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Reviews

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(Prof. Herta Mann)

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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 64 pages. OCLC Number: (OCoLC)63168082 Subject: Contraceptives -- Government policy -- United States. Excerpt: . . . approval of all drugs, but may overrule the decisions of subordinate officials. The authority to approve an OTC switch application ultimately rests with the Secretary of Health and Human Services. This approval authority is delegated to the Commissioner of FDA, then to other high-level management officials, and eventually to other FDA officials within lower levels of the agency. This delegated authority allows decisions to be made at lower levels within the agency but assumes that management agrees with these decisions. The FDA Commissioner and other officials within the Office of the Commissioner usually do not have a role in OTC switch decisions, but have the authority to overrule the decisions of other FDA officials. There are several types of contraceptive drugs and devices, including Contraceptives barrier methods, intrauterine devices, spermicides, and hormonal methods. Several types of hormonal methods of contraception are available, including birth control pills, injectable hormones, hormonal implants, and ECPs. FDA has approved two ECPs, Preven and Plan B, for use by prescription, and Plan B is the first drug in its class to go through the review process by FDA to determine whether it should be allowed to be sold OTC. ECPs are high dose birth control pills and have been available by prescription since 1998, when FDA approved Preven, a 23 dedicated combined ECP containing the hormones estrogen and 24 progestin. Prior to 1998, many physicians instructed patients to take 22 In 1997, a notice in the Federal Register stated that the Commissioner of FDA had concluded that certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as...



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