranquillisers and more than half of all sleeping medications. Studies from other countries confirm that the elderly receive a disproportionately high amount of prescriptions for benzodiazepines. The adverse effects of these drugs are often more severe among the elderly. These include confusion, disorientation and lack of coordination — symptoms that can be misdiagnosed as signs of dementia. In addition, the lack of coordination caused by benzodiazepines can lead to falls and broken bones.

HAI is calling on governments and health workers to take action to limit the use of benzodiazepines in the elderly in particular, and to generally restrict their use for severe anxiety or severe sleep disorders. HAI is also calling for better independent information about the rational use of psychotropic drugs and strict penalties for poor quality promotional material. The development of national and local formularies and therapeutic guidelines for the treatment of anxiety, insomnia and depression and the encouragement of non-drug solutions are seen as ways to improve the current situation.

In the words of consultant psychiatrist, Brian Ballinger, "More emphasis should now be placed on managing sleep disorders and anxiety without using drugs."

- ends (840 words) -

Note to editors

This feature is based upon the information in section 10A (Psychotropics) of *Problem Drugs*. Publication details are as follows:

Chetley, A., *Problem Drugs*, Amsterdam, Health Action International, 1993. 208 pages, indexed by subject, company and drug. ISBN 90-74006-06-X Price: Dfl. 30 + Dfl. 5 postage and handling Payment can be made in Dutch Guilders by Eurocheque, Postal Order or credit cards (VISA, Mastercard or American Express).

For further information, please contact:

Barbara Mintzes, Press Office, HAI Europe J. van Lennepkade 334-T, 1053 NJ Amsterdam, The Netherlands Tel: (31 20) 683 36 84; Fax: (31 20) 685 50 02 Andrew Chetley (author) 24 Speedwell Close, Cambridge CB1 4YZ, UK Tel and Fax: (44 223) 41 36 67 👌 FACTS & FIGURES 👌 FACTS & FIGURES 👌 FACTS & FIGURES 🔷 FACTS & FIGURES 🔷



Health Action International

Problem Drugs: Facts and Figures

Size of the world market

The value of the world pharmaceutical market was estimated by the European pharmaceutical industry (EFPIA) at \$164.5 billion in 1989. The 1990 market was estimated at being between \$174 billion and \$186 billion. The major market areas were: North America, 33.0%; Western Europe, 31.9%; Asia, 25.4%; Latin America, 3.9%; Eastern Europe, 3.1%; Africa, 1.8%; and Australasia, 1.0%. Forecasts for the year 2000 suggest that the global market could reach \$330 billion.

| Drug category | Global sales US\$ millions | Year |
|-------------------------|-------------------------------|-----------------|
| Antidiarrhoeals | 600 | 1993E |
| containing antibiotics | 150 | 1989E |
| Antibiotics | 22,000 | 1993 |
| penicillins | 3,000 | 1988 |
| cephalosporins | 6,800 | 1988 |
| quinolones | 2,250 | 1990 |
| aminoglycosides | 620 | 1988 |
| Analgesics | 15,000 | 1995E |
| NSAIDs | 6,000 | 1991 |
| Cough and cold remedies | 7,300 | 1990 (OTC only) |
| Cognitive enhancers | 1,500 | 2000E |
| Oral contraceptives | 1,800 | 1989 |
| Psychotropics | 4,350 | 1991 |
| hypnotics | 406 | 1991 |
| anti-anxiety drugs | 1,200 | 1991 |
| antidepressants | 1,500 | 1991 |
| antipsychotics | 1,244 | 1991 |

Notes: E = estimated; OTC only = over-the-counter products and does not include prescription medicines

Increasing demand by misleading promotion

A 1990 survey of doctors in the UK found that 66% of doctors said a pharmaceutical company sales representative had claimed more indications for a product than were permitted on the approved data sheet.

Imitative research

Of the 348 new drugs from the 25 largest US drug companies between 1981 and 1988, the US Food and Drug Administration (FDA) said that at the time of introduction:

- 3% (12 drugs) made an "important potential contribution to existing therapies";
- 13% made a "modest potential contribution"; and,
- 84% made "little or no potential contribution".



Population groups where caution is needed

Women make up about 52% of the world's population; children under 15 account for about 32%; people over the age of 65 account for about 6%. All together, at least two-thirds of the world's population are in "special case" categories where more care needs to be taken in the use of drugs and where less is known about the effects of the use of drugs. These are also the groups of people who are most likely to use drugs.

i

- Children: According to the World Health Organization (WHO), two-thirds of all drugs used by children may have little or no value. At least \$1 billion is wasted every year on inappropriate antidiarrhoeal drugs and cough and cold remedies for children.
- Women: Women are more likely to use vitamins than men; two to three times more likely to be prescribed tranquillisers, sleeping tablets and antidepressants; and three times more likely than men to use contraceptives.

The elderly: In the USA, 1 out of every 6 people is over 60, but they consume:

1 out of every 3 tranquillisers

1 out of every 2 sleeping pills

1 out of every 3 antidepressants

2 out of every 3 antihypertensives

2 out of every 5 gastrointestinal drugs

Misuse of antibiotics

Studies from around the world show that between one-third and two-thirds of antibiotic use is inappropriate and unnecessary.

Inappropriate pain killers

Combination pain killers offer no real advantage, are more costly and can be harmful. They are more likely to produce kidney damage than single ingredient pain killers. Yet one out of every three pain killers on the market in developing countries in Asia, the Middle East, Africa, and the Caribbean in 1990 was a combination product.

NSAIDs: a high risk of adverse effects

Non-steroidal anti-inflammatory drugs (NSAIDs) account for 5% of all drugs prescribed in the UK, but are responsible for 25% of all adverse drug reactions reported to the Committee on Safety of Medicines.

Consequences of vitamin misuse

Misuse of vitamins can do harm. For example, it can:

- distort national health priorities;
- drain limited national economic resources and foreign exchange;
- waste limited individual and family financial resources;
- encourage harmful beliefs about the nature of health; and
- encourage ineffective and harmful practices.

Drugs in pregnancy

Surveys from more than 20 countries around the world show that 8 out of 10 women take at least one drug during pregnancy, with an average of three to four drugs.

Prescribing in pregnancy

The editor of a book on drugs in pregnancy, Dr D.F. Hawkins, a consultant obstetrician, gynaecologist, and pharmacologist suggests four basic rules for prescribers.

- 1. Review all patients with medical disorders before they conceive, regarding every woman of reproductive age as a potential antenatal patient, and encouraging them to attend for counselling before planning a pregnancy.
- 2. Question the real need for any drug in pregnancy, giving due consideration to alternative methods of treatment.
- 3. Review all drug regimens in pregnancy to see how careful therapeutics and good control can minimise risks.
- 4. Use medicines that have been widely employed in pregnancy for years in preference to the latest drugs.

Contraceptives

- The pill: Four out of every 10 oral contraceptives on the market in Asia, the Middle East, Africa and the Caribbean during 1990 and 1991 should be avoided because they contain a high level of the hormone oestrogen, or the balance between the oestrogen and progestogen is not acceptable.
- IUDs: A woman who uses an intrauterine device (IUD) is about twice as likely to suffer from pelvic inflammatory disease (PID) -an infection within the fallopian tubes, ovaries or uterus. PID develops in an estimated 1% of young women annually and causes more illness in women of 15 to 25 years of age than all other serious infections combined. PID is a leading cause of infertility.

Hormone replacement therapy (HRT)

In 1988, the most often prescribed drug in the USA was a brand of amoxycillin, Amoxil, produced by Beecham. By 1992, the most widely prescribed drug was an

| Global estimates of th using different metho (1980s) | | | | |
|--|-----------------|--|--|--|
| Method | Number of users | | | |
| Sterilisation | | | | |
| male | 42 million | | | |
| female | 140 million | | | |
| Hormonal contracepti | ves | | | |
| oral | 63 million | | | |
| injectables | 6 million | | | |
| implants | 1.5 million | | | |
| IUD | 80 million* | | | |
| Condom | 40 million | | | |
| Other barrier methods | s 8 million | | | |
| Natural birth control | 32 million | | | |
| Withdrawal | 32 million | | | |
| | | | | |
| *nearly 60 million IUD users are in the | | | | |
| People's Republic of China | | | | |

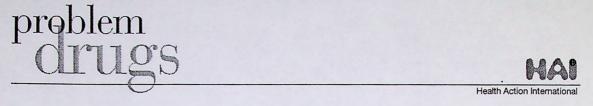
oestrogen product, Premarin, produced by Wyeth-Ayerst and promoted as hormone replacement therapy for postmenopausal women.

Preliminary findings from one health region in the UK suggest that the use of HRT for 10 years from the time of menopause would lead to a reduction of hip fractures 20 years in the future of only some 5 to 10%. Five to 30% of women who receive HRT at a dosage level considered to be sufficient to prevent bone loss nonetheless still suffer a reduction of bone density. As well, most deaths in women with low bone mineral density are unrelated to the occurrence of fractures.

The whole concept of hormone replacement therapy is itself promotional. The hormones are not missing: they do not need to be replaced.

Psychotropics

In the UK, nearly one out every eight people take tranquillisers for periods of four months or more. The UK Committee on the Safety of Medicines advises that these drugs should only be used for the short-term relief (two to four weeks) of anxiety or insomnia that is severe, disabling or subjects the individual to extreme or unacceptable distress.



A few quotes in Problem Drugs

"There is an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way."

- World Health Organization, 1993

"Prescription drugs are marketed as if they were cosmetics or candy. Claims are made beyond what the product will do. Demand is inflated beyond the medical need. Uses are promoted that are neither healthy nor wise."

- David Jones, former executive at Abbott and Ciba-Geigy, 1990

"There are simply not enough sick people around to satisfy the desires of the marketing managers of drug companies. There are not enough sick people around to absorb all the new variations on old drugs which are produced."

- Professor Bill Inman, Drug Safety Unit, University of Southamptom, UK, 1991

"The most important objective of the short-term component of public health policy under conditions of poverty is to set priorities.... Setting priorities, in fact, means preventing avoidable death. It certainly does not mean treating self-limiting diseases."

- Dr Klaus Leisinger, Head of Third World Relations, Ciba-Geigy, 1989

"Children may tend to grow up believing that drugs are the solution to many of life's problems." — World Health Organization, 1987

"A major factor in the number of adverse drug reactions among the elderly is their doctors' overreliance on promotional materials provided by the drug manufacturers."

- US Department of Health and Human Services, 1989

"Antidiarrhoeal drugs generally divert attention from oral rehydration and are also too expensive for most families."

- Rolf Carriere, UNICEF India, 1987

"There are no drugs available at present that will safely and effectively stop diarrhoea." — World Health Organization, 1989

"Rather than attempt to overcome or pre-empt resistance by prescribing yet another agent, the objective should be to prevent resistance by limiting the amount of antibiotic prescriptions."

- T.D. Wyatt and colleagues, British Medical Journal, 1990

"NSAIDs [non-steroidal anti-inflammatory drugs] are overvalued as symptomatic treatments, yet they continue to be prescribed in high quantities.... Empirical evidence suggests that a high proportion of long-term NSAID users can be safely switched to simple analgesics without compromising their therapy.... Not only would there be a real saving of health expenditure through the use of cheaper drugs, but also there would be a considerable reduction in mortality and morbidity from NSAID side-effects."

- P.A. Dieppe and colleagues, Lancet, 1993

"NSAIDs are one of the most common cause of adverse reactions reported to drug regulatory authorities."

- P.M. Brooks, Lancet, 1993

"Although cyproheptadine stimulates appetite in some children, *Medical Letter* consultants believe that promotion of the drug as an appetite stimulant will do more harm than good." — *The Medical Letter on Drugs and Therapeutics*, 1971

"In general, little or nothing is gained by stimulating appetite by drugs." - D.R. Laurence and P.N. Bennett, *Clinical Pharmacology*, 1987

Age-associated memory impairment is "a pseudo-disease. It's having a drug and wanting an illness for that drug. It's a modern disease, when pharmaceutical chemists can produce hundreds of molecules and the industry is desperately wanting to get these molecules on the market." — Prof. Ian Hindmarch, University of Surrey, UK, 1991

"There are few valid indications for vitamin or mineral supplements."

American Medical Association, 1986

"The routine prescription of multivitamin and mineral supplements for pregnant and lactating women is common but generally unnecessary. A well balanced diet designed to meet the needs of pregnant and lactating women minimises the need for supplementation."

American Medical Association, 1986

"DES [diethylstilboestrol] present risk without benefit." — R.J. Stillman, American Journal of Obstetrics and Gynecology, 1982

"The burden of ill health associated with reproduction is divided very unequally between the two sexes, with women bearing the brunt of it.... Contraceptive use worldwide is three times greater among women than men, and among all available methods, those used by women carry more potential health hazards."

- World Health Organization, 1992

"In trying to find a method of birth control, the main action is to interfere with a **normal** body process and this means taking extra-special care. The method will be used by initially healthy women or men and should not make them unhealthy; on the other hand, it could be used by people who are already unhealthy and must not do them additional harm."

- Dr J. Guillebaud, The Pill, 1991

In Thailand, "because of the cost of the method, women are routinely informed when choosing Norplant that the implants are appropriate for long-term spacing and will not be removed for minor side-effects."

- M. Zimmerman and colleagues, Studies in Family Planning, 1990

"Menopause is not a disease, but a life-cycle transition."

- Margaret Lock, medical anthropologist, 1991

"Benzodiazepines do not cure any anxiety disorders — they suppress symptoms which may return when the drug is stopped."

- Prof. Gavin Andrews, Australian Prescriber, 1991

"More emphasis should now be placed on managing sleep disorders and anxiety without using drugs."

- Dr Brian Ballinger, consultant psychiatrist, 1991

"Since 1958, when imipramine (Tofranil) was first reported to be effective in depression, no other antidepressant has been widely shown to be any more effective."

- E.H. Rand, American Family Physician, 1991

problem







the years that COUNT....

Merck, Sharpe and Dohme 's Indian subsidiary, Merind, promotes cyproheptadine as an appetite stimulant in 1991. Cyproheptadine is an antihistamine used to treat allergic reactions.

"Although cyproheptadine stimulates appetite in some children... promotion of the drug as an appetite stimulant will do more harm than good." Anon, "Cyproheptadine (Periactin)", The Medical Letter on Drugs and Therapeutics, Vol 5, No 3, March 1971

"in general, little or nothing is gained by stimulating appetite by drugs." *Lawrence DR and Bennett, PN, Clinical Pharmacology, Edinburgh, Churchill Livingstone, (6th edn), 1987, p365*



HAI

Health Action International



A drug which can improve a child's grades? Misleading promotion for piracetam (Nootropil) by UCB in Peru in 1991





problem drugs



RLOBAL EXPERIENCE BUILDS CONFIDENCE

Lomotil*

The Rapid Control Antidiarrhoeal prescribed by physicians in over 70 countries

Provides fast, antidiarrhoeal action The desire to defecate diminishes after approximately one hour ¹.

Preferred alternative to Imodium (Loperamide)

In a multicentre trial it was found "that on an average Lomotil treated patients reached a cure "nearly six hours before those receiving Imodium"².

Economical

Available to patients at just 19 paise per tablet."

Lomofil

For prompt control of diarrhoea

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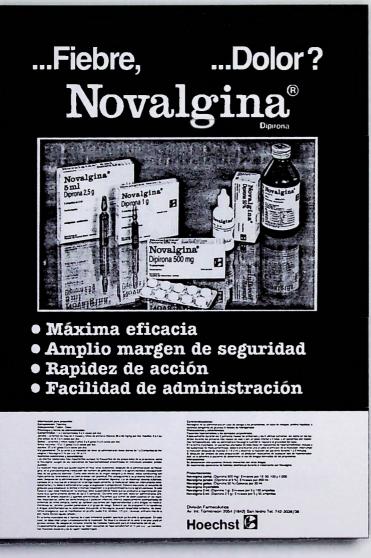
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> 1991 ad in Searle's *Diarrhoea Update* in India for Lomotil (diphenoxylate + atropine), featuring a picture of the Dutch queen.

> Lomotil has been described as "the *worst* means of treating" infectuous diarrhoea because it can prolong the length of time that toxins from the bacteria remain in the intestinal tract. *Lappé, M, When Antibiotics Fail, Berkeley, North Atlantic Books, 1986, p154*

problem drugs





Hoechst advertises dipyrone's "ample safety margin" in *Comahue Medico* in 1992 in Latin America. Fever and pain are listed as indications.

Dipyrone has caused deaths from agranulocytosis (severe loss of white blood cells due to bone marrow damage) and anaphylactic schock (a severe allergic reaction) and has been banned or severely restricted in many countries.

"Since effective, less dangerous alternative drugs are available there is no case for the continued use of aminopyrine and dipyrone." *Dukes, MNG, Side Effects of Drugs Annual 4, Amsterdam, Elsevier,* 1980, pp63-4.

problem



We have taken a Five Year Insurance Plan... We have left no room for Surprises 11111 11111 11/1 The 5 year contraceptive plan ik to your incal CBP or wait your nearest chine or Health centre

1992 poster promoting the contraceptive Norplant (levonorgestrel implants) in Zimbabwe.

No room left for surprises? The long-term risks of this hormonal contraceptive to users – or to babies exposed during breastfeeding – are unknown.

orøblem



Health Action International

OESTROGENEN EN PROGESTAGENEN ZIJN VOOR HEN NÚ AL DE GEWOONSTE ZAAK VAN DE WERELD.



DAT GELDT MET ZUMENON EN DUPHASTON STRAKS ÓÓK VOOR HUN OVERGANG.

Voor veel jonge vrouwen van nu behoort identiek aan het lichaamseigen oestrogeen, het innemen van hormonen tot de routine van alledag. Straks - rond en na de overgang - stagene bescherming. En om het patienten kan dat weer aan de orde zijn. Dan immers worden behandeling en preventie van ernstige postmenopauzale klachten actueel en kan hor-Zumeston. moonsuppletie geïndiceerd zijn

terwijl Duphaston zorgt voor optimale progeextra makkelijk te maken zijn ze ook nog in

Tegen de tijd dat hormoonsuppletie gewenst Zumenon en Duphaston voldoen ruim-schoots aan de eisen voor verantwoorde hor-de jongere generatie zijn hormonen immers moontherapie. Het oestradiol van Zumenon is nu al de gewoonste zaak van de wereld.

ZUMENON EN DUPHASTON OMDAT HORMOONTHERAPIE ZO ZUIVER MOGELIJK MOET ZIJN.

"Oestrogen and progestagen are already the most normal thing in the world for them. This will also be true for Zumenon (estradiol) and Duphason (dydrogesteron) during their menopause."

Duphar promotes their "as pure as possible" hormone therapy for women in the Netherlands in Nederlands Tijdschrift voor Geneeskunde, May 1993

problem arugs





para el tratamiento eficaz de una mayor variedad de pacientes con ansiedad



El ejecutivo sobrecargado de trabajo que está tenso, irritable y tiene dificultad de concentrarse debido a presiones financieras o a cambios de responsabilidades.



El ama de casa ansiosa que se preocupa por la finanzas de la familia y también por conflictos con los hijos, y se pone a llorar facilmente.



El paciente de edad avanzada, solitario, a menudo triste, que se preocupa por su mala salud y tiene dificultades para doriñir y aprensión con respecto al futuro.



El paciente cardíaco asustado que teme otro ataque de corazón, no puede relajarse, se preocupa por su familia y con frecuencia experimenta trastornos digestivos y mareos.

Tranquillisers for the pressures of everyday life

Notepad from Upjohn for doctors in Peru in 1992, promoting a benzodiazepine (Xanax or alprazolam) for treatment of "a large variety of patients with anxiety": the executive who is tense because of financial pressures and new responsibilities; the housewife who is preoccupied with family finances and conflicts with her children; the elderly patient who is lonely and concerned about her poor health; and the cardiac patient worried about having another heart attack and experiencing digestive problems.

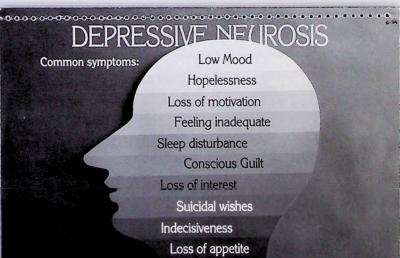
problem



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Sandoz promotes an antipsychotic, thioridazine, in India in 1990, as a substitute for diazepam, and suggests treatment of symptoms such as "feeling inadequate" and "indecisiveness".

The indications for this drug in the British National Formulary are "schizophrenia and other psychoses, mania" and shortterm management of psychotic episodes or severe anxiety, agitation and restlessness. BMA and the Royal Pharmaceutical Society of Great Britain, British National Formulary, London, BMA and The Pharmaceutical Press, No 25, Mar 1993, pp149, 154



Put your patients on Melleril-25 right away.... See them respond WITHIN A WEEK

WHAT IS HEALTH ACTION INTERNATIONAL?

Health Action International (HAI) is an informal network of some 150 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues in 60 countries around the world. HAI has active participants in Africa, Asia, Europe, Latin America, North America and the Pacific region.

HAI believes that all drugs marketed should:

- meet real medical need;
- have therapeutic advantages;
- be acceptably safe;
- offer value for money.

In 1988 the World Health Organisation (WHO) calculated that of the 5 billion people in the world, between 1.3 and 2.5 billion have little or no regular access to essential drugs. At the same time it is estimated that as many as 70% of the drugs on the global market are inessential and/or undesirable products. HAI supports the Essential Drugs Policy of the WHO which concentrates on the supply and use of some 250 drugs considered to be the most essential. HAI also believes that the problem of the enormous numbers of inappropriate and ineffective products must be tackled.

HAI recognises that access to appropriate medicines is only one element of health care and that a significant improvement in world health will be achieved only if the problems of poverty, poor sanitation, and malnutrition are addressed.

HAI works through research, education, action campaigns and dialogue. HAI publications are used by health workers, government drug regulatory agencies and consumers around the world. Research undertaken by HAI's participants contributes to better education about drugs, and is the foundation for campaigns calling for stronger regulations on the production, distribution, marketing and use of drugs. HAI participants organise and participate in educational and training seminars in many parts of the world. Special attention is given to the use of medicines by women and to the development of user information. HAI participants are active in monitoring promotion practices, supporting efforts to establish national drug and health policies, and encouraging the supply of essential drugs.

In the few years since its foundation, the HAI network has achieved successes at both international and national level. HAI's contribution has been important in areas such as:

- achieving a gradual improvement in the advertising standards of many of the major multinational pharmaceutical companies;
- promoting the essential drugs concept and in winning both political acceptance and public understanding of rational drug use;
- establishing an international network which has become accepted as the group protecting the interests of users of medicines;
- campaigns leading to regulatory action in various countries to:
 - ban harmful antidiarrhoeals,
 - stop the inappropriate use of high dose hormonal drugs,
 - end the use of anabolic steroids as growth stimulants for children,

...many examples can be given but much work remains to be done.

HAI works at many different levels: with health workers in many countries; with academics and trainers; with government officials and national health associations; with regional decision making bodies such as the Commission of the European Community; with the pharmaceutical industry; and at the international level. HAI participants have taken part in many consultations and discussions organised by the WHO as part of its revised Drug Strategy and been active in mobilising support for the WHO Action Programme on Essential Drugs and Vaccines.

If you would like more information or would like to become involved in HAI, contact one of HAI's three regional coordinating offices:

HAI Clearinghouse/Action for Rational Drug Use for Asia (ARDA) c/o IOCU, P.O. Box 1045, 10830 Penang, Malaysia tel: + (604) 371396, fax: (604) 366506

AIS Latin America c/o Accion para la Salud, Avda. Palermo 531, Dpto. 104, Lima, Peru tel/fax: (5114) 7123202

HAI-Europe J.van Lennepkade 334-T 1053 NJ Amsterdam, the Netherlands tel:(31 20) 6833684, fax:(31 20) 6855002

Hai believes that all drugs marketed should meet real medical need, have real therapeutic advantages, be acceptably safe and offer satisfactory value for money.

Health Action International is an informal cooperating network of some 150 consumer, development action and other public interest groups worldwide. The HAI network works to further the safe, rational and economic use of pharmaceuticals worldwide; to promote the full implementation of the World Health Organization's Action Programme on Essential Drugs and to look for non-drug solutions to the problems created by impure water and poor sanitation and nutrition.



Health Action International