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For a Sensitive Prescription

Dr. Mira Shiva

Medicines for women raise a pivotal issue, linked so sensitively as it is to birth. Dr. MIRA SHIVA examines some trends that disregard this link with impunity, stressing also the need to make essential drugs available for women.

The Thalidomide disaster in the 60's sent shock waves through the medical world. It was realized that medicine could be hazardous toll, hazardous enough to result in over 40,000 babies being born without limbs because their mothers had been prescribed Thalidomide during pregnancy. The indications for which Thalidomide was introduced by German company, Chemic Grunenthal, first as an antimicrobial against respiratory infection and later as a sedative in 1957, became astoundingly long and covered conditions like: cough, cold, nervousness, neuralgia, headache, migraines, asthma and diarrhea. It became, in other words, West Germany's "baby sitter".

Had it not been for socially conscious layers, journalists and a few committed medical professionals, the tragedy been allowed to go on for much longer.

D.E.S (Diethylstilbestrol)

The D.E.S. (Diethylstilbestrol) scandal followed the Thalidomide disaster. D.E.S. was advertised by manufacturers as "recommended for routine prophylaxis in all pregnancies". It was given for stopping beast milk, against breast cancer in women and prostatic cancer in men. At the same time, it was included as a tonic for hair growth, as a growth stimulator in cattle feed and as a sex pill. In 1953, miscarriages were found to be more common among DES users, yet manufacturers advertised it: "for bigger and stronger babies'" and boasted that, it "makes normal babies more normal" and "creates better maternal environment." It was many years later i.e. in 1971 that it was found that the increasing occurrence of vaginal cancer in young women had a correlation with the use of DES by their mothers when the young women were still in their mothers' wombs. By 1977, deformations of uterus-vagina fallopian tubes in DES daughters was noticed, resulting in increased spontaneous abortions, ectopic pregnancy (conception occurring

in the fallopian tubes instead of the uterus) and premature births. Much later, the correlation between DES taken during pregnancy with testicular problems in dons was observed when the latter grew up. Congenital problems like undescended testes, etc. were noticed. Inevitably, effects on the kidneys or liver of the foetus could be diagnosed only long after birth. Apart from DES users passing on negative effects to the next generation, the users themselves were found to have a higher incidence of cervical cancer.

Fixed Dose Combinations of High Dose EP drugs

It is absolutely essential that drugs known to have teratogenic (negative influences during pregnancy) effects are not prescribed to pregnant women, and warnings on the packs be enforced. The scandal of high dose Estrogen Progesterone combination drugs is perhaps more shocking since it took place in the eighties when adequate information already exited about the association of its use with congenital malformation. Not merely was it being sold without adequate warning of its serious side effects if taken during pregnancy but, ironically, it was being recommended for use as a hormonal pregnancy test, as an abortion inducer and also as treatment for threatened abortion. The fact that its manufacturer, Organon (Infar) was not allowed to even register the product in its parent country, the drug being banned by drug regulatory authorities in several countries and withdrawn by manufacturers themselves could not have been unknown to our own drug control authorities.

The EP campaign was the first major drug campaign in India and was launched by women's health and consumer groups. The issue was not just a demand for withdrawal of a potentially hazardous product but a coordinated collective effort to highlight the deficiencies in drug registration and licensing. Licenses continued to be extended without a review of the safety or therapeutic status of the product concerned even when safer and better alternatives existed. The 8-year process of trying to get these drugs off the market highlighted the gross lacunae in our Drugs and Cosmetics Act of 1940 whereby hazardous drugs could not be banned. (The amendment of 1983 made this possible only theoretically). There was no clause ensuring a demand for consumer caution in regional languages through the pictorial warning of a pregnant woman marked over with a cross. Even the Consumer Protection Act of 1986 could not protect potential victims, as under it, action was possible only after the damage was done.

It was evident that women needed to be informed and warned about certain drugs and a closer scrutiny required of the clinical trials being conducted for drugs meant for 'women only'.

Long Acting Injectable Hormonal Contraceptives

While the controversy over Depo Provera, a long acting injectable hormonal contraceptive for women, was taking place world wide, in India, clinical trials of NETEN (Norethisterone Enanthate) were being conducted in violation of the Helsinki Charter on Clinical Trials. Women's organizations such as Saheli and Stree Sanghatana took up the issue and even challenged it in the Supreme Court. Several queries were raised. In village conditions where hardly any diagnostic or therapeutic facilities exist, how would side effects of these hormonal preparations such as serious menstrual irregularity or even malignancy be managed? What would be the effect of NETEN injections on women already pregnant (the pregnancy diagnosis having been missed)? What would be the effect on breast fed babies if NETEN is given to lactating mothers? If serious side effects were observed, in the absence of antidotes, how could the effect of long acting injectables be stopped?

Linked to this are some essential questions: Why is most contraceptive research directed on women's contraceptives? Why such emphasis on long acting hormonal preparations especially when in a large number of conditions its therapeutic value is seriously doubted. (Ref. Steroid Hormones in Pregnancy-Sathya 1982).

With Norplant (another long acting injectable contraceptive to be inserted under the skin) almost ready to be marketed as part of National Health Programs, it is essential that women, specially women health personnel and others involved with women's health, seek unbiased drug information about these medicines meant for women. It won't be long before an antifertility vaccine as contraceptive and RU 486 as an early abortificient will be available in the market.

Hormonal Drugs for Childbirth

Increasing use of oxytocics (female hormones that induce uterine contractions during childbirth) has been associated with birth anoxia (lack of oxygen), precipitate labor and even prolonged especially when injections are given too early. The wide use of ergometrine injections by rural medical practitioners, dais and untrained personal without adequate information about its safe use and risk potential is well known. This is not to say that oxy-tocics widely used for induction of labor, even in hospitals are always totally safe. Negligence regarding concentrations in the intravenous drip or the rate of the drip can bring on labor too rapidly leading to rapid and severe uterine contractions, giving little time for uterine relaxation. It is only during uterine relaxation that the foetus receives oxygen through the placenta. Also overuse of sedatives in labor

can cause respiratory depression in the baby at the Potentially toxic drugs if given in dosages according to schedules fixed in the west can prove to be relatively more harmful. For it must be remembered that a large number of Indian women are malnourished, anemic and underweight. A proneness to frequent infections only makes matters worse. Moreover, there are sections of our tribal population in Orissa, Gujarat etc. suffering form sickle cell anemia and G6PD, a congenital enzyme deficiency disease of the blood. Sulphas and other drugs can cause severe haemolysis (breakdown of red blood cells). In a population thus affected, the use of certain drugs can be disastrous for the patient, specially if she is pregnant. Such drugs sold in endemic regions must have warnings in regional languages with health personnel and others made aware of these drug reactions.

Essential Drugs

While the safety aspect of drugs used by women is very important - the availability of essential drugs is equally so. Women-related health work has unfortunately been equated with family planning work or child birth-related medical care. Unfortunately, diagnostic and therapeutic facilities for women's common gynecological health problems are inadequate, if not totally non existent in peripheral areas. Non availability of trained women medical personnel, unsuitable hospital timings, long distances, poor transport - all prevent women sufferers from seeking medical help. Even when they do, adequate medicines for many gynecological, problems don't exist.

A community-based study by Dr. Rani Bang in Gadcharoli has shown that around 92 per cent women suffered from some form of gynecological disease. When a sufficient quantity of drugs needed to complete a course don't exist, the emergence of drug resistance in gonorrhea or syphilis only makes matters worse through its increased incidence. Reprehensible practices such as intercourse with virgins as an alleged cure for syphillis only underscores the tragedy. Gynecological infections in women need to be treated early and adequately since complications lead to chronic pelvic infections resulting in infertility or an ectopic pregnancy which endangers the life of the mother.

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Another illness from which women often suffer in silence is the frequency of urinary tract infections. This results from poor hygeine, inadequacy of water availability, a lack of privacy in bathing and cleaning and an inability to ensure proper care during

menstruation. A complete course of the appropriate antibiotic In adequate dosages is required to prevent urinary tract infections from becoming chronic leading to complications in the kidney. Misuse of antibiotics also leads to the spread of drug resistance. Often when medicines are given, advice regarding flushing of the urinary tract with plenty of water is neglected. Supportive care is as important as medicines in rational management.

Preventive Drugs during Pregnancy

Women need m 1 ore iron and calcium during pregnancy to make up for the inadequate amounts contained in their food. Losses of these minerals during childbirth and during heavy menstrual periods are often considerable. Though iron and folic acid is given as part of the Anemia Prophylaxis Program during pregnancy, for moderate and severely anemic women this is inadequate. Adding a pinch of lime in rice or flour is a low cost substitute for a calcium tablet. Two doses (preferably three) of Tetanus Toxoid during pregnancy will prevent neonatal tetanus and tetanus during childbirth.

If ever blood or blood products have to be given or if Anti D is needed (when the pregnant woman is Rh-ive and conceives an Rh+ive baby), these must be screened, for syphilis, malaria, hepatitis B and AIDS.

Commercialization of medical care has led to a mushrooming of pharmaceutical products, often with little or no therapeutic value and sometimes with pronounced side effects. Drugs are sold playing on the deep rooted fears of women being pregnant when they don't wish to be or of bearing a girl child. An Ayurvedic preparation called SELECT is being sold with the explicit bait that if taken after the 45th day of the last menstrual period there are 80 percent chances of ensuring the birth of a boy. How licensing and open advertisements of such drugs by practitioners of western as well as indigenous medicine is allowed, needs serious questioning. Unfortunately, there is great proliferation of such products. While protests have been lodged with the Drug Controller of India as well as MRTP, such exploitation in the name of medicine will continue unless stalled by aware women and health activists themselves.

Dr. Mira Shiva heads the Public Policy division at VHAI. Originally a part of the holistic health team, she initiated campaigns on various issues: school health, babyfood, tobacco and the role of pesticides in the Bhopal tragedy. Coordinator of All India Drug Action Network which campaigns for a rational drug policy, her work on low cost drugs and rational therapeutics began in the field and went on to cover the EP drug case, women and pharmaceuticals and the issue of patent laws on drugs.