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REGULATORY ASPECTS OF CONTRACEPTIVE IN INDIA AND USA

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ABSTRACT

The regulations define requirements of manufacture and distribution to ensure that products reaching market are safe and effective. Presently in India regulatory body CDSCO is governing regulations for regulation of devices which with the time, amendment introducing in the law will provide safety assurance to public health. This review provides a study on different regulatory aspects of medical device implemented in India. The present review discuss about the regulation aspects India and US. Contraception is the intentional prevention of conception through the use of various devices, sexual practices, chemicals, drugs or surgical procedure.

KEYWORDS: Contraceptive, Regulatory, Marketing, India, USA, CDSCO.

1. INTRODUCTION

Regulation is the system of complex systems according to a set of rules and trends. In systems theory, these types of rules exist in various fields of biology and society, but the term has any different meanings according to context.[1] Regulation is the control of complicated structures consistent with a fixed of guidelines and trends. In structures theory, those sorts of guidelines exist how very in numerous fields of biology and society, however the time period has barely unique meanings consistent with context**.** Regulation in the social, political, psychological and economic fields can take many forms: legal restrictions issued by a government agency, contractual obligations. It is achieved through use of contraceptive

methods and the treatment of involuntary infertility. Family Planning (FP) is having the desired number of children and when you want to have them by using safe and effective modern methods. Family planning benefits the wellbeing of families throughout the world. Using contraception can avoid unwanted pregnancies and space births, protect against sexually transmitted infections and provide other health benefits. Hormonal contraception refers to contraceptive methods that act on the endocrine system. Most methods use steroid hormones, although a selective estrogen receptor modulator is marketed as a contraceptive in India. Program to regulate the number and spacing of children in a family through contraceptive practice or other contraceptive methods.[2] Contraception is the intentional prevention of conception through the use of various devices, sexual practices, chemicals, drugs, or surgical procedures. Thus, any device or act whose purpose is to prevent a woman from becoming pregnant can be considered as a contraceptive. The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. The Drug Controller General of India (DCGI) is the head of the Central Drugs Standard Control Organization (CDSCO) in India. All labels of contraceptives should conform as per the specifications under the Drug and Cosmetics Rules 1940 AND 1945. Label must be clear. Abortion is the termination of a pregnancy. It is defined as 'the intentional ending of a pregnancy. The U.S. Food and Drug Administration today permitted marketing of the first mobile medical application (app) that can be used as a method of contraception to prevent pregnancy.[3] Patient Protection and Affordable Care Act (PPACA), also called Affordable Care Act (ACA). The ACA was designed to reduce the cost of health insurance coverage for people who qualify for it. The FDA is a reviewer, not an initiator, of new products.[5]

2. DEVELOPMENT PROCESS OF CONTRACEPTIVES

Contraceptive development involves identifying possible avenues to intervening in the reproductive process, eliminating those that are ineffective, infeasible, or unlikely to be acceptable because of side effects or for other reasons, then testing the remaining drugs or devices for safety and efficacy. Throughout this process, changes may be made in a method's composition, dosage, or mode of administration. Some changes may necessitate additional testing, and some tests may need to be replicated in different populations.[6]

The development of a new contraceptive, like the development of other drugs and therapeutic devices, is a complex, multifaceted process involving a wide variety of scientific disciplines.

Successful contraceptive development requires millions of dollars, takes years to complete, and may involve the testing of thousands of different chemical compounds. Many drug formulations are discarded during the development process because of concern about safety, efficacy, feasibility of delivery, or marketability. In drug development generally, FDA approval is sought for only 1 out of every 10,000 new chemicals synthesized in the laboratory. One study found that, of 20 new chemical entities identified as potential antifertility agents between 1963 and 1976, 17 were placed into human trials, but only 3 were submitted to FDA for approval, of which 2 were actually approved.[7]

It is difficult to estimate the cost of developing a new contraceptive or any other new product because of the problems involved in incorporating the costs of false starts and opportunity costs in the calculations. One recent study estimates that it cost $125 million to successfully bring a new chemical entity to the market in 1986 compared with $54 million in 1976. Although the estimate may not be precise, it does indicate the approximate level of investment required and how that has changed over time.

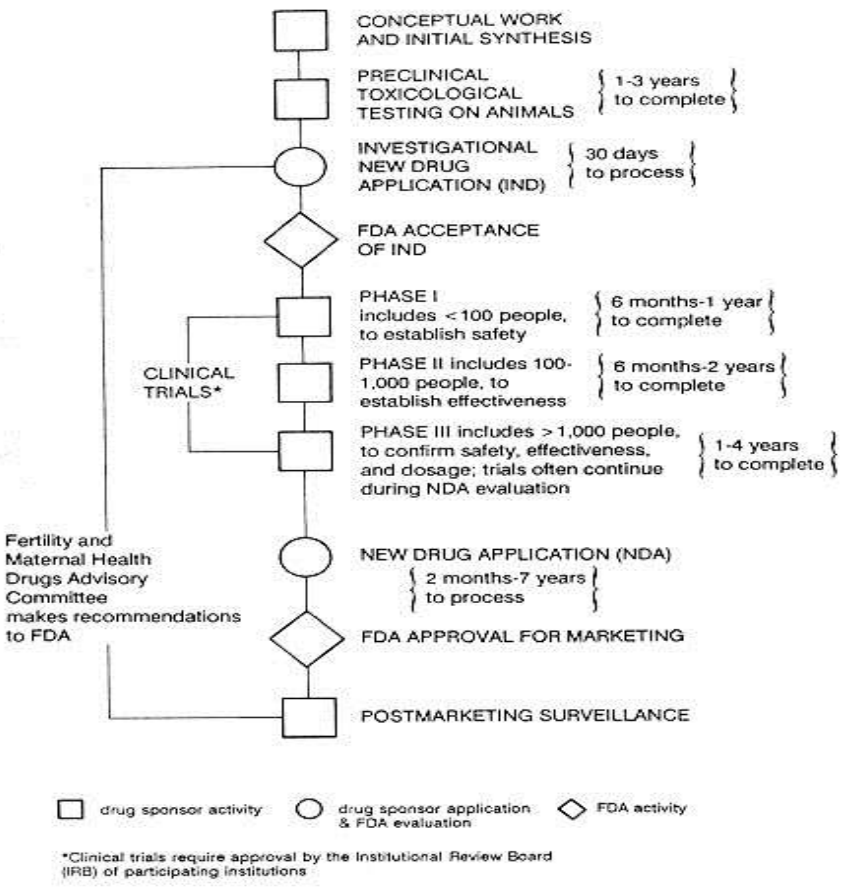


Fig 1: Development process of contraceptives.

When basic research on human reproduction provides a lead for contraceptive development by identifying a possible point for the contraceptive intervention, scientists must then determine what mechanism is best suited to take advantage of the potential point of intervention and how it can be delivered. Prototype delivery systems may then be prepared, which may be modified in light of the results of further research.[8]

Once a drug is identified as a potential contraceptive, it must be carefully screened to establish its full range of effects. Animal studies are conducted initially to screen drugs. If the results have merit, additional animal studies and small-scale human trials follow. These early studies focus on the chemical breakdown of the drug in the body and on absorption and excretion rates. Scientists assess the drug's potency, its pharmacological effects, the onset and duration of action, chemical stability, and probable toxicity. At this stage the delivery system and the expected difficulty of production and formulation are also starting to be considered. Manufacturing processes would typically be designed and tested at this stage to ensure that the drug can be produced in a uniform dosage in large quantities. Following initial synthesis and preliminary animal testing, the developer of a new contraceptive drug submits an application for claimed Investigational New Drug exemption (IND) to the Food and Drug Administration. The IND is an exemption from the statutory restriction against interstate shipment of an unapproved new drug. The IND includes information on the drug's composition, source, synthesis, and possible benefits. It also includes a detailed protocol for human testing. Human trials of the new drug may begin after a 30-day waiting period, if the FDA has not objected. If the FDA requests clarifications or more data, the drug company must respond to the FDA's satisfaction and wait another 30 days from the last response before beginning human trials.

Human clinical testing of new contraceptive drugs is divided into three phases: Phase I studies are usually conducted on a small number of volunteers and are used to determine the safe dose range, the absorption process, and possible levels of toxicity; Phase II studies provide more information about the drug's safety as well as efficacy in carefully selected subjects; and Phase III studies, which may involve several hundred or more participants, are used to establish the drug's safety and efficacy in actual clinical use. Clinical trials for new drugs take an average of five years, but they may continue for as many as 10 years.

When testing has been completed, and assuming no unacceptable problems have been discovered in the process, the developer would submit a New Drug Application (NDA) to the

FDA to obtain approval to market the drug. Each NDA consists of between 2 and 15 volumes of material summarizing all the research the developer has conducted or sponsored on the drug, and 10 to 100 volumes of raw data collected during the development process. The NDA for the NORPLANT® contraceptive implant, which was submitted to FDA in August 1988, contained over 19,000 pages in 53 volumes. The average review time for an NDA is two years, but it can take as long as seven years. IUDs, which have a systemic effect because they contain copper or a hormone, are classified as drugs in the United States and must meet the premarketing requirements for drugs. The FDA approval process for new contraceptive devices, such as diaphragms and inert IUDs, is similar to that for drugs, although the approval time for devices is often shorter, in part because there is usually no backlog of Premarketing Approval Applications (PMAs) for FDA review of devices.

The Fertility and Maternal Health Drugs Advisory Committee, a panel of outside experts who serve 4-year terms, acts as an adviser to the FDA on safety and efficacy issues related to new contraceptives and other drugs. It makes recommendations to the FDA regarding sponsors' applications to market new drugs. These recommendations, although not binding, are usually adopted by the FDA.

Once a drug is approved, the manufacturer can begin to promote it to the medical community and to the public. The FDA requires periodic reports following NDA approval and may require postmarketing studies to determine the incidence of serious adverse reactions.

A major objective of contraceptive researchers is to reduce the incidence and severity of side effects associated with systemic contraception. After more than two decades of use by millions of women, most of the risks and health benefits of oral contraceptives are known. There may, however, be adverse and beneficial effects yet to be identified that are associated with the new oral contraceptive formulations used in the past decade. Almost all of the existing studies of oral contraceptives are based on women using high-dose pills; one hypothesis is that the newer low-dose pills will have fewer side effects, but also fewer health benefits than the high-dose pills. Replicating this experience of widespread, long-term use of oral contraceptives in clinical trials for other methods is not yet possible. Long-term safety issues related to new systemic contraceptive methods will not be completely resolved until they have been in general use for many years.[9]

3. Contraceptives regulation as an international perspectives

FDA, national drug regulatory agencies in other countries have requirements for the approval of contraceptives that exceed the requirements for other drugs. These additional requirements exist because (1) prevention of unwanted pregnancy is not considered to be a curative therapy or prophylaxis; (2) recipients of contraceptive drugs are still exposed to the risk of pregnancy because no contraceptive is 100 percent effective; and (3) contraceptive drugs are taken for longer periods than most other drugs.[10]

Regulatory standards for drugs and medical devices vary among countries with respect to: (1) product development, (2) effectiveness, (3) safety, (4) packaging and quality control, (5) instructions for use, (6) consumer protection, (7) product availability, and (8) pricing (Cook et al., 1982). Although differences among countries in regulatory requirements are probably related to international differences in contraceptive development efforts, broader social and economic factors play a much more important role in determining the extent to which contraceptive development takes place in particular countries.

A 1980 study by the General Accounting Office identified several key differences in the regulatory processes in the Netherlands, Norway, Sweden, the United Kingdom, and Canada compared with the United States. The regulatory processes in these countries were generally faster and more flexible. Among the key differences between the countries studied and the United States were: (1) greater use of expert committees, (2) greater acceptance of foreign data, (3) less politicizing of the drug approval process, and (4) greater cooperation between regulators and industry.

The mean number of months from the NDA application for marketing a new drug to the date when regulatory approval was granted varied widely among the countries: the United Kingdom, 5 months; Canada, 16 months; Norway, 17 months; the United States, 23 months; and Sweden, 28 months (GAO, 1980). It should be pointed out, however, that the period from the filing of the NDA to the date of approval is only a very short segment of the total time required for new drug development. Furthermore, these figures include applications with very minor changes or modifications that are included as NDAs.[11]

3.1 Circumstances Under that the pregnancies might be terminated by register medial practioner

The Registered Medical Practitioner might also additionally terminate a being pregnant if it's far greater than 12 reason of own circle of relatives planning, it could be presumed to represent a grave damage to the weeks however now no longer greater than 20 weeks, if now no longer much less than 2 registered clinical of any contraceptive tool utilized by any married girl or her husband for the practitioners are of the opinion noted in 1 above wherein any being pregnant is claimed with the aid of using the pregnant girl to were due to rape or due to failure The Registered Medical Practitioner might also additionally terminate a being pregnant while it isn't always greater than 12 weeks vintage and the clinical practitioner is of the opinion fashioned in properly faith, that.

(a) Its continuance could end result into extreme damage to the bodily or intellectual fitness of the pregnant girl, or.

(b) The kid to be born could be severely handicapped because of bodily or intellectual abnormalities.

The Registered Medical Practitioner might also additionally terminate a being pregnant if it's far greater than weeks however now no longer greater than 20 weeks, if now no longer much less than 2 registered medical practitioners are of the opinion noted in 1 above wherein any pregnancy alleged with the aid of using the pregnant girl to were due to rape or due to lae of any contraceptive tool utilized by any married girl or her husband for e reason of own circle of relatives planning, it could be presumed to represent a grave damage to intellectual fitness of the pregnant girl.[12]

3.1.1 Objective Of The Medical Termination of Pregnancy Act

An Act to offer for the termination of certain pregnancies by registered medical practitioners and for matters connected there with or incidental thereto.

Preamble clearly shows the objective of MTP act. That only certain pregnancy will be permit to terminate under MTP Act by the medical practitioners.

The act upgrade the maternal health of Indian women and to control the death rate of the women due to unsafe and illegal abortion. After this act safe abortion is available to women.[13]

3.2 Act on Contraceptive in USA

2010: The Patient Protection and Affordable Care Act.

The Affordable Care Act (ACA) is the comprehensive healthcare reform enacted by President Barack Obama in March 2010. Formally known as the Patient Protection and Health Care Act Low Price and often referred to as Obama care.

The important patient benefit of The Patient Protection and Affordable Care Act is elimination of lifetime limit on the insurance coverage.

The Patient Protection and Affordable Care Act is the most consistent social legislation of our generation. The ACA is expected to directly affect every US citizens. Depending on your point of view, it can be positive or negative, health exchanges, and growing regulations, a significant portion of the Americans will remain uninsured.[14]

3.5 Objective of The Patient Protection And Affordable Care Act

To reform the personal coverage marketplace particularly for people and small institution purchasers.

Extend Medicaid to the working poor with incomes up to 133% of the federal poverty line.

Change the way the medical decisions are made.[15]

3.6 Regulatory Guidelines Required for Manufacturing of Contraceptives in India

In India, the import, manufacture, sale and distribution of medical devices are regulated by the Drug and Cosmetics Act 1940; and Rules, 1945, and advice is provided by the Central Drug Standards Control Organization (CDSCO), which is headed by India's Drug Controller General of India (DCGI).

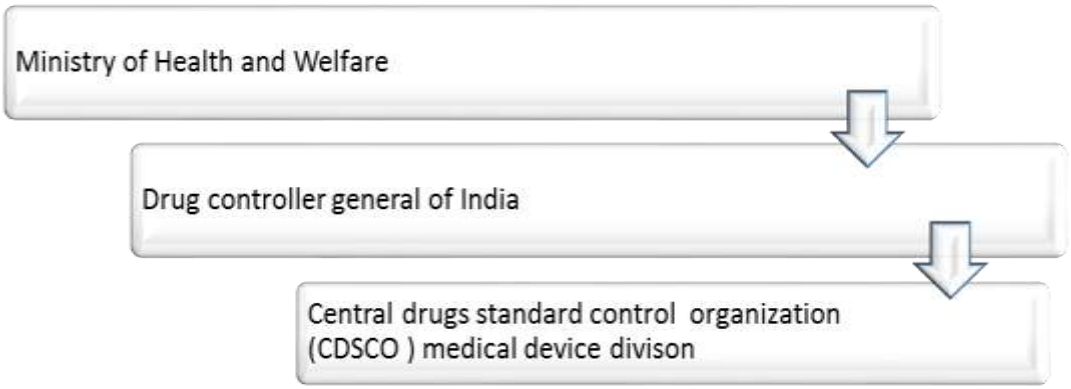
Approval is granted by DCGI by reviewing the production website and file submitted by the Indian manufacturer or agent for the scientific production tool in India. For the manufacture and sale of scientific documents registered under the Central Licensing Approval Authority (CLAA) scheme in India, CDSCO offers Form 28 to be completed through the manufacturer's means with the correct documentation required under the Usually required for medicine and beauty.

Drug and beauty rule seventy six describe the statistics and file required for deliver permission of producing license.[16]

Applicant fill form 27 for the delivery of license for production of scientific tool in India. Application is submitted to the involved State Drugs Licensing Authority, The involved CDSCO Zonal/Sub-Zonal Office.

The general drug controller of India with a necessary cost prescribed in the field of drugs and beauty**.**

4. India's Medical Regulatory Devices Structure



CDSCO Roles

a. Approval of new drugs and clinical trials
b. Registration and CDSCO import license.
c. Licensing of blood banks, vaccines and some medical devices.
d. Amendment of drugs.[17]

4.1 Regulatory Guidelines Required For Manufacturing of Contraceptives in USA

In the USA, medical devices are regulated by the Food and Drug Administration (FDA) with an aim to ensure safety and effectiveness of the devices. The Center for Devices and Radiological Health (CDRH) is an FDA component and looks after this program.

Medical devices are classified into three categories based on the associated risk, namely: Class I, Class II and Class III.

Class I devices will have least associated risk while class III devices will have the highest associated risk. Accordingly, regulatory control surges from Class I devices to Class III devices. With respect to that, most of Class devices are exempted from 510 (k) premarket notification submission, while most of Class II devices are submitted for premarket notification. On the other hand, Class III devices need to go through the Premarket Approval

Application (PMA) and other class II devices, which are exempted from PMA must submit a 510 (k) notification to FDA.[18]

4.2 Regulatory Guidelines Required For Labelling Of Contraceptives In India

Medical Device Manufacturing must follow the labelling requirements and must be done on every medical device packaging. An overview of the process for registration of medical devices in India here. the CDSCO is the Indian FDA which handles all the regulations for medical devices in India. On 25th September, 2014 the CDSCO issued amendments to the Drug and Cosmetics Rules 1945. An important amendment for medical device manufacturers to observe is Rule 109 A-labelling requirements.[19]

4.3 Regulatory Guidelines for Labelling Contraceptive in USA

This section provides FDA recommendations for CHC labeling other than patient labeling. Since all CHCS contain an estrogen and a progestogen, the FDA believes that class labeling based on known estrogen/progestogen information is generally appropriate for many sections of CHC labeling.

This section provides recommended class labeling guidelines. However, there are sections in the labeling that must contain product-specific information (for example, data on efficacy results or bleeding profile demonstrated in clinical studies of the specific product, or results of a drug interaction study conducted with a particular CHC product). These labeling sections are identified in this section and general guidance is given on the type of information to include. For prescribing information highlights, recommendation for the specific product text are listed in the appropriate footnotes directly below the labeling example.

Listed without recommended language, the reader is encouraged to consult the approved CHC labeling in PLR format for guidance.[20]

4.4 Regulatory Guidelines Required For Sale And Distribution Of contraceptives In India

As noted earlier, contraceptives are at specially subsidized price and distributed free of charge through government funded NGO's and government funded family planning clinics.

The pills are sold by prescription only under the program of the Drug and Cosmetic Act 1940 and distributed free to urban family welfare center and primary health centers that can monitor oral pill programs. As the government took action under section 10A and 26A of

Drug and Cosmetic act 1940 to prohit the importation, manufacture, sale and distribution of the medicine 'Quincrine' for use as a contraceptive their supreme court lordships declined to issue further orders. A particular drug would only be banned if the government was satisfied with the dangerous nature of the drug. Importantly, the government must also be satisfied that the public interest justifies such as a ban.[21]

4.5 Regulatory Guidelines Required For Advertisement of Contraceptives in India

Drug and Magic Remedies Act 1954 is designed to prevent misleading advertising, false labels and effectiveness claims for any medicine. The purpose of this law is to prevent, manufacturing, distribution, advertising and sale of false and harmful medical preparation, making it a crime.

Section 3 of the law prescribes that no one shall participate in the publications of any advertisement referring to any drug to obtain a spontaneous abortion in the women or to prevent contraception in the women, or the maintenance or enhancement of the human being for sexual pleasure, correction of menstrual disorders in women or the diagnosis, cure, mitigation, preventive treatment of any venereal disease which may be specified in rules under law.

Section 15 of the act, however gives the central government he power to grant an exemption in this respect if the opinion of the central government, the public interest so required.

The fact is that the contraceptive are advertised in newspaper, radio, television by Indian government have under taken the dissemination of information on family planning through all available mass media, cinema, dance, theater, post offices, press , radio, songs, television etc.[22,23]

CONCLUSION

There are several articles published by various authors regarding the regulations of contraceptives in India and US. Each country has its own regulation when it comes to regulate contraceptives. In India, there is a much need of contraceptive method to be more women friendly, accessible and provide adequate privacy. A variety of contraceptives is essential to meet the needs of all potential users. Not all clinically effective drugs are effective for all people when actually used .therefore, the FDA must consider the target population of each proposed drug to evaluate its effectiveness .In India, The Central Drug

Standard Control Organization (CDCSO) is the Indian FDA which handles all the regulations for medical devices in India. In US, The FDA which handles all the regulations for medical devices in US. The ACA has helped millions of Americans gain insurance coverage, saved thousands of lives, and strengthened the health care system.

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6. Recent legislation in New Jersey, Ohio, Oregon, and Texas allows a manufacturer of an FDA-approved product to assert an "FDA defense" in response to a claim for punitive damages—that is, generally the manufacturer cannot be held liable for punitive damages if the product has been manufactured and labeled in accordance with FDA standards unless the manufacturer withheld from or misrepresented to the FDA material and relevant information. Ohio Rev. Code Ann. §2307.80(C) (Page Supp. 1987); 1987 Or. Laws ch. 774 §5, Prod. Liab. Rep. (CCH) para. 93,835; Tex. Civ. Pract. and Rem. Code Ann. §81.001 et seq. (Supp. 1989); 1987 N.J. Laws, ch. 197.
7. Section 106 of the Uniform Product Liability Act provides that a product seller cannot be found liable on the basis of defective design or failure to warn if the product conformed to an applicable administrative or legislative regulatory standard. This provision does not apply, however, if the claimant can prove by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions.
8. As discussed in Chapter 7, in 1971 the Federal Food, Drug and Cosmetic Act did not require approval by FDA before a medical device could be marketed. FDA could take

enforcement action against a device if it could establish that the device was adulterated or misbranded (21 U.S.C. §331(a)-(c), 351, 352 [1970]). In 1976, Congress enacted the Medical Device Amendments, which require premarketing approval for such devices as the Dalkon Shield (Pub. L. No. 94-295, codified at 21 U.S.C. §360-360K).

9. Compare Ortho Pharmaceutical Corp. v. Heath (722 P.2d 410 [Colo. 1986]), an oral contraceptive case in which the court held that the trial court properly submitted the case to the jury on a design defect theory of strict liability, despite FDA approval of the drug. The court reversed the case and sent it back to the trial court, however, because the facts entitled the defendant to a comment k instruction on unavoidable risk of harm, and the trial court had not given such an instruction. The case was ultimately settled for $800,000 (Bureau of National Affairs, 1987).
10. In the case of Eiser v. Feldman (507 N.Y.S.2d 386 [App. Div. 1986]), the plaintiff took Ortho-Novum pills and suffered visual impairment; in Cobb v. Syntex Laboratories, Inc. (444 So.2d 203 [La. App. 1984]), the plaintiff took Norinyl 1+50 and suffered a stroke; in Reeder v. Hammond (125 Mich. App. 223, 336 N.W.2d 3 [1983]), the plaintiff took Ovral while she was pregnant and gave birth to a retarded child; in Spinden v. Johnson & Johnson (177 N.J. Super. 605, 427 A.2d 597 [1981]), the plaintiff took Ortho-Novum and suffered thrombophlebitis and pulmonary embolism; in Goodson v. Searle Laboratories (471 F.Supp. 546 [D. Conn. 1978]), the plaintiff took Demulen 21 and suffered a stroke; in Dunkin v. Syntex Laboratories, Inc. (443 F.Supp. 121 [W.D. Tenn. 1977]), the plaintiff took Norinyl 1+80 and suffered a stroke; and in Chambers v. G.D. Searle & Co. (441 F. Supp. 377 [D. Md. 1975]), aff'd, 567 F.2d 269 [4th Cir. 1977]), the plaintiff took Enovid E and suffered a stroke.
11. In the case of Jordan v. Ortho Pharmaceutical Corp. (696 S.W.2d 228 [Tex. App. 1985]), the plaintiff took Ortho-Novum and developed liver tumors; and in Lawson v. G.D. Searle & Co. (64 Ill.2d 543, 356 N.E.2d 779 [1976]), the plaintiff took Enovid and died from multiple pulmonary emboli.
12. Seley v. G.D. Searle & Co. (67 Ohio St.2d 192, 423 N.E.2d 831 [1981]), the plaintiff did not inform her prescribing physician that she had suffered from toxemia during her first pregnancy; in Lawson v. G.D. Searle & Co. (64 Ill.2d 543, 356 N.E.2d 779 [1976]), the plaintiff was predisposed to blood clots because she was overweight and because of her parity (she had had five children); and in Vaughn v. G.D. Searle & Co. (272 Ore. 367, 536 P.2d 1247 [1975], cert. denied, 423 U.S. 1054 [1976]), the plaintiff did not inform her treating physicians of premonitory symptoms of a stroke.

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