Is the Health of Women Endangered by Pills and Devices Used for Birth Control and Contraception?

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Abstract

On the background of severe adverse events caused by a contraceptive device approved by the FDA in 2002 and removed from the market by the manufacturer in 2018 the article aims at clarifying as to whether or not contraceptive pills and devices currently used by women World-wide can cause severe adverse events and even have life-threatening sequelae. As a result of an in-depth analysis of information provided by manufacturers and by the FDA the article proves that women are not adequately informed about risks, potential complications, and hazards for their well-being. In conclusion an explanation is furnished for the failures on the part of health care providers who refrain from counseling women and on the importance of enabling each individual woman to make an intelligent choice according to her personal needs.

Keywords: Contraception; Sterilization; Healthcare provider; Pharmaceutical company; Bioethics; FDA

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Literature Review

Safety of contraceptive pills and devices according to professional publications

Before media reported on the harm caused by the device, on reactions by the FDA, and on statements made by the producing company, contraceptive devices and pills were generally judged safe. From scholarly articles as well as from publications by government agencies and institutions it transpired that there is general agreement concerning the safety of the most commonly used contraceptive methods. In one of the more recent salient studies on Long-Acting Reversible Contraception (LARC) the authors claim repeatedly that all women can safely use these devices, ie, implants and intrauterine inserts. Safety of IUDs and hormonal implants for almost all women is highlighted as one of the clinical key points of the article: IUDs and hormonal implants are safe for almost all women, including adolescents, as well as women in the postpartum or post abortion period [1]. In focusing on intrauterine devices, the authors affirm that they are safe for almost all women: Almost all women can safely use IUDs. Exceptions include women who have hypersensitivity to copper [1]. For implants it is reaffirmed: Almost all women can safely use implants; exceptions are women who have hypersensitivity to barium or to the components of the implant [1]. Concerning special populations, almost all women, including young and nulliparous, can safely use Long-Acting Reversible Contraception: LARC methods are safe for use in almost all women, including young and nulliparous women [1]. The safety of LARC is affirmed also for postpartum and post abortion periods: Both IUDs and implants are safe for use in the postpartum and post abortion periods, including immediately post-partum and post abortion [1]. Even for expulsion, which some authors consider as the most serious complication besides ascending infection [2], no special concerns are indicated in the study on LARC: Although IUDs are generally safe for use in the postpartum period, the relative risk of expulsion of IUDs that are placed immediately post-partum is higher than the risk with IUDs placed at 6 weeks post-partum or later [1]. In their conclusion the authors reaffirm that safety for women of all ages is one of the noteworthy characteristics of LARC methods and stipulate worldwide dissemination of their insights: All adolescents and adult women should be informed about the availability of LARC methods, given their extremely high effectiveness, safety, and high rate of continuation [1]. Besides the article on LARC there are other publications that affirm the safety of presently available contraceptive pill and devices. Some authors do not even mention well-known adverse events but hail only the alleged benefits of contraception: Contraception has direct health benefits, such as prevention of unintended pregnancy and, subsequently, decreased maternal mortality and morbidity [3]. In a study reviewing extended and continuous oral contraceptives, the authors affirm the safety of these products, although they cannot avoid to mention a considerable number of side effects and complications such as, breakthrough vaginal bleeding as the most common side effect, headaches, genital irritation, tiredness, bloating, vaginal spotting, and menstrual pain. As rare adverse the authors list cholecystitis, thrombotic event, ectopic pregnancy, and enlarged uterine fibroids. As metabolic effects, production of clotting factors resulting in increased risk of venous thromboembolism, increased
gallstone formation, and risk of liver adenomas are mentioned. Despite these adverse events, the authors conclude that continuous oral contraceptive pills are not only safe but also reliable. Continuous OCPs are a safe and reliable form of birth control. The most commonly reported side effect of continuous OCP dosing is irregular vaginal bleeding, but the incidence of this decreases over time and most patients will obtain amenorrhea after 1 year of treatment [4]. As an additional advantage of OCP, the existence of excellent safety data for endometrial histology is underscored. Additionally, there is no temporal limitation to the use of continuous OCPs as excellent safety data exist for endometrial histology. Women who wish to limit cyclic bleeding, for personal or medical reasons, are excellent candidates for continuous OCPs [4]. In a study on the use of combined oral hormonal contraceptives by obese women, the authors conclude that progestin-only methods are safe and that LARC combine optimally safety, efficacy, and convenience. Current evidence supports the safe use of combined hormonal contraceptives by obese women. Progestin-only methods are generally safe, and long-acting reversible contraceptives hold the best combination of efficacy, safety, and convenience for this group, although individualization is advisable [5]. Safety is ascertained also for ulipristal acetate, a substance used for emergency contraception (EC). The manufacturer of ulipristal acetate affirms: Safety and efficacy of ella have been established in women of reproductive age. Safety and efficacy are expected to be the same for post pubertal adolescents less than 18 years and for users 18 years and older [6].

The shocking news about a safe contraceptive device

The safety of contraceptive pills and devices emphasized by the above mentioned citations has been severely shaken in 2018, when a contraceptive device for sterilization became the focus of interest of various media world-wide. Owing to complaints lodged by thousands of women who had used the device and experienced severe adverse events, the Australian press reported: But there have been reports women experienced changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergic reactions and immune-type reactions after being implanted with the device [7]. Other media highlighted additional adverse events: Patients have reported cases of pain, bleeding, allergic reactions and cases where the implant punctured the uterus or shifted out of place [8]. Given the severity of adverse events legal reverberations were a logical consequence. It has been the subject of an estimated 16,000 lawsuits or claims filed by women who reported severe injuries, including perforation of the uterus and the fallopian tubes. Several deaths, including of a few infants, have also been attributed to the device or to complications from it [8]. One of the most instrumental proponents in the troubled history of the device was the U.S. Food and Drug Administration (FDA) which had approved the device as safe and still insisted on its safety 16 years later. This insistence on the safety of the device is surprising not only in light of complaints by thousands of women but also in the face of the company's announcement that the device will be removed from the market. Bayer announced that they will no longer sell or distribute Essure in the U.S. after December 31, 2018, for business reasons. This information does not change the FDA's understanding of the safety and effectiveness of the device; however, the FDA emphasizes that women with Essure should speak with their physician about any medical questions they may have [8]. The FDA's emphasis on patient-physician communication brings to light the most crucial issue of the troubled history of the device, namely the role of healthcare providers. In fact, the FDA implies that serious problems could have been avoided, if healthcare providers had cooperated with the company and had informed women about risks and potential complications. According to media reports, the FDA went so far as to restrict the use of the implant to those women who had signed a statement acknowledging familiarity with the risks and had received also their doctor’s signature prior to insertion. The Food and Drug Administration said only women who read and have the opportunity to sign a brochure about the risks of the device will be able to receive the implant made by Bayer. The checklist of risks must also be signed by the woman’s doctor [8]. As can be seen, the lack of cooperation on the part of healthcare providers has been the target of critique by both, the FDA and the producing company. Apparently, women choosing the implant for permanent contraception were not adequately informed about adverse events, risks, and possible complications. Despite previous efforts to alert women to the potential complications of Essure, we know that some patients still aren’t receiving this important information,' said FDA Commissioner Scott Gottlieb, in a statement. ‘That is simply unacceptable [8]. In describing the prevailing lack of information as unacceptable the FDA implicitly refers to the ethical obligation of healthcare providers to honor the principle of informed consent. As is known, this principle emphasizes the patient’s right to obtain comprehensive and comprehensible information so that she is enabled to make an intelligent choice [9]. Apparently, in the case of the sterilization device, this principle was gravely neglected and women could not make an intelligent choice but remained ignorant of highly important information that should have been conveyed to them [10]. The FDA's implicit reference to the principle of informed consent brings another crucial issue to the forefront, ie, the quality of patient information provided by manufacturers. In the case of the controversial insert for permanent contraception, the manufacturer was criticised by a member of the consumer advocacy group that the information provided is too lengthy, too technical and confusing. 'How many people do you know who would carefully read a 22-page document before signing it?' said Diana Zuckerman, president of the National Center for Health Research, a consumer advocacy group. ‘In addition to being much too long and technical, the information provided will be confusing to many consumers [8].

Is patient information disseminated by pharmaceutical companies adequate for the consumer?
In light of this critical comment on the information provided by the manufacturer the question arises as to whether inadequate information is disseminated also by other manufacturers of contraceptive pills and devices. In a recent study on this topic it has been found that there are in fact serious deficits in packaging labels, highlights of prescribing information, and consumer leaflets destined to inform the consumer about adverse events, risks, and possible complications [11]. For instance, information provided by the manufacturer of the controversial nickel-titanium coil for permanent contraception fails to clearly describe the mechanism of action of the device. This mechanism is described as a three step process: tubal occlusion owing to the space-filling design; a benign occlusive response of tissue; and tissue in-growth owing to PET fibers. Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention, resulting in tubal occlusion and contraception [12] Why and how this tissue in-growth should take place due to PET, ie, polyethylene terephthalate fibers [12] is inexplicable from a physiological viewpoint. It is not surprising therefore, that some commentators avoid the imprecise terminus in-growth and speak of a scar tissue, ie, a tissue that is the result of a wound. The Essure implant consists of two small coils made of a nickel alloy and a polyester-like /sic! / Fiber. It is placed through the vagina into the fallopian tubes, and is designed to create an inflammatory response that causes scar tissue to form, blocking the tubes [13]. Inadequate information can be found also in packaging labels of other manufacturers. Thus, the manufacturer of a levonorgestrel-containing intrauterine device (IUD) mentions capacitation of sperm as a mechanism of action and expects, rather unrealistically, the reader to know that this nomenclature refers to the process where sperms acquire additional capacity for fertilization within the female reproductive tract [13]. In light of such shortcomings in patient information provided by manufacturers the critique of the above mentioned consumer advocacy group concerning too technical and even confusing information seems justified, and this critique might be decisive for the upcoming forensic proceedings against the manufacturer of the nickel-titanium alloy. Hopefully, during these proceedings the pivotal issue will be addressed, namely the concept of safety and its interpretation through the FDA and manufacturers. Is the FDA justified in approving and in declaring a device as safe if it causes severe injuries to thousands of women or should the terminus safe be restricted to those foods and drugs that cause no more than transitory side effects without impacting substantially on a person’s quality of life or even threaten her life [15]. Additional scepticism regarding the FDA’s approval policy comes from a pharmacological study focusing on packaging labels and patient information provided by pharmaceutical companies. Frequently these patient information material contains explicit warnings about risks and complications. Thus in the case of LARC methods, discussed at the beginning of this article the manufacturer explicitly warns about breakage, perforation, dislocation and migration of the device to the pelvic cavity or to the lungs via the pulmonary artery. Above all, the life-threatening sequelae of an ectopic pregnancy are appropriately underscored [16]. An explicit warning to this effect has been issued also by the manufacturer of the nickel-titanium coil. Ectopic pregnancies (pregnancy outside the uterus) may occur with Essure. This can be life-threatening [17]. Along the same line the manufacturer of the levonorgestrel-containing intrauterine device Mirena warns about the life- threatening character of a GAS (group a streptococcal) sepsis and insists on aseptic technique during the insertion of Mirena. Aseptic technique during insertion of Mirena is essential [14]. Concerning oral hormonal contraceptives, it is well-known that manufacturers consistently warn about lethal consequences of thromboembolic events and liver adenomas. Thus, the manufacturer of Orthonovum combined oral contraceptive pill draws attention to hepatic adenomas. Rupture of benign, hepatic adenomas may cause death through intra-abdominal hemorrhage [18]. Along the same line the manufacturer of the minipill mentions that in rare instances combined oral contraceptives can cause benign liver tumours. These benign liver tumours can rupture and cause fatal internal bleeding [18].

**Discussion**

Until recently, the safety of contraception and birth control methods has been taken for granted by women and their healthcare providers. Consumers of contraceptive pills and devices were reassured that all products are reasonably safe, that means causing no harm in the sense of the principle nilnocere. This safe scenario of contraception and birth control has been shattered unexpectedly in 2018 when a contraceptive device for sterilization caused serious harm to women world-wide, gave rise to thousands of lawsuits and finally was removed from the market by the manufacturer - although it had been approved by the FDA in 2002 and was still declared as safe. During the year 2018, media reported repeatedly on the harm caused by the nickel- titanium coil, a device intended for permanent contraception through insertion into the fallopian tubes where it prevents contact between sperm and ovum.

**Consequences**

Given that information disseminated by pharmaceutical companies is frequently inappropriate, given the FDA's role in approving products as safe which cause severe injuries, and given critical comments regarding the lack of cooperation on the part of physicians it must be stipulated that pharmaceutical companies intensify their efforts to provide comprehensible and comprehensive information on all aspect of their products. Concerning the role of the FDA it should be clarified why a product can be approved by the FDA and declared as safe when it causes severe injuries to thousands of women. With respect to complaints about cooperation on the part of healthcare providers it should be examined whether physicians are not willing or not in a position to counsel their patients in conformity with bioethical principles. It is conceivable that they argue, similar to their
counterparts in European countries, that economic principles such as cost-efficiency and profit-making must have priority over ethical imperatives. The ultimate goal of all future efforts must be the health of every single woman according to the principle nil nocere. Each individual woman should be enabled to decide whether a product is safe for her personally, given her general health, her age, her genetic profile, her professional career, and similar variables. One possibility to foster a better understanding of safety would be a modifying nomenclature which distinguishes between high, moderate and low safety, as has been proposed recently in a Safety-Efficacy-Cost-Convenience Table. This table enables not only women to obtain an instant synoptic overview of all possible options, but assists also health care providers in counselling their patients according to ethical principles without unnecessary investment of precious time.

**Conclusion**

On the basis of the foregoing discussion it is doubtful as to whether claims made by authors describing products for contraception and birth control in professional journals are trustworthy. Women seeking information on contraceptive pills and devices cannot rely on such claims but depend primarily on counselling through their healthcare providers. However, according to the statements made by the FDA counselling by physicians is unsatisfactory or even non-existent.

**Conflict of Interest**

The author declares no conflict of interest.

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