February 14, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 10-61
5630 Fishers Lane
Rockville MD 20857

CITIZEN'S PETITION

The American Public Health Association, the American Medical Women's Association, the Association of Reproductive Health Professionals, the National Asian Women's Health Organizations, the National Black Women's Health Project, the National Family Planning and Reproductive Health Association, the Planned Parenthood Federation of America, the Reproductive Health Technologies Project and 58 other organizations listed below, by their counsel, the Center for Reproductive Law & Policy, submit this petition pursuant to 21 C.F.R. § 10.30 (1999), to request that the Food and Drug Administration (FDA) switch from prescription to over-the-counter (OTC) status two FDA-approved emergency contraceptive drugs, *Preven*™ and *Plan B*®, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Preven*™ or *Plan B*® (hereinafter these drugs will be collectively referred to as EC). Such a switch is authorized under 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b) because, as set forth below and in the supporting Declaration of David Grimes, M.D ("Grimes Dec."), EC is safe and effective for OTC use. Accordingly, the FDA should grant this Petition and exempt EC from prescription dispensing limitations.

ACTION REQUESTED

Petitioners request that the FDA exempt from prescription-dispensing requirements, pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b), *Preven*™, *Plan B*®, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Preven*™ or *Plan B*®.

STATEMENT OF GROUNDS

Under the Food, Drug and Cosmetic Act and FDA regulations, "[a]ny drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b); *see also* 21 U.S.C. § 353(b)(3) ("The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health."). FDA regulations also explicitly authorize the use of a citizen's petition to seek a switch from prescription to OTC status: "A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by . . . any interested person . . . . fil[ing] a petition . . . pursuant to Part 10 of this chapter . . . ." 21 C.F.R. § 310.200(b).

Limiting EC to prescription use is not necessary for the protection of public health. As set forth in greater detail in the accompanying Declaration of Dr. Grimes, EC meets all the criteria for OTC availability. In general, an approved drug is suitable for OTC use when: (1) the drug is safe for self-medication, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(i) (1999); Tamar Nordenberg, *Now Available Without a Prescription*, FDA Consumer 7, 9 (Nov. 6,

1996); Marian Segal, *Rx to OTC: The Switch is On*, www.fda.gov/bbs/topics/consumer/CN00012c.html (March 1991); R. William Soller, "*OTCness*", 32 Drug Information Journal 555, 556-58 (1998); Debra L. Bowen, *Making the Switch to OTC*, III Cosmetics & Toiletries 102 (May 1996); Nancy L. Buc, *The Switch from Prescription to Over the Counter, in* The Pill: From Prescription to Over the Counter 237, 238-39 (eds. Samuels & Smith 1994); (2) the drug is effective when self-administered, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(ii)(1999); Soller, *supra* at 556, 558-59; Bowen, *supra*; Buc, *supra*; Nordenberg, *supra* at 7; (3) the condition to be treated is self-diagnosable, Segal, *supra*; Bowen, *supra*, Buc, *supra*; and (4) the drug's labeling is tailored to self-administration, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(v)(1999); Soller, *supra,* at 559-60; Segal, *supra*; Bowen, *supra*; Buc, *supra*; Nordenberg, *supra* at 7-8, 9, 11.

First, EC is safe for self-medication because it is not toxic to the woman (or to the embryo or fetus if a pregnancy had been previously established in the woman); it has a low risk of abuse or overdose; overdose is unlikely to lead to serious consequences; and its side effects are well known and minor. Grimes Dec. ¶¶ 8A, B, C, F. Second, EC is effective when self-administered. Its administration is simple and relies only on assessments as to time elapsed since sexual intercourse that can be independently made by the woman, and any interaction between EC and other drugs would be nonfatal and unlikely to seriously affect EC's efficacy. Grimes Dec. ¶ 8I. Third, the condition EC treats — contraceptive failure or failure to use contraception during intercourse — is one that is readily diagnosable by a woman, and EC has no contraindications that would pose a danger to the patient. Grimes Dec. ¶ 8D. Fourth, the existing patient labeling for *Preven*™ and *Plan B*® is tailored to self-administration in that it is simple, clear, comprehensive and easy to follow. Grimes Dec. ¶ 8H. Finally, switching EC to

OTC status will promote public health because EC is only effective for a short time after unprotected sex, and it works most effectively if used within twenty-four hours of unprotected sex. Because contacting a physician and obtaining and filling a prescription hinder women from obtaining EC in a timely fashion, making EC available OTC will allow more women to use the treatment, and enable more women to prevent unwanted pregnancies, to the benefit of public health. Grimes Dec. ¶¶ 5, 6, 7. Accordingly, both the American Medical Association and the American College of Obstetricians and Gynecologists have publicly supported efforts to move EC to OTC status. *See* Dec. 5, 2000 Statement of American Medical Association, http:/www.ama-assn.org/ama/pub/article/1617-3547.html (copy attached hereto); February 14, 2001 Statement of the American College of Obstetricians & Gynecologists Supporting the Availability of Over-the-Counter Contraception (filed herewith).

Because limiting EC to prescription dispensing is not necessary for the protection of public health, the FDA should exempt it from that limitation. 21 C.F.R. § 310.200(b) (a drug "shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health").

ENVIRONMENTAL IMPACT

The proposed action is exempt from the requirement of an environmental impact statement under 21 C.F.R. §§ 25.24(a)(8) and (c)(6).

ECONOMIC IMPACT

No information is required at this time.

CERTIFICATION

The Center for Reproductive Law & Policy, counsel for petitioners certifies that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies. The petitioners know of no data unfavorable to the petition.

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PETITIONERS

Advocates for Youth

The Alaska Emergency Contraceptive Project

American Association of University Women

American Academy of Pediatrics

American College of Nurse-Midwives

Americans for Democratic Action

American Medical Women's Association

The American Nurses Association

American Public Health Association

American Society for Emergency Contraception

American Society for Reproductive Medicine

Arizona Family Planning Council

Association of Reproductive Health Professionals

Beaverhead Family Planning Clinic

Center for Entrepreneurship in International Health and Development, School of Public Health, University of California, Berkeley

Center for Women's Policy Studies

Choice USA

The Compton Foundation

The Consortium for Emergency Contraception

Family Health Care, Inc.

Family Health International

Family Planning Association of Northern Ohio, Inc.

Family Planning Council

Family Planning Councils of America

Family Planning Council of Iowa

Family Planning Association of Maine

Family Tree Clinic

Fargo Cass Public Health

Health Care of Southeast Massachusetts

Health Quarters

Ipas

Lake County Family Planning

Medical and Health Research Association of New York City, Inc

National Abortion Federation

National Abortion and Reproductive Rights Action League

- California Abortion and Reproductive Rights Action League
- Massachusetts Abortion and Reproductive Rights Action League
- Minnesota Abortion and Reproductive Rights Action League
- New York Abortion and Reproductive Rights Action League

National Asian Women's Health Organization

National Association of Nurse Practitioners in Women's Health

National Black Women's Health Project

National Coalition Against Domestic Violence

National Consumers League

National Family Planning and Reproductive Health Association

The National Organization for Women Legal Defense and Education Fund

The National Organization on Adolescent Pregnancy, Parenting & Prevention

National Partnership for Women and Families

Okanogan Family Planning

Oops- Emergency Contraception Hotline

Pacific Institute for Women's Health

Pathfinder International

Physicians for Reproductive Choice and Health

Planned Parenthood Federation of America and all Planned Parenthood Affiliates Nationwide

- Planned Parenthood of Central Washington
- Planned Parenthood/ Chicago Area
- Planned Parenthood of Connecticut
- Planned Parenthood Heart of Illinois
- Planned Parenthood of Houston and Southeast Texas, Inc

Planned Parenthood Association of Lubbock

Planned Parenthood of Nassau County

Planned Parenthood of the Saint Louis Region

Planned Parenthood of Southern Arizona

Planned Parenthood of Stark County

Planned Parenthood of the Texas Capital Region

Planned Parenthood of Western Washington

The Population Council

Population Services International, U.S. Programs

Pro Choice Resource Center

Program for Appropriate Technology in Health

The Reproductive Health Technologies Project

The Sexuality Information and Education Council of the United States

Texas Family Planning Association

Tri City Health Center

Voters for Choice

Women's Health Center of West Virginia

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AMA on access to emergency contraception

For immediate release
December 5, 2000

Statement attributable to:
Edward J. Hill, MD
AMA trustee

"The AMA today approved recommendations regarding greater access to emergency contraception pills (ECPs). Two brand names for emergency contraceptive pills are Preven and Plan B.

"In addition to reaffirming current AMA policy that holds that no physician or other professional personnel should be required to perform an act that violates personally held moral principles, the AMA passed new policies to encourage physicians to play a more active role in providing education about access to ECPs. The new policies also direct the AMA to intensify efforts to improve awareness and understanding about the drugs and to enhance efforts to expand access to them, including making them more available through hospitals, clinics, emergency rooms, acute care centers, and physicians' offices.

"In order to expand access to ECPs, the AMA also decided to support and monitor the application process of manufacturers filing for over-the-counter approval of emergency contraception pills with the Food and Drug Administration (FDA). If the FDA determines that ECPs are safe for over-the-counter use, the AMA would support that increased access."

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ACOG News Release

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Statement of
The American College Of Obstetricians and Gynecologists
Supporting the Availability of
Over-the-Counter Emergency Contraception

February 14, 2001

The American College of Obstetricians and Gynecologists (ACOG) supports making emergency oral contraception available to women over the counter in a designated product.

The time has come for women to have access to a product that they need. Almost half of the 6.3 million annual pregnancies in the US are unintended. Emergency contraception holds the potential to cut this figure in half. This in turn could substantially reduce the US abortion rate of about 1 in every 4 pregnancies.

The US Food and Drug Administration has declared emergency contraceptive pills to be safe and effective in preventing pregnancy. Yet substantial barriers exist to women obtaining this fallback contraceptive method that must be used within 72 hours after unprotected intercourse. We believe that emergency oral contraception can meet the FDA criteria for over-the-counter availability. Then, at last, women would have access to an important method of preventing pregnancy.

###

The American College of Obstetricians and Gynecologists is the national medical organization representing over 40,000 physicians who provide health care for women.

Declaration of David A. Grimes, MD, and Elizabeth G. Raymond, MD, MPH

1. We are both obstetrician-gynecologists with special expertise in epidemiology and public health. We are licensed to practice in North Carolina and are clinically active. We serve on the National Medical Committee of Planned Parenthood Federation of America. Moreover, we have conducted research on emergency contraception in the U.S. and internationally[1-7] and are recognized experts in the field of emergency contraception. Our curricula vitae are attached as appendices.

2. In the past several years, two emergency contraceptive pill (ECP) regimens have been approved by the US Food and Drug Administration. Both regimens consist of two doses of hormone taken 12 hours apart. The Yuzpe regimen (currently marketed as *Preven*™, Gynetics, Inc., Somerville, NJ) contains both an estrogen, ethinyl estradiol, and a progestin, levonorgestrel, in each dose. The levonorgestrel regimen (marketed as *Plan B*®, Women's Capital Corporation, Kirkland, WA) contains only levonorgestrel. Both of these regimens are currently available only by prescription.

3. We write to advocate an immediate switch of these regimens from prescription to over-the-counter status. Our reasoning is based on two considerations: first, the prescription requirement limits access to the pills, which prevents effective use of the treatment, and second, no medical justification exists for maintaining prescription status.

4. Unintended pregnancy is a major public health problem in the United States. Almost half of all US women aged 15 to 44 years in 1994 have had at least one unplanned pregnancy at some time in their lives, and almost half of the 5.4 million pregnancies ending in 1994 were unintended and resulted in unwanted or mistimed births or in abortion. If current abortion rates persist, more than 40% of US women will have had at least one induced abortion by menopause.[8] Although

the unintended pregnancy rate has decreased in the past decade, the US rate remains substantially higher than that in other developed countries[9] and is particularly high among young, less educated, and poor women.[8] The consequences of unintended pregnancy can be serious, including maternal death and morbidity, abortion, low birth weight, birth defects, infant death, maternal and child abuse, and social and economic hardship for all involved.[9,10]

5. ECPs have the potential to reduce the incidence of unintended pregnancy substantially.[11] Most unintended pregnancies occur after an immediately apparent contraceptive failure – a condom breaks, oral contraceptive pills are missed, a spermicide tablet fails to melt – or after a couple fails to use any contraception at all. At least one of these events has been estimated to occur in more than 64 million menstrual cycles per year in the United States.[12] If ECPs were used in three-quarters of these situations, unintended pregnancies and consequent abortions could be reduced by as much as half.[13]

6. These benefits can be realized, however, only if women have ready access to the therapy. Both ECP products currently approved by the FDA are labeled for use within the first 72 hours after intercourse. Even within this time period, both regimens appear to be substantially more effective the sooner they are used: in one recent study, the chance of pregnancy was at least 4 times greater if ECPs were taken between 48 and 72 hours after coitus than if they were taken within less than 24 hours.[7] Any delay in treatment reduces efficacy, leading to an increased risk of treatment failure and consequent unintended pregnancy.

7. Prescription status is a major barrier to access to ECPs. Patients are often unable to see or contact a health care provider quickly to obtain a prescription, especially on weekends and in evenings when contraceptive accidents are most likely to occur. Removing the prescription requirement and allowing women to purchase ECPs directly over the counter is the most expedient way to ensure that women can obtain and use them immediately whenever the need arises.

8. In addition, prescription status is medically unwarranted.[14,15] Both ECP regimens fulfill all the customary criteria[16] for over-the-counter distribution:

A. ***Low toxicity.*** The hormones contained in ECPs have been used in oral contraceptive pills by tens of millions of women around the world for more than three decades. Indeed, the oral contraceptive pill is arguably the most extensively studied medication in the history of pharmaceuticals. The incidence of serious complications of chronic use of these pills has proven to be extremely low.[17] In the largest study of the two FDA-approved ECP regimens reported to date, the most commonly reported complaints were nausea, breast tenderness, lower abdominal pain, fatigue, headache, heavier or lighter menstrual bleeding, dizziness, and vomiting, and diarrhea (Table 1).[5] No deaths have ever been attributed to use of ECPs, and the few case reports of serious adverse events in ECP users do not suggest a causal connection.[18] ECPs are certainly safer than many drugs currently sold over the counter in the United States. For example, hundreds of deaths are recorded yearly in this country from overdoses of aspirin and other antipyretics and analgesics.[19] To allow unrestricted access to aspirin while requiring a physician's prescription for ECPs makes no sense.

B. ***No potential for overdose and addiction.*** An overdose of ECPs could lead to the side effects previously mentioned, but to our knowledge, no deaths, suicides, or other serious consequences of an acute overdose of either hormone have been reported. Indeed, a study by the World Health Organization found menstrual irregularities to be the most notable side effect of levonorgestrel used repeatedly for postcoital contraception.[20] The hormones contained in the two approved ECP products are not addictive.

C. ***No teratogenicity or danger in pregnancy.*** Extensive studies over four decades have confirmed that use of hormonal contraception during early pregnancy carries no risk of damage to an embryo.[21] The FDA removed warnings about possible teratogenic effects

from labeling of oral contraceptive pills several years ago, and approved labeling of ECPs also does not carry this warning. Guidelines from expert organizations do not require a pregnancy test before treatment with ECPs,[22,23] nor does FDA-approved labeling of the *Plan B®* product.

D. ***No contraindications requiring screening by a medical professional.*** The package labels for the two ECP products approved by the FDA list a number of contraindications (Table 2). However, other than pregnancy, none of these contraindications are supported by medical evidence.[22,23] These lists appear to have been adapted from package labeling for oral contraceptive pills, which is inappropriate given the different patterns of use. No reason exists to believe that contraindications to oral contraceptive pills, which are used daily over months or years, should apply to ECPs, which are used in a single 12 hour period and which contain a much lower total hormone dose. These contraindications should be removed from the labeling of ECPs.

Pregnancy is a legitimate contraindication to use of ECPs, but only because the treatment is ineffective during pregnancy, not because it places the woman or the pregnancy at risk. Pregnancy can usually be ruled out by a woman herself without examination by, or even consultation with, a medical professional. In cases of doubt, she can use an over-the-counter pregnancy test or see her health care provider. Because ECPs are not dangerous to a pregnancy, if a pregnant woman inadvertently takes ECPs, no harm is expected to result.

E. ***No need for screening to recognize indication for therapy.*** The only indication for use of ECPs is unprotected intercourse. Identification of this indication does not require professional expertise.

F. ***No need for professional monitoring of treatment.*** The duration of treatment with ECPs is short (12 hours), and the elimination half life of each of the two hormones is less than 24 hours.[24] Side effects are self-limited and generally mild. Severe symptoms, if

they occur, are usually managed with over-the-counter analgesics or antiemetics. If ECPs fail, a woman will eventually recognize on her own that she is pregnant. Professional monitoring will neither reduce the incidence of side effects nor increase the efficacy of therapy and is unnecessary.

G. ***Same dose for all women.*** Both currently approved regimens of ECPs consist of two equal doses taken 12 hours apart. Because this dose is applicable to all women, professional expertise is not needed to determine the correct dose. In this respect, ECPs are much simpler than medications currently sold over the counter which require tailoring of dose based on patient characteristics (such as age) or therapeutic response.

H. ***Simplicity of treatment regimen.*** The instructions for use of ECPs are straightforward: take one dose as soon as possible, and a second, identical dose 12 hours later. The existing patient instructions for *Preven*™ and *Plan B*®, which are attached as appendices, are simple and easy to follow. Consumers regularly follow much more complicated instructions for other over-the-counter medications by reading the package label.

I. ***No important drug interactions.*** Evidence suggests that the efficacy of oral contraceptive pills may be reduced by concomitant use of certain medications, such as rifampin and certain anticonvulsant drugs, and possibly by use of the nutritional supplement St. John's Wort.[25,26] Similar interactions may occur with ECPs as well. However, no conclusive information is available on how or even whether the ECP dose should be adjusted for women taking these drugs. The prescription requirement for ECPs does not resolve the problem posed by this lack of knowledge. Once data on this matter become available, labeling of ECPs could be modified to advise women taking these drugs to alter the ECP dose appropriately or to consult their physicians. Contraceptive steroids are not known to have substantial effects on activity of other drugs.

9. Because of the urgent need to improve access to ECPs and the lack of any compelling reason to prohibit women from exercising control over this contraceptive method, family planning programs in the United States and abroad are already moving to "OTC-like" distribution approaches for ECPs. Of note, Planned Parenthood Federation of America has endorsed prescription of ECPs by telephone, as well as provision of ECPs prophylactically, so that patients may keep the pills at home in case of future need. These approaches are similar to over-the-counter distribution in that the patient is not examined before she takes the pills; and in the case of advance provision, she may not have had any screening or counseling by a medical professional for weeks, months, or even years before pill use. Planned Parenthood affiliate clinics and other reproductive health service clinics around the country have instituted these practices with no known problems. In October, 2000, ECPs become available over the counter in Norway.

10. In summary, the requirement for a prescription to obtain ECPs hurts women's health by posing an unnecessary obstacle to the prompt, effective use of this important therapy. This requirement indirectly contributes to the epidemic of unintended pregnancies and induced abortions in this country. These outcomes are both antithetical to the mission of the FDA and damaging to public health. No medical reason exists to maintain prescription status for ECPs, as professional intervention is not necessary to ensure safe and correct use. Following the primary principle of medical care "first, do no harm," the prescription requirement for ECPs should be dropped.[14,15,27]

We declare under penalty of perjury that the foregoing is true.

Dated this 8th day of February 2001.

David A. Grimes, MD

Elizabeth G. Raymond, MD, MPH

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Table 1. Side effects associated with two ECP regimens

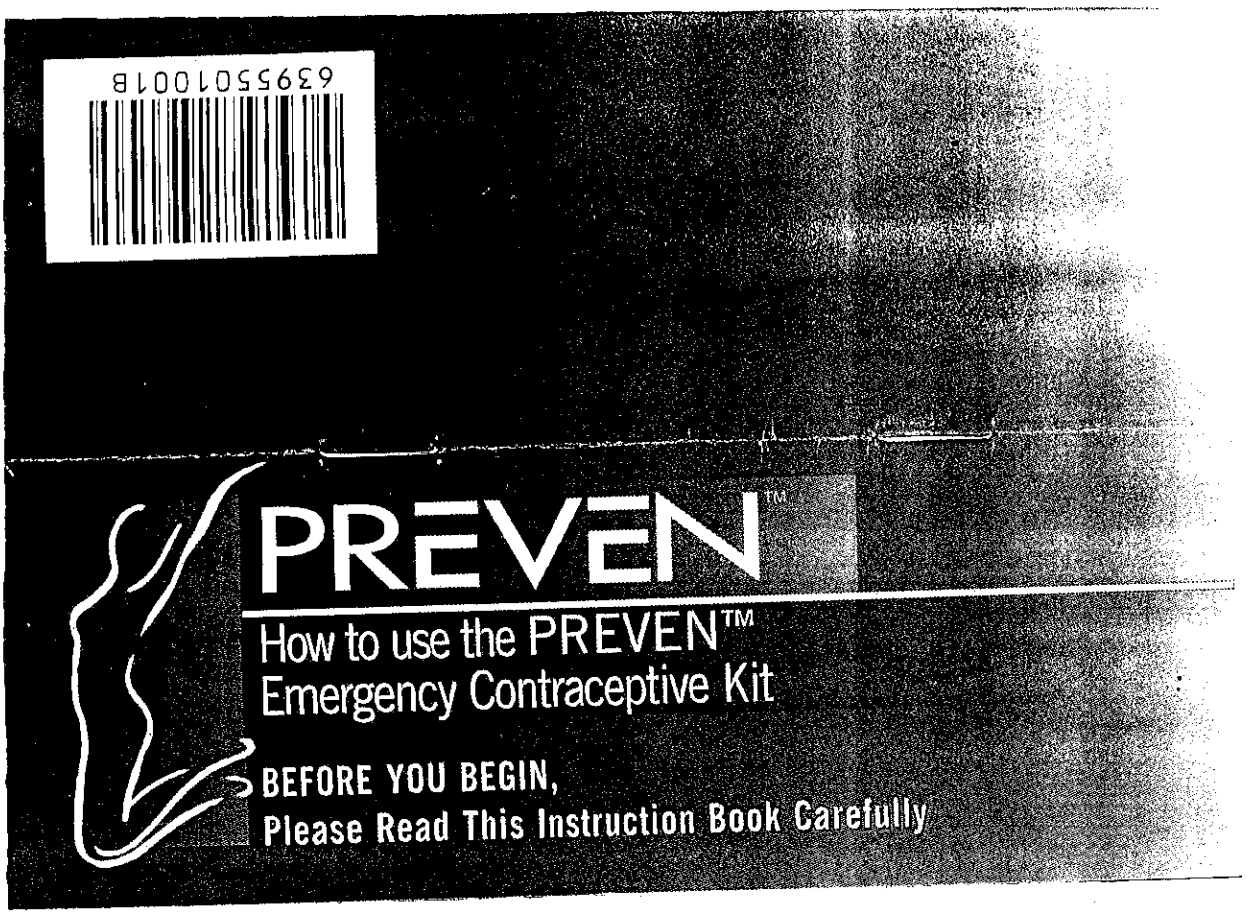
	% with symptom (95% CI)	
	Yuzpe (n=979)	Levonorgestrel (n=977)
Nausea	50.5 (47.3 – 53.6)	23.1 (20.5 – 25.9)
Vomiting	18.8 (16.4 – 21.4)	5.6 (4.3 – 7.3)
Dizziness	16.7 (14.4 – 19.1)	11.2 (9.3 – 13.3)
Fatigue	28.5 (25.7 – 31.4)	16.9 (14.6 – 19.4)
Headache	20.2 (17.8 – 22.9)	16.8 (14.5 – 19.3)
Breast tenderness	12.1 (10.1 – 14.3)	10.8 (8.9 – 12.9)
Low abdominal pain	20.9 (18.4 – 23.6)	17.6 (15.3 – 20.1)
All other adverse effects*	16.7 (14.4 – 19.1)	13.5 (11.4 – 15.8)

*Mostly diarrhea and some irregular bleeding or spotting.

From: Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Lancet 1998;352:428-33.

Table 2. Contraindications listed on FDA approved labeling of two approved ECP products

Preven™	*Plan B*®
Combination oral contraceptive pills [including *Preven*™] should not be used by women who have: • pregnancy • history of blood clots in deep veins of legs • history of heart attack • history of stroke • valvular heart disease with complications • severe high blood pressure • diabetes with blood vessel involvement • severe headaches • liver tumors • active liver disease • heavy smoking and older than 35 years • allergy to any components of the product "May not be advisable to use ECPs" if you have had: • heart attack or stroke • blood clots in legs, lungs, or eyes • breast, endometrial, cervical, or vaginal cancer • unexplained vaginal bleeding • jaundice during pregnancy or OCP use • liver tumor	*Plan B*® should not be used by women who have: • pregnancy • unexplained vaginal bleeding • allergy to any ingredient in the product



INTRODUCTION

This book is to help teach you how to use the PREVEN™ Emergency Contraceptive Kit correctly. When used according to the directions, only 2 out of 100 women might become pregnant after a single act of intercourse. If no method of contraception is used, about 8 out of 100 might become pregnant.

Like all oral contraceptives, emergency contraceptive pills do not protect against infection with HIV (the virus that causes AIDS) and other sexually transmitted diseases. For more detailed information, please refer to the Detailed Patient Labeling included in this kit. If you still have questions or do not fully understand how to use the kit after reading this book, you should talk to your healthcare professional.

Your healthcare professional has prescribed the PREVEN™ Emergency Contraceptive Kit for you in the event you may be at risk for an unintended pregnancy after unprotected sex. Unprotected sex is when you know or suspect that your birth control failed (for instance, a condom broke during sex) or you may have had sex without using birth control.

The pills in the PREVEN™ Emergency Contraceptive Kit will reduce the risk of unintended pregnancy if you start taking them as soon as possible but within **72 hours** of having unprotected sex. They will **not** work if you are already pregnant.

What are Emergency Contraceptive Pills (ECPs)?

The PREVEN™ Emergency Contraceptive Kit pills contain hormones similar to those found in daily, combination birth control pills (COCs): an estrogen (ethinyl estradiol) and a progestin (levonorgestrel). The difference is that daily combination birth control pills are taken one pill each day for 21 per cycle to prevent pregnancy, whereas emergency contraceptive pills are taken as two pills in two doses to prevent pregnancy. The first dose of two pills is taken as soon as possible but **within 72 hours** after unprotected sex, and the second dose of two pills is taken **12 hours** later. **The pills in the PREVEN™ Emergency Contraceptive Kit are meant for emergency use only and should not be used as your regular method of birth control.**

What does the kit contain?

The PREVEN™ Emergency Contraceptive Kit contains:

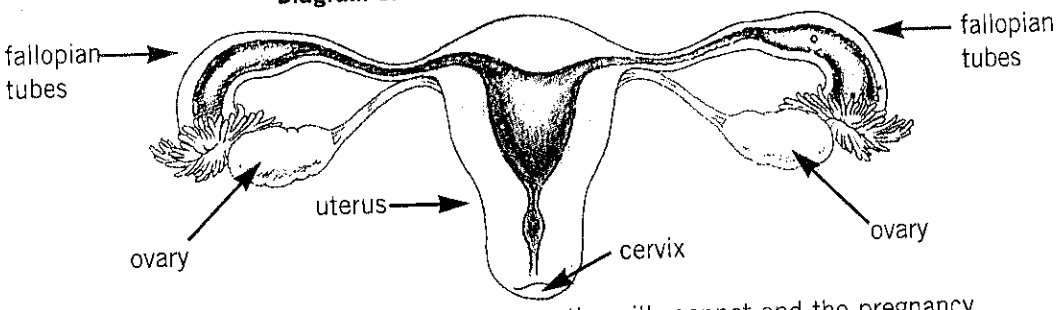
- this Patient Information Book and Detailed Patient Information;
- a pregnancy test;
- four light blue emergency contraceptive pills.

How do the pills in the PREVEN™ Emergency Contraceptive Kit prevent pregnancy?

The hormones contained in the emergency contraceptive pills prevent pregnancy in the same way that daily birth control pills do.

- they delay or prevent ovulation (the process of maturation and the release of an egg from the ovary);
- they may make it difficult for sperm to fertilize an egg if one has been released from the ovary;
- they may produce changes in the lining of the womb (uterus).

Diagram of the Female Reproductive System



If you are already pregnant, emergency contraceptive pills cannot end the pregnancy. Instead, the pills prevent a pregnancy from beginning.

Who should not use PREVEN™ Emergency Contraceptive Kit pills?

Do not use the pills in the PREVEN™ Emergency Contraceptive Kit if you are already pregnant as a result of a previous intercourse (not the intercourse within the last 72 hours).

Emergency contraceptive pills may not be right for all women. It may not be advisable to use ECPs if you have had:

- a heart attack, or a stroke;
- blood clots in your legs, lungs, or eyes;
- breast cancer or cancer of the lining of the uterus, cervix, or vagina;

- unexplained vaginal bleeding;
- jaundice (yellowing of the whites of the eyes or skin) during a prior pregnancy or during previous daily use of the combination birth control pill;
- a liver tumor.

Be sure to tell your healthcare professional if you have ever had any of these conditions.

How to use the PREVEN™ Emergency Contraceptive Kit

Step 1. Please finish reading this patient book in full before using the Kit.

Step 2. Use the pregnancy test.

The pregnancy test is provided to help you determine if you are already pregnant from sex earlier in the month or in previous months. It will not tell you if you are pregnant from sex which took place within the previous 72 hours. The test detects pregnancy by showing if a hormone called human chorionic gonadotropin or (hCG) (made by cells which are a part of the pregnancy) is present in your urine.

How to use the pregnancy test:

- Perform the test while sitting on the toilet.
- Remove the test from the foil wrapper by tearing at the notches on the package. Throw away the freshness packet (drying agent) inside the wrapper.

- Take off the protective cap covering the absorbent tip.
- Hold the test stick with the absorbent tip pointing downward and place the tip into your urine stream for **at least five seconds**. The entire tip should get wet. **Do not urinate** on the windows of the test stick.
- Remove the test stick from the urine stream. It is not necessary to replace the cap over the tip.

- Lay the test stick on a flat surface with the windows facing up. As the test begins to work, you will notice a pink/purple color moving across the windows. Don't be alarmed—this is the normal 'development' process.

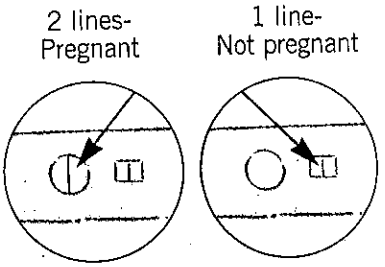
How to read the pregnancy test:

- You should wait at least three minutes after exposure to your urine for the results, but not longer than 20 minutes. You can tell the test is ready to be read when you see a pink/purple line in the SQUARE control window. All tests which have been performed correctly will show a pink/purple line in the SQUARE control window. You must see a line in this SQUARE control window in order

for the test to be valid. Contact your healthcare professional if you do not see the pink/purple line in the SQUARE control window.

- If a pink/purple line appears in the ROUND result window, you are pregnant.

IMPORTANT: If you get a positive pregnancy result, do not take any of the pills in the PREVEN™ Emergency Contraceptive Kit. Contact your healthcare professional.



- The lines can be any shade of pink, as long as you can see two clear and distinct lines as shown.
- The test may show you are pregnant when you are not if you have had a miscarriage or have given birth within the past 8 weeks. You should ask your healthcare professional for help in interpreting the result of your pregnancy test if you have recently been pregnant.

NOTE: It doesn't matter which line is darker. As long as there is a line in the SQUARE control window to indicate the test is meaningful, the presence of a line in the ROUND result window indicates you are pregnant.

- If the test is negative–meaning **no** pink/purple line appears in the ROUND result window–continue on to step 3.

IMPORTANT: If the pregnancy test shows that you are already pregnant, do **not** take the pills in the PREVEN™ Emergency Contraceptive Kit. The pills will **not** work.

Step 3. Take the PREVEN™ Emergency Contraceptive Kit Pills.

Each kit contains four light blue pills, which are taken in two doses of two pills per dose.

- Take the first dose of two pills as soon as possible but **within 72 hours** of having unprotected sex.
- Take the second dose of two pills **12 hours** after the first dose. For example, if you take the first two pills at 8 a.m., you must take the second dose of two pills at 8 p.m.

TIP: Try to take the first dose at a time that will make it convenient to take the second dose 12 hours later. However, remember that the first dose must be taken as soon as possible but within 72 hours after unprotected sex.

- Do not take any extra pills unless recommended by your healthcare professional.

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Side Effects

Some women who use the pills in the PREVEN™ Emergency Contraceptive Kit will experience side effects.

The most common side effect is nausea (being sick to your stomach). It is usually mild, and goes away within a few hours, but may last one to two days. Taking the pills with food may reduce the chance of nausea.

Some women who take the pills in the PREVEN™ Emergency Contraceptive Kit may also vomit. If vomiting occurs within an hour after you take either dose of emergency contraceptive pills, call your healthcare professional to discuss whether to repeat the dose or to take antinausea medication.

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Your next menstrual period may arrive a few days earlier or later than you expect. Menstrual blood flow may also be heavier or lighter than usual. If bleeding lasts longer than your period normally does, or if your period doesn't arrive within 21 days of taking emergency contraceptive pills, contact your healthcare professional.

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WARNING SIGNALS

If you experience any of the following ill effects during or shortly after taking emergency contraceptive pills, contact your healthcare professional immediately:

- chest pain, coughing up of blood, or sudden shortness of breath;
- severe pain in the calf;
- sudden severe headache, dizziness, weakness, numbness, or faintness;
- sudden difficulty seeing or speaking;
- severe pain or tenderness in the stomach area;
- jaundice (yellowing of the skin or eyeballs).

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COMMONLY ASKED QUESTIONS AND ANSWERS

How do I know if the PREVEN™ Emergency Contraceptive Kit pills have worked?

Within 21 days, you should get your menstrual period. If you don't, see your healthcare professional.

After using PREVEN™ Emergency Contraceptive Kit pills, when can I have sex again?

You can have sex again right away, but you should use a regular form of birth control to protect yourself from pregnancy. You may want to contact your healthcare professional to discuss your contraception.

Will PREVEN™ Emergency Contraceptive Kit pills taken now prevent me from pregnancy if I have sex without birth control in the future?

No, they will not. ECPs will also not protect you from sexually transmitted diseases.

How often can I use PREVEN™ Emergency Contraceptive Kit pills?

ECPs are meant for one-time emergency protection. ECPs are not as effective as some forms of regular birth control. If you have unprotected sex more than once per menstrual cycle and have already taken the emergency contraceptive pills for that cycle, you are advised to consult with your healthcare professional.

Can I still use PREVEN™ Emergency Contraceptive Kit pills if my healthcare professional has told me that I should not take combination oral contraceptives?

You and your healthcare professional should discuss the risks and benefits of the PREVEN™ Emergency Contraceptive Kit pills and agree on the best course of action for you.

What happens if I don't perform the pregnancy test correctly, and it says I'm not pregnant when I really am? Will taking the PREVEN™ Emergency Contraceptive Kit pills harm my baby?

The pills in the PREVEN™ Emergency Contraceptive Kit contain the same or similar hormones as found in combination oral contraceptive pills. Scientific studies do not suggest that use of combination oral contraceptives is associated with an increased risk of harm to the fetus, when taken inadvertently during early pregnancy.

Will taking PREVEN™ Emergency Contraceptive Kit pills cause changes in my menstrual cycle?

You may find that your next menstrual period comes a few days earlier or later than expected. Your menstrual blood flow may also be heavier or lighter than usual. If menstrual bleeding lasts longer than your normal period or if your period does not arrive within 21 days of taking the emergency contraceptive pills, contact your healthcare professional.

FOR MORE INFORMATION

If you have additional questions about the use of the PREVEN™ Emergency Contraceptive Kit, please consult the package insert. Information is also available at our website at www.PREVEN.com and our toll free line 1-888-PREVEN2.

Gynétics Inc.

P.O. Box 8509,
Somerville, NJ 08876

Issued: October, 1998
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PREVEN™ Emergency Contraceptive Kit is made in the USA
Printed in USA

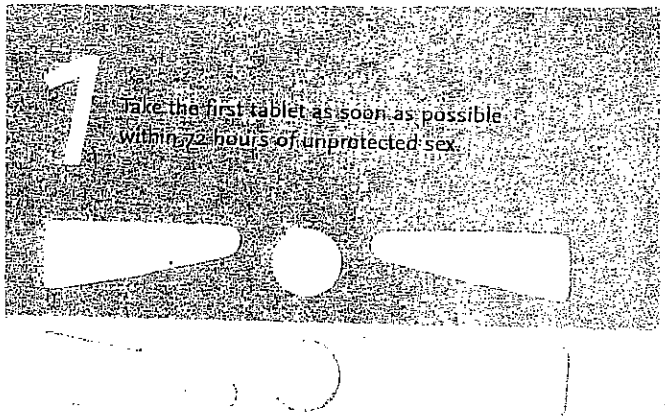
INTRODUCTION

Any woman who considers using ***Plan B***® should understand the benefits and risks. The following information should help your understanding, but it is not meant to replace a discussion between you and your health care provider.

WHAT IS PLAN B?

Plan B is intended to prevent pregnancy after unprotected sex (if a contraceptive fails or if no contraception was used). It contains levonorgestrel, which is a synthetic hormone (progestin) commonly used in birth control pills. ***Plan B*** is for emergency use, and should not be used in place of regular contraception since it is not as effective as regular contraceptives.

Plan B does not protect against HIV (the virus causing AIDS), or any other sexually transmitted disease.



2 Take the second tablet 12 hours after you take the first tablet.

HOW EFFECTIVE IS PLAN B?

Plan B reduces the risk of pregnancy following a single act of unprotected sex from about 8% down to 1%. This represents an 89% reduction in risk of pregnancy for this single act of unprotected sex.

Plan B is more effective the sooner treatment is started following unprotected sex.

WHO SHOULD NOT TAKE PLAN B?

Plan B should not be taken if you are already pregnant or if you have an allergy to any ingredient in ***Plan B***. Do not use ***Plan B*** if you have unexplained vaginal bleeding.

WHAT IF I AM ALREADY PREGNANT AND TAKE PLAN B?

Plan B is not appropriate if you are already pregnant; it will not work. However, if you take ***Plan B*** and are already pregnant, it is unlikely that this would affect the pregnancy. Several studies involving the long-term use of progestin hormone–containing contraceptives have not shown any effects on the fetus.

OVERDOSAGE: Taking too much **Plan B** may cause nausea or vomiting. You should contact your health care provider if you take too much Plan B.

OTHER INFORMATION: Plan B has been prescribed specifically for you; do not give it to others.

Mfg. by Gedeon Richter, Ltd., Budapest, Hungary
Distributed by Women's Capital Corporation
5400 Carillon Point
Kirkland WA. 98033
Phone: 1-800-330-1271
Fax: 1-877-407-3801

WHAT ARE THE RISKS AND SIDE EFFECTS OF TAKING PLAN B?

Menstrual bleeding is sometimes heavier and sometimes lighter than usual after women take ***Plan B.*** After taking ***Plan B,*** most women (87%) get their next period within one week of when it is expected. If your period is more than one week late, you should check with your health care provider to see if you are pregnant.

Progestin contraceptive pills used for routine daily contraception can increase your risk for a tubal (ectopic) pregnancy. ***Plan B*** contains progestin. It is unknown if two doses of ***Plan B*** would increase the risk of tubal pregnancy. You should contact your health care provider if you develop severe abdominal pain, since this can be a warning sign of a tubal pregnancy.

The most common side effects include nausea (23% of users), abdominal pain (18%), tiredness (17%), and headache (17%). Dizziness and breast tenderness occur in about 10% of patients, and 5–6% of patients experience either vomiting or diarrhea.

HOW SUPPLIED: Each ***Plan B*** tablet contains 0.75 mg of the active ingredient levonorgestrel,18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-, (17α)-(-)-, a totally synthetic progestin. The inactive ingredients present are colloidal silicon dioxide, potato starch, gelatin, magnesium stearate, talc, corn starch, and lactose monohydrate.

Plan B tablets are supplied in packages of two tablets each. The tablet is white, round, and marked: INOR.

Store at 25°C (77°F). Excursions permitted to 15–30°C (59–86°F). See USP Controlled Room Temperature.

CAUTION: Rx Only.

January, 2001

CURRICULUM VITAE

DAVID A. GRIMES, M.D.

BORN: February 18, 1947
Waterbury, Connecticut

PERSONAL:

Wife: Katherine
Children (name and birth year): Robin, (1970) and Heather (1973)

EDUCATION:

1965-1969	Harvard University, 1969, B.A. cum laude
1969-1973	University of North Carolina
	School of Medicine, 1973, M.D.
1973-1975	Resident, Obstetrics and Gynecology,
1977-1979	N.C. Memorial Hospital, Chapel Hill

MILITARY SERVICE:

1975-1977	Surgeon (04)
1979-1980	Surgeon (04)
1981-1986	Senior Surgeon (05)

U.S. Public Health Service
Centers for Disease Control

HONORS:

- Harvard National Scholar 1965
- Morehead Scholar 1965
- Morehead Fellow in Medicine 1969
- Isaac Hall Manning Award 1971
- Whitehead Society First Award, Student Research Day, 1971 and 1973
- North Carolina Obstetrical and Gynecological Society
- Student Aptitude Award, 1972
- Alpha Omega Alpha 1972
- William deB. MacNider Award 1973
- Alumni Loyalty Merit Award 1973
- Lange Book Award 1973
- Second Prize Paper: Presented at the District IV Meeting, American College of Obstetricians and Gynecologists, Junior Fellow Research Awards, 1976
- Prize Paper: Presented at the District IV Meeting, American College of Obstetricians and Gynecologists, Junior Fellow Research Awards, 1980
- Honorary Member of the Graduating Class, Emory University School of Medicine, 1981
- Commendation Medal, U.S. Public Health Service, 1982

- Ortho Prize Paper: Presented at the 21st Annual Scientific Meeting of the Association of Planned Parenthood Professionals, 1983
- DSA Medical Services Prize Paper: Presented at the Eighth Annual Meeting, National Abortion Federation, 1984
- Christopher Tietze Humanitarian Award, National Abortion Federation, 1987
- Kaiser Permanente Award for Excellence in Teaching in the Clinical Sciences, USC School of Medicine, 1989
- Lester T. Hibbard Teaching Award, Department of Obstetrics and Gynecology, USC School of Medicine, 1989
- Carl Schultz Award, Population and Family Planning Section, American Public Health Association 1990
- Max Bulian Memorial Lecturer, Beth Israel Hospital, Boston, 1991
- Fundamental Right of Reproductive Freedom Award, American Civil Liberties Union of Southern California, 1992
- Bitterman Distinguished Lecturer, Beth Israel Medical Center, New York, 1992
- Eliot L. Silbar Memorial Lecturer, Northwestern University School of
- Medicine, 1992
- Outstanding Academic Faculty, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, 1993
- Paul C. Weinberg Memorial Lecturer, American Society for Psychosomatic Obstetrics and Gynecology, 1994
- ACOG Issue of the Year Award, 1994
- Distinction in Teaching Award, Academic Senate, University of California,
- San Francisco, 1994
- Alan Guttmacher Lectureship, Association of Reproductive Health Professionals, 1994
- Frank R. Lock Lecturer, Bowman Gray School of Medicine, 1994
- Clinical Faculty Teaching Award, University of California, San Francisco, 1995
- Visiting Professor, Alpha Omega Alpha, UCSF, 1995
- Outstanding Lecture Award, 1995-96, UCSF Class of 1999
- C. Houston Alexander Lecturer, St. Joseph Hospital, Denver, 1996
- Rumbolz Visiting Professor, University of Nebraska Medical Center, 1996
- Rubovits Memorial Lecturer, University of Illinois at Chicago, 1996
- John Figgis Jewett Lecturer, Massachusetts Medical Society, 1996
- Edith Potter Memorial Lecturer, American College of Obstetricians and Gynecologists, 1996
- Alvin F. Goldfarb, M.D. Lecturer, North American Society for Pediatrics and Adolescent Gynecology, 1996
- Catherine L. Dobson Visiting Professor, University of Chicago, 1997 and 1999
- Rudolph Holmes Memorial Lecturer, Chicago Gynecological Society, 1997
- Clinical Faculty Teaching Award; University of California, San Francisco, 1997
- Distinguished Service Award, American College of Obstetricians and Gynecologists, 1997
- Presidential Speaker, North Carolina Obstetrical and Gynecological Society, 1997
- Gallagher Lecturer, Society for Adolescent Medicine, 1997
- Duncan Reid Lecturer, Harvard Medical School, 1997
- Julian Wells Memorial Lecturer, Baylor University Medical Center, 1997
- Atlee Memorial Lecturer, Dalhousie University School of Medicine,

Halifax, Nova Scotia, 1997

- Frank Kaltreider Memorial Lecturer, Johns Hopkins University School of Medicine, 1997
- Keynote Speaker, Kenya Obstetrical and Gynaecological Society, 1999
- Frederick Zuspan Scholar and Allan Barnes Memorial Lecturer, Ohio State University College of Medicine, 1999
- R. T. Weaver Lecturer, McMaster University School of Medicine, 1999
- Outstanding Scientific Achievement Award, The National Family Planning and Reproductive Health Association, Inc., 2000
- Distinguished Technical Communication, Society for Technical Communication, NY Metro Chapter, 1999-2000
- Bradford W. Kincheloe Lecturer, University of Tennessee, Memphis, 2000
- Honorable Mention, Special Service Award, National Association for Women's Health, 2000

BOARD CERTIFICATION:

1981	American Board of Obstetrics and Gynecology Recertified, 1991
1986	American Board of Preventive Medicine

FACULTY APPOINTMENTS:

1979-1982	Clinical Assistant Professor, Department of Gynecology and Obstetrics, Emory University School of Medicine
1981-1985	Clinical Assistant Professor, Department of Community Health, Emory University School of Medicine
1983-1986	Clinical Associate Professor, Department of Gynecology and Obstetrics, Emory University School of Medicine
1985-1986	Clinical Associate Professor, Department of Community Health, Emory University School of Medicine
1986-1992	Professor, Department of Obstetrics and Gynecology, University of Southern California School of Medicine
1986-1992	Professor, Department of Preventive Medicine, University of Southern California School of Medicine
1993-1997	Professor and Vice Chairman Department of Obstetrics, Gynecology and Reproductive Sciences University of California, San Francisco

1993-1997	Professor, Department of Epidemiology and Biostatistics University of California, San Francisco
1998-	Clinical Professor, Department of Obstetrics and Gynecology University of North Carolina School of Medicine
2000-	Fellow, Cecil G. Sheps Center for Health Services Research University of North Carolina

GOVERNMENT POSITIONS:

1975-1977	Epidemic Intelligence Service Officer, Centers for Disease Control
1979-1982	Assistant Chief, Abortion Surveillance Branch, Centers for Disease Control
1982-1983	Chief, Abortion Surveillance Branch, Centers for Disease Control
1983-1984	Medical Epidemiologist, Pregnancy Epidemiology Branch, Centers for Disease Control
1984-1986	Clinical Research Investigator, Division of Sexually Transmitted Diseases, Centers for Disease Control

HOSPITAL POSITIONS:

1987-1992	Chief, Ambulatory Care Services Women's Hospital, Los Angeles
1987-1992	Vice Chairman, Infection Control Committee, Women's Hospital, Los Angeles
1987-1992	Chairman, Quality Assurance Committee, Women's Hospital, Los Angeles
1993-1997	Chief, Department of Obstetrics, Gynecology and Reproductive Sciences San Francisco General Hospital
1993-1997	Clinical Service Chiefs Committee Strategic Planning Committee Library Committee Research Committee Executive Staff Committee Clinical Provider Group Emergency Department Advisory Committee

San Francisco General Hospital

CURRENT POSITION:

Vice President of Biomedical Affairs
Family Health International

SOCIETY OFFICES:

1980-1982 Member, Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists

1981-1983 Member, Governing Council, American Public Health Association

1983-1985 Chairperson, Postgraduate Education, Association of Planned Parenthood Professionals

1984-1987 Secretary, Association of Planned Parenthood Professionals

1986-1987 Board of Directors, National Abortion Federation

1983 Consultant, Committee on Gynecologic Practice, American College of Obstetrics and Gynecologists

1985-1986 Member, PROLOG Task Force for Patient Management in the Office, American College of Obstetricians and Gynecologists

1986-1989 Member, Committee on Patient Education, American College of Obstetricians and Gynecologists

1990-1991 Chairman, PROLOG Task Force for Patient Management in the Office, American College of Obstetricians and Gynecologists

1991-1995 Member, Health Care Commission, American College of Obstetricians and Gynecologists

1994-1995 Vice Chairman, Health Care Commission, American College of Obstetricians and Gynecologists

1995 Chairman, Task Force on Violence, American College of Obstetricians and Gynecologists

1995-1996 Member, Task Force on Health Policy, American College of Obstetricians and Gynecologists

1995 Member, Practice Patterns Working Group, American College of Obstetricians and Gynecologists

1995-1996 Program Chairperson, San Francisco Gynecological Society

1996-1999 Member of Council, American Gynecological and Obstetrical Society

1997- Member, FIGO Expert Advisory Panel on Contraception

EDITORIAL OFFICES:

1977-1981 Editorial Board, Journal of Obstetric, Gynecologic, and Neonatal Nursing

1979-1981 Editorial Board, Advances in Planned Parenthood

1989-1993 Editorial Advisory Board, Family Planning Perspectives

1986-1988 Advisory Board, Studies in Family Planning

1986- Associate Editor, Contraception

1987-1992 Editorial Advisory Board, Contraceptive Technology Update

1987-1993 Editorial Board, American Journal of Gynecologic Health

1989- Executive Editor, The Contraception Report

1989-1993 Editorial Board, Obstetrics and Gynecology

1990- Associate Editor, Obstetrical and Gynecological Survey

1998-1999 Editorial board, JAMA Women's Health Web Site

1999- Editorial board, Medscape Web Site

INTERNATIONAL SERVICES:

1974 Consultant to International Fertility Research Program, Yugoslavia and Hungary

1978 Consultant to Johns Hopkins Program for International Education in Gynecology and Obstetrics, Afghanistan

1980, 1981 Consultant to U.S. Agency for International Development, Bangladesh

1982 Course Director, Reproductive Epidemiology, Bangladesh

1982 Member, WHO Scientific Group on Trophoblastic Diseases, Geneva

1983 Course Co-Director, Reproductive Epidemiology, Kenya

1984	Consultant, Department of Obstetrics and Gynaecology, University of Nairobi, Kenya
1985	Consultant, WHO Program in Maternal and Infant Health, Ethiopia
1986	Member, WHO Scientific Group on Intrauterine Devices, Geneva
1993-	Board of Directors, Society for the Advancement of Reproductive Care
1993-1996	Member, International Committee for Research in Reproduction
1994-1997	Chair, Steering Committee, Task Force on Post-ovulatory Methods for Fertility Regulation, World Health Organization
1999	Course Co-Director, Reproductive Epidemiology, India

CONSULTANT:

1974-1975	Alumni Advisory Committee, University of North Carolina School of Medicine
1979-1980	National Institute of Child Health and Human Development
1983	National Cancer Institute
1981-1984	Chairperson, Surgical Services and Infertility Subcommittee, National Medical Committee, Planned Parenthood Federation of America
1986-1988	Vice Chairperson, National Medical Committee, Planned Parenthood Federation of America
1982-1984	Faculty Advisor, Beta Chapter of Georgia, Alpha Omega Alpha
1987-1992	Affiliate Medical Advisory Committee, Planned Parenthood of Los Angeles
1987-1992	Medical Advisory Committee, Los Angeles Regional Family Planning Council
1987-1991	Member, Science Advisory Panel, Alan Guttmacher Institute
1987-	Course Director, Berlex Foundation Resident Education Course
1988-	Examiner, American Board of Obstetrics and Gynecology, Inc.
1988-1991	Board of Directors, International Projects Assistance Services
1988-1990	Diagnostic and Therapeutic Technology Assessment Panel, Journal of the American Medical Association

1988-1991 Chairperson, National Medical Committee Planned Parenthood Federation of America

1989 Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives

1989- Board of Directors, Berlex Foundation

1988-1991 Board of Directors, Planned Parenthood Federation of America

1988-1991 Board of Directors, Association of Reproductive Health Professionals

1990 National Institute of Allergy and Infectious Disease

1990-1995 Member, U.S. Preventive Services Task Force

1990 Subcommittee on Civil and Constitutional Rights, Committee on the Judiciary, U.S. House of Representatives

1991-1992 Committee to Review Educational Activities, USC School of Medicine

1991 Regulation, Business Opportunities, and Energy Subcommittee, Committee on Small Business, U.S. House of Representatives

1994 Member, NIH Consensus Development Conference Panel on the Effect of Corticosteroids for Fetal Maturation in Perinatal Outcomes

1995-1997 Member, Technical Advisory Committee, Family Health International

1996-1997 Member, Committee on Curriculum and Educational Policy, UCSF

1997- Member National Medical Committee, Planned Parenthood Federation of America

1997- Scientific Advisory Committee, National Institute of Child Health and Human Development

SOCIETY MEMBERSHIP:

- American Gynecological and Obstetrical Society
- Society for Gynecologic Investigation
- American College of Obstetricians and Gynecologists
- American College of Preventive Medicine
- American Society for Reproductive Medicine
- South Atlantic Association of Obstetricians and Gynecologists
- American Public Health Association
- Association of Reproductive Health Professionals

- Associate, The Alan Guttmacher Institute
- Robert A. Ross Obstetrical and Gynecological Society
- National Abortion Federation
- Washington State Obstetrical Association (Hon.)
- San Francisco Gynecological Society
- Chicago Gynecological Society (Hon.)
- Pacific Northwest Obstetrical and Gynecological Association (Hon.)

VISITING PROFESSORSHIPS:

1987	George Washington University School of Medicine
1987	Georgetown University School of Medicine
1988	University of Illinois College of Medicine at Urbana-Champaign
1988, 1991	Louisiana State University School of Medicine
1990	University of North Carolina School of Medicine
1991	University of California, Irvine College of Medicine M.D.-Ph.D. Program
1991	Mayo Clinic
1991	University of Massachusetts School of Medicine
1992	Maricopa County General Hospital
1993	University of Indiana School of Medicine
1994	Brown University School of Medicine
1996	University of Illinois at Chicago
1996	University of Nebraska Medical Center
2000	Christiana Medical Center, Wilmington, Delaware

PUBLICATIONS: (Peer Review Journals)

1. Grimes DA, Johnson G Jr, Grice OD: "The iliac steal" phenomenon. Arch Surg 1972; 104:333-336

2. Brenner WE, Dingfelder JR, Staurovsky LG, Kumarasamy T, Grimes DA: Intramuscular administration of 15(S)-methyl-prostaglandin E2-methyl ester for induction of abortion. Am J Obstet Gynecol 1974; 120:833-836

3. Brenner WE, Dingfelder JR, Staurovsky LG, Kumarasamy T, Grimes DA: Intramuscular administration of 15 (S)-15-methyl-prostaglandin E2-methyl ester for induction of abortion: A comparison of two dose schedules. Fertil Steril 1975; 26:369-379

4. Grimes DA, Stritter FT, Flair MD, Hendricks CH: A residency elective in medical education. J Med Educ 1975; 50:365-370

5. Stritter FT, Hain JD, Grimes DA: Clinical teaching re-examined. J Med Educ 1975; 50:876-882

6. Grimes DA, Romm FJ: Fertility and family planning among white teenagers in metropolitan Atlanta. Am J Public Health 1975; 65:700-707

7. Staurovsky LG, Brenner WE, Dingfelder JR, Grimes DA: The effect of meperidine analgesia on midtrimester abortions induced with intraamniotic prostaglandin F2a. Am J Obstet Gynecol 1976; 125:185-187

8. Grimes DA, Cates W Jr.: Deaths from paracervical anesthesia used for first trimester abortion, 1972-1975. N Engl J Med 1976; 295:1397-1399

9. Cates W Jr, Grimes DA, Haber RJ, Tyler CW Jr: Abortion deaths associated with the use of prostaglandin F2a. Am J Obstet Gynecol 1977; 127:219-222

10. Grimes DA, Cates W Jr, Tyler CW Jr: Death after legal abortion by catheter placement. Am J Obstet Gynecol 1977; 129:107-108

11. Cates W Jr, Grimes DA, Smith JC, Tyler CW Jr: Legal abortion mortality in the United States. Epidemiologic surveillance, 1972-1974. JAMA 1977; 237:452-455

12. Grimes DA, Ross WC, Hatcher RA: Rh immunoglobulin utilization after spontaneous and induced abortion. Obstet Gynecol 1977; 50:261-263

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CURRENT POSITIONS

Associate Medical Director *February 1994-present*
Family Health International, Research Triangle Park, NC

Responsible for the design, overall management, and analysis of clinical trials and other research studies. Represent FHI in the Consortium for Emergency Contraception. Served as Acting Division Director, Clinical Trials Division, for 6 months in 1996. Recent projects have included:

- Efficacy Trial of Spermicidal Agents. Randomized clinical trial comparing the efficacy, safety, and acceptability of five spermicides. Ongoing since June, 1998. Will enroll 1,800 participants at 12 domestic research centers. Funded by NICHD.
- Provision of ECPs to Spermicide Users in Ghana. Cohort study of ECP and spermicide use among women intending to use spermicides who are also provided with ECPs. Enrolled 211 participants at four at family planning clinics in Ghana. Funded by USAID.
- Comparative Clinical Evaluation of VCF and Conceptrol. Randomized clinical trial comparing the efficacy, safety, and acceptability of two spermicides. Enrolled 765 participants at 8 research centers in Africa and North, Central, and South America. Funded by USAID.
- Effectiveness of Meclizine for Prevention of Nausea Associated with Emergency Contraceptive Pills. Randomized clinical trial to determine whether meclizine is effective for preventing nausea from the Yuzpe regimen. Enrolled 342 participants at 2 domestic research centers. Funded by USAID, Kaiser Family Foundation, Rockefeller Foundation.
- Effect of Emergency Contraceptive Pills on Uterine Receptivity. Enrolled 19 participants at 1 research center. Funded by Mellon Foundation and USAID.

Staff Physician *July 1996-present*
Planned Parenthood of the Capital and Coast, Raleigh NC

General outpatient gynecology practice, one afternoon each week.

Assistant Consulting Professor *1994-present*
Obstetrics and Gynecology Department, Duke University Medical Center, Durham, NC

PREVIOUS POSITIONS

Aug. 1994-Jun. 1996 **Staff physician**
Department of Surgery
Veterans Administration Medical Center, Durham, NC
General outpatient gynecology practice, one half day per week

Jul. 1991-Jan. 1994 **Senior Staff Fellow**
Division of Epidemiology, Statistics, and Prevention Research
National Institute of Child Health and Human Development, National Institutes of Health

- Project Officer, Prostaglandins in Preeclampsia Study
- Assistant Project Officer, Trial of Calcium for Preeclampsia Prevention
- Co-Investigator, Study of Perinatal Health Services in the District of Columbia
- Co-Investigator, Maternal and Child Health Study of Assiut, Egypt

Jul. 1988-Jun. 1990 **Obstetrician-gynecologist**
Tuba City Indian Medical Center, Tuba City, AZ

EDUCATION

1991 Master of Public Health, Johns Hopkins School of Hygiene and Public Health, Baltimore, MD. Course work concentrated in epidemiology, statistics, and population dynamics.

1988 Residency, Obstetrics and Gynecology, Duke University Medical Center, Durham, NC

1984 Doctor of Medicine, Columbia University College of Physicians and Surgeons, New York, NY

1980 Bachelor of Arts with Distinction, Swarthmore College, Swarthmore, PA. Major in Biology.

MEDICAL CERTIFICATION

North Carolina Medical License number 30084
North Carolina Medical Registration Certificate number 13596
Diplomate, American Board of Obstetrics and Gynecology, 1990-2000

AWARDS AND HONORS

Public Health Service Quality Increase, 1989
Phi Beta Kappa, Swarthmore College, 1980
Sigma Xi, Swarthmore College, 1980

PUBLICATIONS

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