PILLS FOR ALL ?

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In November 1982, the Union Health ministry announced its intention to allow distribution of the oral contraceptive pill(OC) through village — level health workers and to introduce 'social marketing' or over-the-counter sale so as to raise the number of OC users in this country from the present 1.1 lakh to two million in the near future. A year later, in October 1983, the British media began renewal of the focus on long-term safety of the Pill, a debate revived by the publication of two studies in the reputed UK journal, **The Lancet** (October 22, 1983), which linked Pill use with breast and cervical cancers.

While this new debate over long-term risks is expected to be a prolonged one, it would be appropriate to take a comprehensive look at the implications and possible consequences of the government's proposed Pill programme. Two questions of importance arise : 1) What are the pitfalls of a mass Pill programme in a developing country in the light of the experiences of other such countries, and in the light of this country's own past experience ? 2) Are the claims of Pill safety relevant to a target population which has poor access to back-up medical care ?

This paper besides exploring these questions, will a) Sum up the findings so far known regarding risks and benefits of OCs. b) Briefly outline the current debate on cancer risks. c) List the brands and types of OCs sold through the private sector and distributed through government channels in this country.

Possible Pitfalls.

The implications and consequences of a mass Pill programme have been summed up in a letter sent to Union Health minister B. Shankaranand in March 1983 by the Hyderabad branch of the Indian Women Scientists' Association (IWSA). The full text is reproduced below because of its importance.

"We, members of the Hyderabad branch of the Indian Women Scientists' Association (IWSA) are seriously concerned over the Health ministry's recently announced proposal to liberalise the distribution of oral contraceptives (OC) through village-level health workers (VHWs).

"While we fully realise the need to reach safe and effective birth control to rural and urban men and women, **the proposed Pill programme will be neither safe nor effective.** (all emphasis in the original).

"At a meeting on March 9, we discussed the implications of allowing the Pill to be prescribed by the lowest level paramedical staff, and we are unanimously agreed that such a move will not only fail to serve the purpose of reducing the population growth rate, but will be counter-productive. **We therefore urge you to drop the proposed Pill campaign** and utilise the funds more effectively for augmenting the health services and popularising other methods of contraception such as the barrier methods, the intra-uterine devices, tubectomy and vasectomy. Also, the facilities for safe abortion need to be improved in rural areas.

"Some of us are doctors and scientists who know from past field experience that VHWs cannot be expected to ensure safe Pill distribution. **No training can overnight change this fact.** Also, target-oriented incentives will result in irresponsible Pill promotion, which will eventually backfire on the entire family planning programme. Though oral Pills are effective if taken daily and safe for women not having certain contraindications, they cannot be prescribed for women with past or present history of a variety of diseases such as diabetes, liver disorders, blood pressure, thrombo embolism, rheumatic heart disease, cancer, depression, and others. In addition, there are no national data available on the prevalence of these diseases in Indian women. A VHW can never identify the women at risk nor can one be sure that the women would consult a doctor within two or three months of starting the OC as envisaged. A VHW would not be able to ensure regular Pill intake. If for some reason there is short supply, he or she may distribute the few Pills all round, little realising the ill-consequences. There is every possibility that under a mistaken notion oral Pills will be used (without success) to terminate unwanted pregnancies. OC taken during early pregnancy can be injurious to the foetus. The method failure rate due to irregular OC intake is likely to be as much as in other safer methods such as barrier methods and much more than with IUDs.

"In rural India, prolonged lactation provides natural contraception with an inter-pregnancy interval of two to three years. OCs are known to suppress lactation and thereby increase the chances of conception. Effects of contraceptive steroids secreted in milk are not yet known. Unfortunately the cervical cap which used to be available at one time, is no longer available in India. Even the loop is not made freely available to Government and private doctors who are keen to do family planning work. The services of VHWs can be better utilised to motivate couples to use these safer, reversible methods for spacing and encourage sterilisation of the husband or wife when the family size is complete.

In the very few instances where the woman and the doctor feel that OC is the best option, only a doctor should prescribe it and perhaps in those few select cases, the services of the VHWs can be taken to reach the Pill packet every month to the women and ensure the women come for a check-up once in three-four months.

"We wish the Government's efforts towards family welfare every success. In this connection we may mention that the main objectives or our organisation are dissemination of scientific knowledge and creation of scientific temper in society. We have arranged lectures, discussions and exhibitions on health and family welfare, in Hyderabad and surrounding rural areas, and give these subjects high priority in our programme.

"We hope that your ministry will give kind attention to our appeal and reconsider your decision to allow VHWs to distribute oral contraceptive Pills."

The Bangladesh Experience

Steve Minkin, formerly of UNICEF, has listed the consequences of the Bangladesh government's 'inundation' programme with the Pill in the 1970s. (1) Quoting a USAID-funded study, which evaluated the programme, he writes : "It was found that even the 'trained' family planning workers could not answer the most elementary questions concerning the use and effects of oral contraceptives. After three years of experience with the inundation programme 44 per cent could not say how many days after the onset of menstruation a woman should start taking the Pill; 82 per cent did not know what advice to give to a woman who missed taking the Pill on five consecutive days; and more than 75 per cent could not say what type of side-effects might be anticipated by women on the Pill."

Referring to 'social marketing' by which shopkeepers were supposed to screen potential acceptors with the help of a set of questions, Minkin observes : "Subjects such as birth control are not easily discussed between men and women in Bengali society. Screening is further

complicated by the fact that married women do not do the shopping in this Moslem country. The shopkeeper's cursory screening would be a second-hand account from a woman's husband."

The socio-economic and cultural features common to Bangladesh and India suggest that the above experience has relevance for this country. A second relevant lesson from the Bangladesh situation relates to the promotion of the Pill to lactating mothers.

Intensive family planning drives in Bangladesh have offered the Pill to breastfeeding mothers with disastrous consequences. The Pill inhibits production of breastmilk and also affects its nutritional quality. "In Bangladesh where breastfeeding accounts for a long natural birth interval in rural populations, there is evidence that indiscriminate promotion of the Pill meant that even breatfeeding women took it. Their milk then dried up, so they abandoned the Pill. They then had protection neither from breastfeeding nor from artificial contraception. As a result women became pregnant much sooner than they would have done in normal circumstances."(2)

The latest WHO directive in this regard is clear (3) : national FP programme should maximise on the contraceptive effects of lactation and should not promote the combination OCs (the type of Pill most widely used) to breastfeeding mothers in the first four to six months. Will the proposed Pill programme implement this directive carefully? Special instruction will be needed for village level Pill distributors especially if the FP drive is target-oriented and offers incentives for recruiting acceptors.

The Indian Experience

India had in the past, contemplated and rejected the idea of a mass Pill programme. The following extract is revealing (S.P. Jain, 1975, (4)) : "The government of India conducted trials in about 300 centres throughout the country and covered about 10,000 women to study the medical and social acceptability of oral contraception among Indian women with the objective to determine its value for the Indian FP programme on an appropriate scale. The special committee which reviewed the experience considers that the Pill may not be accepted in any mass programme but should be administered in closed communities under medical supervision. Its continued use is not advisable. There should be intervals of non-use. The National Institute of Family Planning analysed the experience of 1512 acceptors and found that 46 per cent discontinued after six months, 61 per cent after 12 months and 73 per cent after 18 months. The experiment is comparable to that in Taiwan. High discontinuation rate was due to nausea, vomiting, dizziness, bleeding and planned and unplanned pregnancy...

Checklist for prescription of oral contraceptives as prescribed by WHO (Oral Contraceptives : Technical & Safety Aspects, 1982).

Check the following by history and examination :

	Yes	No
Above 40 years of age	.....	.....
Above 35 years of age and a heavy smoker	.....	.....
Seizures	.....	.....
Severe pain in the calves or thighs	.....	.....
Symptomatic varicose veins in the legs	.....	.....
Severe chest pains	.....	.....
Unusual shortness of breath after exertion	.....	.....
Severe headaches and/or visual disturbances	.....	.....
Lactating (Yes = for less than 6 months)	.....	.....
Intermenstrual bleeding and/or bleeding after sexual intercourse	.....	.....
Amenorrhoea	.....	.....
Abnormally yellow skin, eyes	.....	.....
Blood pressure (Yes = above 140 mm Hg	.....	.....
(18.7 kPa) systolic and/or 90 mm Hg	.....	.....
(12 kPa) diastolic)	.....	.....
Mass in the breast	.....	.....
Swollen legs (oedema)	.....	.....

Instructions

If all the above are negative, the woman may be given oral contraceptives. If any are positive, she must first be seen by a doctor.

WHO Recommendations for Training of Personnel

The training of the personnel responsible for providing the pills in any given system must ensure that the participants :

- Understand the concepts and rationale of family planning;
- Are capable of describing the different contraceptive methods available and their risks and benefits;
- Indentify the cases that present a contra-indication to the use of the Pill, or special problems that require medical intervention and/or supervision;
- Effectively instruct the women how to take the Pill and when to come back for follow-up;
- Recognize complications and make the necessary referrals;
- Maintain basic records for patient management and programme evaluation.

Follow-up routine.

Women should be re-examined 3 months after starting oral contraception and thereafter at 6-monthly or at least yearly intervals.

In countries where screening programmes for cervical cytology exist, oral contraceptive users should be encouraged to take the opportunity to have such a screening every 2 years. Discovery of cervical dysplasia should be handled according to standard gynaecological practice.

An annual examination of the pelvis and of the breasts is recommended.

Where a woman with special problems is taking oral contraceptives she should be seen more frequently. If a change in the type of Pill is medically indicated, the reasons must be carefully explained to and understood by the woman.

The physician or other health worker should be alert to the possible development of thrombotic or vascular disorders : leg vein thrombosis or pulmonary embolism, coronary heart disease, cerebrovascular disorders, and retinal vein thrombosis.

Women with a history of depression or who experience depression, when on the Pill, should be carefully observed and the contraceptive discontinued if evidence of hormone-related depression occurs.

The wife's education was the strongest factor among all the variables" (i.e. for acceptance and continuation).

Safety of a Mass Pill Programme

Advocates of mass Pill distribution (without a doctor's prescription) in developing countries argue that the risks of the Pill are far less serious than the risks of repeated child bearing and maternal mortality, and that the benefits of effective contraception are more important to Third World women. They also claim that the health risks of the Pill are most serious for women who smoke and that most Third World women don't smoke.

Apart from the points already raised in the IWSA letter earlier quoted, the following criteria contradict the above arguments (**New Internationalist,** 1979 (5)): The **NI** article quotes FP consultant Dr. Geraldine Howard who talks of her experience in Ghana and Nigeria and stresses, "the haphazard way in which rural women would take the Pill for a while, then possibly give it to some friend, run out of Pills and stop," A USAID study quoted in the same article of 360 villages in Bangladesh showed that though 13,087 women had initially accepted the Pill, three months later only 2,835 were actually taking it. The dangers of irregular Pill intake include unwanted pregnancy and birth defects.

The **NI** article also refers to a variety of reasons for irregular intake and dropping out. Sometimes it is because of an uncertain delivery system, aggravated by poor road transport and communication facilities to remote areas. Sometimes supply is held up by delays in ports and warehouses. Often women drop out because of side effects. This last point has two important dimensions.

One, in many Third World countries, only one type of Pill (usually with 50 mcg estrogen) is available in the government programme because of bulk buying. This means that if there are side effects, an alternative type of Pill may not be offered and so women may drop out. Even if alternative types are produced they may not be widely stocked in a mass distribution system, nor may the village level workers be knowledgeable enough to suggest a switch to a different dose pill. Second, there is also the factor of the health hierarchy being supportive and sympathetic enough to reassure women who experience side effects and to persuade them not to drop out. This seems doubtful under the present health set-up.

Some other safety aspects also exist (6). There is no provision at all in the present situation for the Pap smear which in the West is an absolute must for women who contemplate taking the Pill. Even WHO Pill studies in India have never included this important screening test for the subjects of Pill trials. (There are ICMR contraceptive testing units all over the country which collarborate with the WHO). Estrogen is known to aggravate already existing cancers, hence the need for screening of Pill acceptors for cancer. Cervical dysplasia (pre-cancerous changes in the cells) is widely prevalent among the low-income groups, and in the light of the current debate over Pill use and cervical cancer, the absence of adequate health-care back-up has serious implications in a mass Pill programme.

It has been argued that health workers and guides will be given a list of questions by which to screen out women at risk. Not only can some of the serious contraindications **not** be diagnosed through a yes/no question-answer session, but also some of the conditions may develop later when a woman is already on the Pill. If she has no access to medical advice, she may never be told that she must stop the Pill. Although the Pill programme on paper envisages medical check-ups for acceptors, the health care system has too many lacunae at present to make this a realistic possibility. It is worth recalling that the IUD programme of the 60s backfired precisely because of inadequate follow-up support and treatment to women experiencing severe side-effects.

How Pills Work

OCs contain synthetic hormones (steroids) similar to estrogen and progesterone produced during the menstrual cycle. Estrogen inhibits ovulation so that no egg is released and pregnancy is prevented. Progesterone thickens the cervical mucus, making it a barrier to sperm, and also makes the uterine lining unsuitable for implantation. The widely used OCs are 'combination' Pills containing both synthetic estrogen and progestin.

There is also the 'Mini Pill' containing only progestin, sometimes recommended for women who cannot tolerate the side-effects of estrogen. Its contraceptive effectiveness is less reliable and it causes irregular menstrual bleeding which is often unacceptable. WHO suggests that if at all OCs are needed by lactating mothers, a progestin -only Pill is preferable to the combination OC because progestin alone is not known to inhibit milk production.(3)

Different brands of OCs have different kinds, strengths and ratios of synthetic estrogen and progestin. 'Low-dose' OCs with 30 mcg of estrogen are increasingly preferred in the West but these sometimes cause spotting between periods. The earliest OCs had an unacceptably high hormone content. Two kinds of synthetic estrogen used are ethinyl estradiol and mestranol. Numerous kinds of progestins are used and the side-effects are related to the estrogen in the Pill.

Currently, trials are on with 'biphasic' and 'triphasic' Pills designed to imitate the hormonal pattern of the menstrual cycle. The 'sequential' Pills used in earlier years were intended to work on a similar principle but were discontinued because they were thought to be harmful.

Low-dose OCs may be less effective for poorly nourished women who absorb less hormone than do other women. Since OCs interact with certain other drugs, low-dose OCs may be less effective during therapy with these drugs. **(Population Report,** 1982)

Indications for Discontinuation

Medication should be discontinued under the following circumstances :

- Suspected pregnancy;
- *Thromboembolic disorders*, such as thrombophlebitis, pulmonary embolism, cerebrovascular disorders, myocardial ischaemia, mesenteric thrombosis, and retinal thrombosis;
- Visual defects, partial or complete, proptosis, diplopia, papilloedema, or ophthalmic vascular lesions;
- Severe headache of unknown etiology or migraine;
- Epilepsy, if aggravated;
- *Migraine when requiring treatment with* vasoconstrictors;
- Elective surgery;
- Jaundice;
- Appearance of hypertension
- Occurrence of apparently hormone-related depression; and
- The woman reaching 40 years of age.

Risks and Benefits of Pill use

Studies on US and British women have shown that OC use increases risk of : venous thromboembolism or blood clots in the veins; ischemic heart disease including heart attacks; cerebrovascular disease or stroke; hypertension or blood pressure.

OC use is also linked with a higher incidence of urinary and vaginal infections, changes in glucose tolerance and insulin metabolism, gall bladder disease and liver tumours. Certain other adverse effects which are disputed or occur only in some women, or are considered 'minor' or 'temporary' include : depression, nausea, changes in sexual desire and response, weight gain, skin problems like acne and changes in pigmentation, gum inflammation, fluid retention, and lower immunity to virus infections. Findings linking the Pill with pituitary tumours and melanoma (cancer of the skin) are considered inconclusive.

Among the benefits are : almost 100 per cent contraceptive effectiveness provided the Pill is taken regularly; reduced risk of endometrial and ovarian cancers; scantier menstrual bleeding which could be beneficial to the anaemic; regular periods and relief from menstrual cramps and pre-menstrual syndrome.

Other Effects

OCs interact with certain drugs (used in therapy) so that the effectiveness of both may be reduced. They also have an adverse effect on nutritional status. Because the Pill induces a deficiency of the B-complex group of vitamins, especially B6, as well as of vitamins C and E and folic acid, supplements of these are considered necessary for women on the Pill. Studies on undernourished women have not shown any deterioration of already existing severe deficiences as a result of Pill intake.

The occurrence of an unexpectedly high number of pregnancies among women taking the Pill who were being treated for tuberculosis with the antibiotic rifampicin, showed there was an 'antagonism' between OCs and this drug. The popular prescribers' guide, **MIMS**(8) in its section on oral contraceptives adds : "Drugs affecting OCs include phenytoin, primidone, barbiturates, rifampicin, ampicillin, sulphamethoxypyridazine and chloramphenicol which have all been reported to result in contraceptive failure."

Various laboratory tests may also show altered readings for women on the Pill, and some of the tests may be "seriously compromised". Regarding the interaction between OCs and endemic diseases in developing countries, **Population Report** A-6(1982) says : "Hormonal contraceptives could, in theory, interact with disease endemic in developing countries to create or aggravate other conditions. Two case-control studies have suggested that the Pill may alter immunological response to malaria, lowering users' resistance to the disease. Liver damage caused by parasites might alter hormone metabolism, increase levels of hormone in the blood, and so aggravate OC side-effects. According to South Korean and Thai studies, however, liver function is not significantly changed in OC users who have liver flukes. Schistosomiasis causes greater liver damage than liver flukes and so could be a greater problem for OC users but it has not yet been studied. Sickle-cell anaemia increases blood coagulability and stresses the liver, so OC users with sickle-cell disease might be at higher risk of thromboembolic or liver disease. The evidence available is, however, limited and inconclusive."

OCs have resulted in temporary infertility after discontinuation in some women although conception is possible in most. Women going off the Pill are advised to avoid pregnancy for a few months by using other forms of contraception so as to avoid possible birth defects. Opinion varies regarding how long a woman should remain on the Pill. Two or three-year intervals with three-month breaks in between is one suggestion. In a mass Pill programme it is not clear how the authorities propose to look after this aspect, and what methods women will be advised to adopt during intervals of non-use.

Current Debate on Pill Safety

The Lancet (October 22, 1983) published two studies on OCs : one by Professor Pike and his colleagues from Los Angeles linked prolonged use of certain OCs before the age of 25 to an increase in breast cancer at younger ages. The other by Professor Vessey and his colleagues at Oxford suggests that long-term use of OCs may increase the risk of cancer of the uterine cervix.

These findings are being hotly debated and 1984 is expected to see several conferences and discussions by international experts to assess the relevance of the new findings. Earlier studies had actually suggested that Pill users are protected from benign breast disease and therefore from breast cancer as well.

In the wake of the Lancet articles, the Family Planning Association of UK(9) recommended that Pill brands with the lowest possible hormone content should alone be prescribed, urged women who are on, or had been on, the Pill to volunteer for screening for cervical cancer, and to learn self-examination for early detection of symptoms of breast cancer. The British FPA has also recommended regular Pap smears, before Pill use, one year after, and thereafter every three or five years till the age of 65.

Since the Los Angeles study linked breast cancer with high levels of progestins in the OCs, it is necessary to know in the Indian context an assessment of the dosage and potency in currently available brands and types of OCs in India for this risk factor.

In November 1983, the International Planned Parenthood Federation (IPPF) said that it considered that recent findings as inconclusive(10) but that 're-analysis' of the data is underway, and that any policy change regarding the Pill would be made only in the light of further evidence.

Selection of oral contraceptive pills for a family-planning programme

When selecting oral contraceptive pills for a family planning programme, the administrative should particularly consider using those from manufacturers who can guarantee continuity of supply and ensure a shelf-life of the products of more than 4 years. The selection of the specific products to be stocked should also be based on factors that indicate maximum efficacy, safety and likely continuation of use.

Products containing 30 or 35 ug of estrogen should be the oral contraceptives of first choice. Additional products containing the same type of progestogens but 50 ug of estrogen can be used for women experiencing an unaccepted degree of breakthrough bleeding or spotting while taking the lower dose preparations.

The 2 dose levels of estrogen should be available in combination with each of 2 progestogens - for example, levonorgestrel and norethisterone. The availability of an alternative progestogen will ensure that a high incidence of side-effects attributable specifically to one progestogen can be avoided by changing to a product containing a different progestogen.

To the minimal requirement of 4 combination pill products can be added 2 progestogen-only products containing two different progestogens.

As barrier contraceptives (particularly condoms, diaphragms, and spermicides) are periodically required by pill users, these should also be stocked. The shelf-life of barrier contraceptives may be affected adversely by different environmental factors, and they require special storage facilities.

When a change of pill is indicated, the reasons should be explained and understood by the woman in order to allay undue anxiety. This is true even when the same pill is given with a different brand name or package design.

All extracts from WHO offset publication no. 64. Oral contraceptives : Technical & Safety Aspects.

OCs in India

Under the section, 'Oral Contraceptives', **MIMS**(November 1983) lists the following brands. (Some have 21 or 22 tablets, with the remaining days of the cycle being tablet-free, to start again on the fifth day of the menstrual period. Packets with 28 tablets have seven inert tablets in a different colour and there is no break in continuity. Sometimes the 28-tablet pack has iron tablets instead of inert ones.)

Lyndiol(Organon) : Lynestrenol 1 mg, ethinyloestradiol 0.05 mg, 22 tabs.
Minovlar ED(German Remedies) : Noresthisterone acetate 1 mg, ethinylestradiol 0.05 mg, 28 tabs.
Noracyclin(Ciba-Geigy) : Lynestrenol 1 mg, ethinyloestradiol 0.05 mg, 22 tabs.
Orlest-28(Parke-Davis) : Norethisterone acetate 1 mg, ethinyloestradiol 0.05 mg, 28 tabs.
Ortho Novin(Ethnor) : Norethisterone 1 mg, mestranol 0.05 mg, 21 tabs.
Ovral(Wyeth) : Norgestrel 0.5 mg, ethinylostradiol 0.05 mg, 21 tabs.
Ovral-L(Wyeth) : Norgestrel 0.3 mg, ethinyloestradiol 0.03 mg, 21 tabs.
Ovulen-50(Searle) : Ethinodiol diacetate 1 mg, ethinyloestradiol 50 mcg, 21 tabs.
Primovlar 30(German Remedies) : Norgestrel 0.5 mg, ethinyloestradiol 0.03 mg, 21 tabs.
Primovlar 50(German Remedies) : Norgestrel 0.5 mg, ethinyloestradiol 0.05 mg, 21 tabs.
Primovlar 50 ED(German Remedies) : Norgestrel 0.5 mg, ethinyloestradiol 0.05 mg, 21 tabs.

The prices of the above brands range from Rs. 4.25 to Rs. 6 for a month's supply.

The public sector Indian Drugs and Pharmaceuticals Ltd (IDPL) manufactures an OC for free distribution through government hospitals and family planning clinics as well as through the Family Planning Association of India. It contains : Norethisterone Acetate B.P. 1 mg, ethinyl estradiol I.P. 30 mcg — 21 tablets, plus seven tablets of ferrous fumarate (iron). An IDPL variety of OC containing 50 mcg of estrogen is also reportedly available.

Although at present in India OCs belong to the Schedule L group of prescription-only drugs, they can easily be bought over the counter. In USA and UK, OCs are strictly prescription-only drugs which cannot also be advertised to the lay public in the general media. In those Third World countries where OCs are liberally distributed, they are advertised like consumer products in the lay press, and over radio and television. Every OC ad in US medical journals and periodicals carries a statutory warning to the effect that : Serious as well as minor side-effects have been reported with OC use. Physicians should be fully informed of these and should be alert to any symptoms of serious disease and discontinue OC when appropriate. According to Dianne Melrose (**Bitter Pills,** Oxfam, 1982), Pill advertisements to the general public in the Third World tend to keep 'negative' information to a minimum and present a 'rosy' picture. A press advertisement for **Maya** brand OC in the **Bangladesh Times** in 1980 describes the product as one which will "keep the women in you alive and young" and that it "improves your complexion."

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All boxes have been extracted from "Oral Contraceptives: Technical Safety Aspects, WHO Offset Publication No.64 (1982)

Questions on the benefits and risks of the Pill are not limited to developing countries. In the West the debate still continues. We reproduce an excerpt from the article "Reselling of the Pill" which appeared in the June '83 issue of "Second Opinion", the monthly publication of the Coalition for the Medical Rights of Women.

The Reselling of the Pill

By Alice Wolfson

In recent months there has been a spate of publicity proclaiming the benefits of the "Pill" and downplaying what had previously been thought to be the dangers associated with its use. Those of us who had taken the pill at some point in our lives began to breathe a sigh of relief. The time-bomb we thought we were sitting on appeared to be defusing itself. If only this were true.

The safety of the "Pill" was one of the earliest issues addressed by the women's health movement. The issues of informed consent, benefits versus risks, and the ethical issue of feeding a powerful hormone to millions of healthy women sprang to national prominence after a group of Washington, D.C. women demonstrated at Senate hearings investigating the safety of the pill. The women, who had originally attended the hearings out of personal interest, were shocked at the news that they heard. The pill was relatively untested; scientific opinion differed markedly with regard to safety; and bowing to the interests of the Population Control establishment, the FDA Committee on Obstetrics and Gynecology were actually considering repressing British evidence pointing to a direct link between the pill and thromboembolic disorders - i.e. stroke, blood clots and heart attacks - and the pill.

Refusing to sit quietly by, D.C. Women's Liberation began a national movement that demanded a warning label on the pill so that women who were considering taking the drug could do so in as informed a fashion as possible. The original warning was extremely short, but it was the first time that drug manufacturers were ordered to inform patients about the possible side effects of a medication. Not satisfied with this warning, the women's health movement, led by the newly formed National Women's Health Movement, continued to agitate for a longer warning, one which would more clearly outline the known and suspected risks associated with pill usage. In 1977, full patient package inserts (PPI) were included with each package of birth control pills.

Dating from that year, pill sales have been steadily dropping. Although this trend is difficult to document exactly, Barbara Seaman, women's health activist, journalist, and one of the first people to ring a warning bell with regard to oral contraceptives, has tried to merge clinic figures of pill usage with figures issued by the Population Council and pharmacy sales figures. Seaman estimates that pill use has dropped from ten million to six million women a year. This drop, directly attributed to package inserts, represents a substantial loss of income to companies manufacturing oral contraceptives.

In 1980, the first wave of the "reselling of the Pill" began with the release of the "Walnut Creek Study". Accompanied by a great deal of media hype, the study, based on 16,000 women at Kaiser Hospital, Walnut Creek, claimed that the pill's hazards were "negligible", at least for healthy, white, middle-class women. Contradicting all other published research, the study went so far as to say that women taking the pill did not have an increased risk of heart attack, blood clots, strokes or death from any cause. The study, partially paid for by five pill manufacturers, including G.D. Searle & Co., was first revealed at a symposium sponsored by Searle. The researchers then participated in a nationwide public relations campaign sponsored by two manufacturers.

For the two clearly negative findings, increased rates of cervical cancer and malignant melanoma, the author of the study, Dr. Savitri Ramcharan, blamed the victims. Ramcharan intimated that pill users have too much sex and sunbathe more than other people. From such findings one might draw the conclusion that the pill is safe for young, white, middle-class women who do not have sex and who live in dark closets.

In March of this year, the **Journal of the American Medical Association** reported that two federal health agencies, the Center for Disease Control (CDC) and the National Institute for Child Health and Human Development, had found no association between pill use and breast cancer, and said that the pill might actually provide protection against endometrial and ovarian cancers. The report also noted that the pill seemed to protect women against developing rheumatoid arthritis. Again, both studies cited an increased incidence of malignant melanoma.

As one of those women who led the original women's liberation protest discussed earlier, I was amazed, excited and curious about these findings. Could it be that the estrogen in oral contraceptives, unlike any other estrogen preparation, could actually prevent, rather than cause, cancer ?

According to Barbara Seaman, in the cases of other estrogen-related cancers, like those caused by DES and Estrogen Replacement Therapy, it took thirty years of use before enough statistical evidence could be gathered to make the relationship between cancer and drug use apparent to epidemiologists. Seaman wonders why CDC appears to be so eager to proclaim the safety of the pill. She also questions some of the other findings.

According to Seaman, the Rheumatoid Arthritis Foundation has lodged a formal protest with regard to the findings on arthritis. They believe that if there is a relationship between the pill and arthritis, the pill seems to exacerbate arthritis. Moreover, the Foundation is sure that the pill seems to make women more susceptible to lupus, and lupus is a disease that can kill.

The CDC report also claimed that the pill seems to reduce iron deficiency anemia. Since many women who take the pill will take it without a break and thus do not menstruate they would, of course, be less susceptible to anemia. The report omitted any mention of the B6, folic acid, zinc, and vitamin C deficiencies which are generally accepted as directly related to pill usage. Additionally, the reports left out or de-emphasized those side effects where pill use seems to be more directly associated with tumor growth, such as the liver, the thyroid, the pituitary and the cervix.

Based on these reports, the FDA is being pressured to change the labelling on the pill to include a listing of its supposed benefits, the benefits cited in the studies just discussed. If the FDA does this it will be clearly bowing to drug company, population control establishment, and physician pressures. The only benefits ever listed for a drug are for its prescribed indications. Therefore an appropriate benefit for the pill would, of course, be to prevent pregnancy, or perhaps to regulate menstruation. To include in such a listing of benefits the prevention of breast cancer or ovarian cancer represents an extremely biased presentation of questionable data as well as a breach of generally accepted practice.

One of the reasons most commonly offered for treating people with drugs that have side effects which may cause serious or tragic physical disease or disabilities is that the side effects aren't as bad as the disease. In the case of oral contraceptives the "disease state" appears to be pregnancy; the assumption is that the only way to prevent it is with the pill, and many women are making the choice to use it without fully understanding its side effects. It took nine years after the marketing of the pill before any public mention of its potential hazards was made. The powerful forces that ensured this initial silence appear to be hard at work, once again manipulating the FDA, downplaying the hazards of the pill, and attempting to resell it based not on its lack of side effects, but rather on its potential for producing beneficial side effects.

Those of us who are of child-bearing age are faced with a dilemma: There is no 100% effective, risk-free form of birth control. Our alternatives are limited. What works for one person or relationship may not work for another. It is clear, too, that the choice of birth control method involves much more than simply weighing medical risks vs. effectiveness. Decisions involve feelings about one's own sexuality, male/female dynamics and the developmental stage of a particular relationship. Weighing these different factors, many of us may, indeed, choose the pill. But if we do so we have the right to make that choice as fully informed consumers of health care and not as a target audience for a high-powered media campaign orchestrated by Madison Avenue for selling us the "PILL".

Thromboembolism : The clotting of a blood vessel as a result of a clot having broken away from the wall of a distant blood vessel and travelling through the circulation.

Thrombophlebitis : Inflammation of a vein with blood clot formation within the vein.

Myocardial ischemia : Lack of blood supply to the heart muscle (myocardium) due to a spasm or shutting down of the artery which supplies it. Coronary artery spasm causes temporary ischemia of heart muscle.

Hg : Chemical symbol for mercury.

kPa systolic : The force with which blood is pumped when the heart muscle is contracting.

kPa diastolic : The blood pressure level during the time the heart muscle is relaxed.

Retinal Thrombosis : Blood clot in the retinal artery (artery which supplies the retina of the eye) leading to blindness.

Mesenteric Thrombosis : Blood clot in the arteries which originate in the abdominal aorta and supply blood to the intestinal tract.

Proptosis : Falling out of position of an organ, such as bulging of the eyes seen in some cases of overactivity of the thyroid gland; prolapse.

Diplopia : Seeing double.

Papilledema : Swelling of the optic nerve in the back of the eye. When seen through an ophthalmoscope, it may indicate increased pressure within the skull.

Vaso constriction : The narrowing and contraction of blood vessels.

Schistosomiasis : 1. "Swimmer's itch" - a skin condition incurred by swimming in waters infested with a parasite of snails. 2. In Asian and tropical countries it is a serious disease caused by infestation with the parasite known as bilharzia.

Liver flukes : A worm of the Tremotoda group. Various forms cause disease in organs such as the intestines the liver, the lungs and the blood stream.

Sickle-cell anaemic : A type of anemia, characterized by a sickleshape to the red blood cells. It is seen mostly in Negroes or dark skinned people.

The CED Health Cell specializes in documentation and dissemination of information on health issues. This 'Counterfact' has been written by Vimal Balasubrahmanyan who writes on socio-medical, feminist and population issues.

With this issue, we are starting a new experiment. From henceforth, to each counterfact we will add further contributions and counterpoints from readers as well as excerpts from other publications. We are beginning right now by including an extract from 'Second opinion', which highlights the 'reselling' of the pill in the eighties.

Send your comments or criticism to :

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