



Silent No More

National Help Line 1-866-482-LIFE

www.operationoutcry.org

December 19, 2003

Dr. Janet Woodcock
Director of U.S. Food and Drug Administration Center for Drug Evaluation and Research
C/o Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: 2001P-0075: "Switch Status of Emergency Contraceptives from Rx to OTC"

To Dr. Woodcock:

I am submitting in hardcopy and to your <http://www.fda.gov/cder/comment/commentdrug.htm> site, a Citizen's Petition to the U.S. Food and Drug Administration **OPPOSING** Over-The-Counter Sale of Emergency Contraception. I formally request revocation of the FDA's decision to allow sale of any emergency contraception without a doctor's prescription.

If you can accept and post online "petitions" such as this one, <http://www.fda.gov/ohrms/dockets/dailys/01/Sep01/091701/c000223.pdf>, a crass, immature, hand-scrawling-covered, completely undocumented "petition" the FDA accepted in 2001 and actually displayed on your website at this URL, then you surely can accept the enclosed documented and scientific-research-footnoted petition.

The US Food and Drug Administration has just approved the over-the-counter selling of the abortifacient "Morning After Pill" or emergency contraceptive. Now anyone, including our teen daughters, can buy this without a prescription and without us knowing it—until they come down with "unexplained" infertility, life-threatening tubal pregnancy, and/or blood clots which can lead to stroke or death. All of these can be caused by this Morning After Pill you have just approved for OTC purchase. Our teens can get these pills right NOW ANYWAY, ONLINE, without any doctor prescription or parents' knowledge.

Here's what you and the FDA have just delivered to us wholesale as a nation:

- 1) In Washington State, where emergency contraceptives are already available without a prescription, chlamydia infection has risen nearly 20%. Not to mention the disease's personal impact, have you factored in the increased economic burden the government will shoulder for the costs of treating these increased STDs?
- 2) In May 2003, the UK Public Health Laboratory Service showed that, after four years of giving out free emergency contraceptives to women and girls in local pharmacies, syphilis among British men has grown 612% in the six years ending in 2001 and in women, it has grown 206%. In the

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same time period, chlamydia infections for men and women have grown more than 100%, while herpes, genital warts, and gonorrhea have all grown substantially.*

Again, the economic costs of the explosion in STDs in this country alone is something on the order of \$17 BILLION in 1994 dollars** (now ten-year-old data!) since the sexual promiscuity explosion beginning in the Sixties.

How is the FDA considering and providing the money for treatment of this problem to which it is contributing? Or is this how you plan to stay in business yourselves and help drug companies even further by providing them "steady pipelines" of lucrative STD patient business?

3) In 1967, 1 out of 32 sexually active people contacted SEXUALLY TRANSMITTED DISEASES (STDs). In 1983, 1 out of 18 sexually active people contacted STDs. In 1996, 1 out of 4 sexually active people contacted STDs.

4) Women who take the Birth Control Pill are 14 times more likely to develop blood clots while flying in an airplane (The MAP is essentially a triple or quadruple dose of Birth Control Pills) [<http://archinte.ama-assn.org/cgi/content/abstract/163/22/2771>].

5) Women who use Birth Control Pills for 10 years or longer have twice the risk of developing cervical cancer, women who had taken the Pill for 5-9 years had a 60% increased risk, and for under 5 years, a 10% increased risk of cervical cancer, compared with women who had never taken birth control pills. From an April 04, 2003 study published in the Lancet, by researchers from Cancer Research UK's Epidemiology Unit in Oxford, England, and the International Agency for Research on Cancer in Lyon, France. (Reaney, Reuters).***

6) A 16-YEAR OLD GIRL MAY HAVE DIED FROM USING EMERGENCY CONTRACEPTION: "A New Zealand coroner... [stated recently]... that... the suspicious death of a teenage girl a year ago may have been caused by the contraceptive pill called ESTELLE-35D [the generic form of DIANE-35]... The New Zealand Herald [reported] that... Stacey Bindle was lying on her bed 'convulsed and frightened, unaware that a small but deadly blood clot was slowly traveling to her lungs.' The girl's mother said her daughter was calling out 'in a scared little voice,' that she 'could not breathe.' Four hours later Stacey Brindle was dead." ****

THESE PILLS ARE EASILY OBTAINABLE HERE IN THE U.S. BY SHOPPING AT WEBSITES LIKE THIS, USING A CREDIT CARD:

<https://mars.powweb.com:5021/mof15/orderd.htm> . HERE, OUR TEENS CAN BUY 63 DIANE-35 TABLETS FOR \$45 U.S. OR THE GENERIC ESTELLE-35ED PILLS AT QTY 84 FOR \$35 U.S. even though THESE PILLS ARE NOT YET AVAILABLE FROM OUR DOCTORS HERE. *****

7) HELSINKI, March 18, 2003 - The use of the abortifacient morning-after pill quadrupled in Finland [in a single year] after the pills became available without prescription. The Helsingin Sanomat reported yesterday that about 100,000 euros worth of the Norlevo pills were sold in 2001, when they still required a prescription. Last year a total of 36,000 packages were sold, at a total cost of 400,000 euros. **THE PAPER NOTES THAT THE OVERALL ABORTION RATE - SOME 10,000 PER YEAR - REMAINED VIRTUALLY THE SAME. HOWEVER, THE NUMBER OF GIRLS UNDER 15 COMMITTING ABORTIONS HAS RISEN FROM 73 IN 2001 TO 90 LAST YEAR.** [<http://www.helsinki-hs.net/news.asp?id=20030317IE4> ; <http://www.lifesite.net/ldn/2003/mar/03031906.html>]

The American College of Obstetricians and Gynecologists, the American Nurses Association, and the American Medical Women's Association have all petitioned the FDA to allow pharmacists to provide over-the-counter Emergency Contraception. They all think it is "safe" and "affordable" and that it will "help meet the health needs of millions of women and help resolve our planet's skyrocketing overpopulation crisis."

Firstly, it is NOT safe, as shown above and in the footnotes below. Secondly, there IS NO skyrocketing population crisis. In fact, it has been proven that in many developing countries, population growth is already in reverse and will not sustain these countries' survival since the negative population trend continues. Lastly, it will NOT meet the health needs of OVER 17 MILLION OTHER women, such as those of us who are regrettably post-abortive and would never do such a thing again. As Hanna Klaus, MD, Executive Director of the Natural Family Planning Center of Washington, D.C., testified at your hearing, many women have ethical objections against aborting an embryo at any stage of development, which is exactly what can happen because emergency contraceptives will prevent implantation of the embryo when conception has already occurred.

We are those women. What about OUR personal rights, and our rights to protect our minority children, born and unborn, from the harm you have just unleashed on them? I demand that the FDA revoke and never re-approve this "OTC Morning After Pill" decision to unleash such harm on women and babies again.

Sincerely,



Annie Rice Banno

OPERATION OUTCRY: SILENT NO MORE Connecticut State Leader

203-820-9898; E-mail: smok22@charter.net

P.O. Box 267

Fairfield, CT 06824-0267

National Toll-Free Helpline: 1-866-482-LIFE

<http://www.iamsilentnomore.com> or <http://www.operationoutcry.org>

www.CatholicExchange.com Columnist

http://catholicexchange.com/vm/archives.asp?vm_id=26&aut=553

CC: Acting CDER Ombudsman, Warren Rumble

CDER Ombudsman (HFD-1)

5600 Fishers Lane, Room 9-74

Rockville, MD 20857

Direct phone line: 301-594-5480 ; Fax: (301) 827-4312

E-mail address: ombudsman@cder.fda.gov

Website: <http://www.fda.gov/cder/ombud/default.htm>

["The Ombudsman's responsibilities include getting feedback from inside and outside the Center about the effectiveness of programs and about problems that impede CDER's performance of its mission or conflict with its values/operating principles..."]

FOOTNOTES AND ADDED BACKGROUND INFORMATION for my Petition:

*** BRITISH EXPERIMENT SHOWS EMERGENCY CONTRACEPTION MAY SPREAD STDS :**
CULTURE & COSMOS, November 4, 2003, Volume 1, Number 14

Great Britain is experiencing an explosion of sexually transmitted diseases, especially among the young. According to British government figures, infections across the board have grown rapidly at least since 1996.

Figures released last May from the Public Health Laboratory Service show that syphilis among British men has grown 612% in the six years ending in 2001 while similar infections in women have grown 206%. In the same time period, chlamydia infections for men and women have grown more than 100%, while herpes, genital warts, and gonorrhea have all grown substantially.

Some fear that a four-year-old public health experiment may contribute to what some are calling an impending public health emergency. In 1999 the British government started giving out free emergency contraception to women and girls in some local pharmacies. Emergency contraception is a heightened level of the regular contraceptive pill that when taken within 72 hours of intercourse can prevent a fertilized embryo from implanting in the mother's uterus. In this effect, emergency contraception causes an abortion.

Prior to 1999 most women who thought they were newly pregnant and wanted to end the pregnancy and who did not want to wait for a surgical abortion were required to get a doctor's prescription for emergency contraception, a process that could take more than the prescribed 72 hours. Besides adult women, the new experiment allowed girls as young as 16 to receive the drug. And the girls are allowed to get this over-the-counter abortifacient without parental consent.

Public health officials do not tell the women and girls that emergency contraception can cause abortion. It is marketed simply as a contraceptive and as something of a guarantee of avoiding pregnancy, a guarantee that experts fear can lead to risky behavior. More than one girl and several pharmacists confirmed this with researchers from the University of Nottingham, sponsors of the emergency contraception experiment. One girl told researchers "if I hadn't known I could have got (sic) it (emergency contraception) so easily, I would have been more careful, to be honest.

Even some of the pharmacists, who were almost unanimous in support of the program, were sometimes critical. Some pharmacists reported girls asking repeatedly for the drug. Some of them feared the easy availability of the drug would lead to sexual promiscuity and an increase in sexually transmitted diseases, a fear possibly born out by the burgeoning disease rate.

The most controversial aspect of the program focuses on giving the drug to girls as young as 16, especially without parental consent. One pharmacist reported a girl as young as ten years old requesting the drug.

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Website: <http://www.culture-of-life.org>

** "Total costs for a selected group of common STDs and related syndromes are estimated to be approximately \$10 billion in 1994 dollars (Table 2-5). Important to note is that this rough, conservative estimate does not capture the economic consequences of several other STDs and associated syndromes such as vaginal bacteriosis, trichomoniasis, nongonococcal urethritis, mucopurulent cervicitis, lymphogranuloma venereum, molluscum contagiosum, scabies, and pediculosis pubis. Nor does this estimate include the annual cost of sexually transmitted HIV/AIDS-related illness, which is estimated to be \$6.7 billion (Table 2-5). Inclusion of these costs raises the overall cost of sexually transmitted illnesses in the United States to nearly \$17 billion in 1994. These cost estimates underscore the enormous burden of STDs on the U.S. economy. They also represent compelling evidence of the need for effective STD prevention programs, especially in light of the fact that a sizable proportion of the direct costs of STDs results from failure to detect and effectively manage STDs in the initial, acute stage. For example, nearly three-fourths of the \$1.5 billion cost of chlamydial infections is due to preventable consequences of untreated, initially uncomplicated infections (Washington et al., 1987; Appendix D)."

From The Hidden Epidemic: Confronting Sexually Transmitted Diseases (1997), Institute of Medicine

<http://books.nap.edu/books/0309054958/html/58.html#pagetop>

*** Long-Term Use of Birth Control Pill Could Increase Cervical Cancer Risk, Study Says [Reuters, Apr 04, 2003]: A woman's risk of developing cervical cancer increases the longer she takes oral contraceptives, according to a study published in today's issue of the *Lancet*, BBC News reports (BBC News, 4/4). Researchers from Cancer Research UK's Epidemiology Unit in Oxford, England, and the International Agency for Research on Cancer in Lyon, France, examined 28 studies -- half of which were conducted in developing countries and half of which were conducted in the United States or Europe -- that included 12,531 women with cervical cancer. Researchers combined data from the studies to examine the link between invasive and non-invasive cervical cancer and the duration and time since last use of hormonal contraceptives (Smith et al., *Lancet*, 4/5). Researchers found that women who had used oral contraceptives for less than five years had a 10% increased risk of cervical cancer, compared with women who had never taken birth control pills; women who had taken the pills for five to nine years had a 60% increased risk; and women who had taken the pill for 10 years or longer had twice the risk of developing cervical cancer (Reaney, Reuters, 4/3). Researchers also compiled data separately from the 12 studies -- which included approximately 3,000 women -- that restricted analysis to women who tested positive for human papillomavirus, which is known to cause the majority of cervical cancer cases. The researchers found the same pattern of increasing risk with longer oral contraceptive use even when a woman's HPV status, smoking status, number of sexual partners, use of barrier contraception and access to regular Pap tests were taken into account. The researchers said that the findings demonstrate that the relative risk of cervical cancer becomes larger with the increasing duration of oral contraceptive use "in virtually every way that data were examined." The researchers state that more studies are necessary to determine if the findings are "biased or confounded" by HPV infection, which they said is "likely to be the most important cause of cervical cancer" (*Lancet*, 4/5). The researchers said that "some evidence" exists to suggest that a woman's increased risk of the cancer drops after she discontinues taking the pills but it is unclear (Boseley, *Guardian*, 4/4). Dr. Amy Berrington, one of the researchers, said that

the next step is to further investigate this possibility, adding that the results of that research would be available sometime next year (Reuters, 4/3).

****** SIXTEEN YEAR OLD GIRL MAY HAVE DIED FROM CONTRACEPTIVE USE
CULTURE & COSMOS; November 11, 2003, Volume 1, Number 15
[NOTE FROM AUTHOR OF CITIZEN'S PETITION TO FDA: THE TWO PILLS NAMED IN
THE FOLLOWING THREE ARTICLES ARE NOT YET AVAILABLE FROM U.S.
DOCTORS HERE, BUT THEY ARE EASILY OBTAINABLE BY SHOPPING AT WEBSITES
LIKE THIS, USING A CREDIT CARD: <https://mars.powweb.com:5021/mof15/orderd.htm> .
ON THESE WEBSITES, OUR TEENS ALREADY CAN BUY 63 DIANE TABLETS FOR \$45
U.S. OR THE GENERIC ESTELLE PILLS AT 84 FOR \$35 U.S.]**

A New Zealand coroner issued a report this week that says the suspicious death of a teenage girl a year ago may have been caused by the contraceptive pill called Estelle 35D.

It was reported in the New Zealand Herald that at the end, Stacey Bindle was lying on her bed "convulsed and frightened, unaware that a small but deadly blood clot was slowly traveling to her lungs." The girl's mother said her daughter was calling out "in a scared little voice," that she "could not breath." Four hours later Stacey Brindle was dead.

Her parents say Stacey was not sexually active but that she went to the Hamilton Family Planning Clinic to get Estelle 35D to treat mild acne. The Clinic is not legally bound to inform parents of dispensing potentially life-threatening drugs to minors and so gave the girl the prescription, which led to her death. Contraceptives are routinely handed out to adolescent girls in the developing world, but also in the US and the EU, frequently without parental consent.

The New Zealand Ministry of Health announced more than a year ago that women taking Estelle 35D and another contraceptive pill called Diane 35/35D should visit their doctor "after studies showed women taking them have an increased risk of blood clots." Estelle and Diane contraceptive pills contain "oestrogen and cyproterone acetate," which researchers believe can lead to blood clotting.

Given the risks involved, and that the belief that girl was likely not told of health risks associated with taking the contraceptive drug, the Bindles may join what is a growing trend of law suits against contraceptive manufacturers. Five hundred women in the United Kingdom and 200 women in Sweden have sued manufacturers over the health risks attendant to the use of contraceptive pills.

According to the Alan Guttmacher Institute, the research arm of Planned Parenthood, the largest abortion provider in the United States, "61% of reproductive-age women who practice contraception use reversible methods such as oral contraceptives or the condom." Guttmacher also reports that out of "2.7 million teenage women (sic) who use contraceptives, 44% -- more than 1 million women "rely on the pill" and that he pill "is the method most widely used by women in their 20s."

These particular drugs are not yet available in the United States, though the contraceptives used here also pose health risks. Even so, it is relatively easy to obtain Estelle and Diane simply by shopping on-line with a credit card.

The report on Stacey Bindle's death comes on the heels of the recent report that 18-year old Holly Patterson of Livermore, California died after taking the abortion pill RU-486, a death that has initiated

Congressional action to ban the drug. ~ Copyright © Culture of Life Foundation.

***** MHPD-DPSC This document is also available in PDF format [diane-35_dhpl_e.pdf]
Pages: 03, Size: 23.7K, Date: 2003-04-10 ; http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/diane-35_dhpl_e.html

IMPORTANT SAFETY INFORMATION ABOUT DIANE®-35 AND THE RISK OF VENOUS THROMBOEMBOLISM

- Berlex Canada Inc.
- Health Professional Advisory

The Marketed Health Products Directorate (MHPD), Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) post safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although MHPD, TPD and BGTD approve therapeutic products, MHPD, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from Berlex Canada Inc. Contact the company for a copy of any references, attachments or enclosures.

April 10, 2003: IMPORTANT DRUG SAFETY INFORMATION ABOUT DIANE®-35 AND THE RISK OF VENOUS THROMBOEMBOLISM

DIANE®-35, as with all estrogen/progestogen combinations, is contraindicated in women with thrombophlebitis, thromboembolic disorders, or a history of these conditions.

DIANE®-35 users appear to have an elevated risk of venous thromboembolic events compared to users of combination oral contraceptives in some published studies.

DIANE®-35 should not be prescribed for the purpose of contraception alone.

During treatment with DIANE®-35, other oral contraceptives should not be used.

Dear Health Care Professional(s),

Berlex Canada Inc., following discussions with Health Canada, would like to inform you about recent published information on the risk of venous thromboembolism (VTE) with DIANE®-35 (cyproterone acetate and ethinyl estradiol). DIANE®-35, like all estrogen/progestogen combinations, is associated with an increased risk of VTE compared with no use.

DIANE®-35 is a therapeutic agent indicated for the treatment of women with severe acne, unresponsive to oral antibiotic and other available treatments, with associated symptoms of androgenization, including seborrhea and mild hirsutism. It should be discontinued 3 to 4 cycles after signs have completely resolved. DIANE®-35 has many properties in common with combination oral contraceptives and the same contraindications, warnings and precautions apply to DIANE®-35.

Based on an independent analysis, commissioned by Berlex, of recently published information 1-7, cases of non-fatal VTE ranging in incidence from 1.2 to 9.9 events per 10,000 women-years have been observed in users of DIANE®-35. As context, the incidence of VTE in non-users of

any oral contraceptive is estimated to be 0.5 to 1 event per 10,000 women-years, and increases to 4 events per 10,000 women-years in long-term users of low estrogen content (< 50 µg ethinyl estradiol) combination oral contraceptives⁸. These event rates are rare, but still justify caution in the use of DIANE®-35.

Since market introduction in 1998, Health Canada has received 11 reports of VTE (deep vein thrombosis, pulmonary embolism, and stroke) equivalent to a reporting rate of 0.33 events per 10,000 women-years. One of these cases involved a death. It should be noted that reporting rates determined on the basis of spontaneously reported post-marketing adverse events are generally presumed to underestimate the risks associated with drug treatments.

Women with androgen-related conditions (e.g., severe acne or hirsutism) may have an inherently increased cardiovascular risk. The excess risk of VTE is highest during the first year a woman ever uses a combination oral contraceptive.

Berlex Canada Inc. is committed to providing you with the most current product safety information on its products. We hope this information will be helpful to you in caring for your patients on DIANE®-35. The official DIANE®-35 Product Monograph is being updated to reflect this new information.

The identification, characterization, and management of drug-related adverse events are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Health care professionals are asked to report any suspected adverse reactions in patients receiving DIANE®-35 directly to Berlex Canada Inc. at the following address:

Berlex Canada Inc.
334 Avro Avenue
Pointe-Claire, Quebec H9R 5W5
Tel: (800) 361-0240 or by
fax at (514) 631-4721

Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed drug use.

If you have any questions regarding DIANE®-35, please contact Berlex Canada at 1-800-361-0240.

Yours sincerely,
original signed by
Dr. Jean-Louis Stril, M.D.
Manager, Disease Management and Drug Safety
Berlex Canada Inc.

- 1 Lidegaard O. et al. *Contraception* 2002; 65:187-196.
- 2 Pini M et al. *Rec Prog Med* 1996; 87:331-337.
- 3 Farmer RDT et al. *Br J Clin Pharmacol* 2000; 49:580-590.
- 4 Vasilakis-Scaramozza C and Jick H. *The Lancet* 2001; 358:1427-1429.
- 5 Seaman HE et al. *Human Reproduction* 2003; 18:522-526.
- 6 WHO 1995 *Lancet* 1995; 346:1582-1588.
- 7 Farmer RDT. *Hum Rep Upd* 1999; 5:688-706.

8 The European Agency for the Evaluation of Medicinal Products (EMEA). EMEA committee for proprietary medicinal products (CPMP) Public Assessment Report. Combined oral contraceptives and venous thromboembolism. 28 September 2001.
<http://www.emea.eu.int/pdfs/human/regaffair/0220101en.pdf>

Any suspected adverse reactions can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free for consumers and health professionals:
Tel: 866 234-2345, Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the TPD web site or in The Canadian Compendium of Pharmaceuticals and Specialties.

***** Last updated - 2003-07-10 Important Notices : Adverse Reaction Reporting and IMMP
Adverse Reactions of Current Concern, Web site: last updated March 2003
<http://www.medsafe.govt.nz/Profs/adverse/cc.htm>

The Medicines Adverse Reactions Committee (MARC) first initiated the list of Adverse reactions of current concern in 1994, as a means of bringing particular medicine adverse reactions to the attention of prescribers. The purpose of the list is also to encourage prescribers to report the reactions to the Centre for Adverse Reactions Monitoring (CARM) so that more information can be gathered, and further action taken if necessary. The reports provide a New Zealand perspective on emerging medicine safety issues.

Since initiation, the number of reactions listed has grown, and is revised from time to time. Amendments are made either in response to reactions reported in New Zealand or international pharmacovigilance issues.

As with any adverse reactions monitoring scheme, analysis can only be based on reports that are received. Prescribers are therefore encouraged to continue reporting adverse reactions to CARM so that the MARC can make the best possible recommendations based on information reflecting the New Zealand situation.

Please report all cases of these adverse reactions, to the Centre for Adverse Reactions Monitoring (CARM), PO Box 913, Dunedin.

Medicine	Adverse reactions	Date of addition to list
Diane-35™	venous thromboembolism	November 2000
Estelle-35™	venous thromboembolism	October 2001

Thromboembolism with oral contraceptives
February 2002 update - Oral contraceptives were added to the list of adverse reactions of current concern in February 1996 (12) after international studies (13-16) found that third generation oral contraceptives (OCs) were associated with a higher risk of venous thromboembolism, compared

to second generation OCs. Since listing, CARM has received 32 reports of pulmonary embolism (nine fatal) and 48 reports of other venous thrombotic events with combined OCs. No fatal cases have been reported since 1999, possibly reflecting reduced prescribing of the third generation OCs, greater attention to risk factors, and higher index of suspicion for early diagnosis and treatment of VTE.

Diane 35/35ED™ (cyproterone acetate and ethinyloestradiol), for use in women with androgenic disorders who require contraception, were added to the list in February 2001 following reports of venous thromboembolism in women taking Diane-35, in New Zealand. Estelle 35/35ED™ (a generic brand) were also added to the list of adverse reactions of current concern in October 2001.

Prescribers are encouraged to keep reporting venous thromboembolism with all OCs to CARM as the reactions remain under active surveillance by the MARC.

(12) Therapeutics section, Ministry of Health. The risk of venous thromboembolism with third generation oral contraceptives. Prescriber Update February 1996(11):14-16
<http://www.medsafe.govt.nz/Profs/PUarticles/contraceptivesFeb96.htm>

(13) WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Effect of different progestagens in low oestrogen oral contraceptives on venous thromboembolic disease. Lancet 1995;346:1582-1588.

(16) Spitzer WO, Lewis MA, Heinemann LAJ, et al. Third generation oral contraceptives and risk of venous thromboembolic disorders: an international case-control study. BMJ 1996;312:83-88.