C · R · L · P

THE CENTER FOR REPRODUCTIVE LAW AND POLICY

2672 '02 FEB 14 P3:03

120 WALL STREET

NEW YORK

NEW YORK 10005

USA

917/637-3600

917/637-3666 *fax*

1146 19TH STREET, NW

WASHINGTON, DC 20036

USA

202/530-2975

202/530-2976 *fax*

HTTP://WWW.CRLP.ORG

February 14,200 1

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

To Whom it May Concern:

Enclosed for filing, please find the original and three copies of a Citizen's Petition filed on behalf of 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 therein.

Thank you for your attention to this matter.

Daniel Yuhas

01P-0075

CP1

ORIGINAL

February 14, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 10-6 1
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)(l)(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. Crimes, 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. § 3 10.200(b)(1999); 21 C.F.R. § *330.1* 0(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. § *3*10.200(b)(*1999); 2* 1 C.F.R. § *330.1* 0(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. Crimes 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. Crimes Dec. ¶ 81. 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. Crimes 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. 2 1 C.F.R. § 3 10.200(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.

Bonnie Scott Jones
Simon Heller
The Center for Reproductive
Law & Policy
Attorneys for Petitioners
120 Wall Street, 14th floor
New York NY 10005
(917) 637-3600

Counsel for Petitioners

Helene T. Krasno ff
Planned Parenthood Federation of America
1780 Massachusetts Avenue, NW
Washington, DC 20036
(202) 973-4890

Of-Counsel for Petitioner Planned Parenthood Federation of America

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

Statements

print story | bookmark page

- AMA terms Aetna's decision to drop all-products clauses an important victory for patients and physicians
- AMA welcomes President-elect Bush and the new Congress and looks forward to progress on key health issues
- AMA on access to emergency contraception
- AMA: GAO Report confirms National Practitioner Data Bank is seriously flawed
- AMA says media reports mischaracterize new business venture
- AMA applauds defeat of Maine assisted suicide referendum
- AMA condemns price gouging by distributors of influenza vaccine
- 4.5% Medicare physician payment update: Good for America's seniors and the physicians who care for them
- U.S. House and Senate now have a clear majority to pass a real patients' bill of rights
- AMA welcomes new yardstick to measure Medicare quality successes

more articles » »

AMA on access to emergency contraception

For immediate release
December 5, 2000

Statement attributable to:
Edward J. Hill, M D
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."

###

Last updated: Dec 05, 2000
Content Provided By: AMA Media Relations

Read Another Article

PREV NEXT Statements

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

ACOG News Release

OFFICE OF COMMUNICATIONS
PO Box 96920
Washington DC
20090-6920

T: 202.484.3321 F: 202.479.6826 email: communications@acog.org

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.*

11. Trussell J, Ellertson C, Stewart F, Koenig J, Raymond EG. Emergency contraception: a cost effective approach to preventing unintended pregnancy. Woman Health Primary Care 1998;1:52-69.

12. Ellertson C, Koenig J, Trussell J, Bull J. How many U.S. women need emergency contraception? Contemp Ob Gyn 1997;42: 102-28.

13. Trussell J, Stewart F, Guest F, Hatcher RA. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. Fam Plann Perspect 1992;24:269-73.

14. Ellertson C, Trussell J, Stewart FH, Winikoff B. Should emergency contraceptive pills be available without prescription? J Am Med Womens Assoc 1998;53:226-9, 232.

15. Grimes DA. Emergency contraceptives over the counter. Allowing easy access is important [published erratum appears in West J Med 2000 May; 172(5):340]. West J Med 2000; 172: 148-9.

16. Jacobs LR. Prescription to over-the-counter drug reclassification. Am Fam Physician 1998;57:2209-14.

17. Grimes DA. The safety of oral contraceptives: epidemiologic insights from the first 30 years. Am J Obstet Gynecol 1992; 166: 1950-4.

18. Lake SR, Vernon SA. Emergency contraception and retinal vein thrombosis. Br J Ophthalmol 1999$3:630-l.

19. U. S. Department of Health and Human Services. Vital statistics of the United States 1992, Volume II Mortality Part A. Hyattsville, Maryland: National Center for Health Statistics, 1996.

20. Efficacy and side effects of immediate postcoital levonorgestrel used repeatedly for contraception. United Nations Development Programme/ United Nations Population Fund/World Health Organization/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Post-Ovulatory Methods of Fertility Regulation. Contraception 2000;61:303-8.

21. Raman-Wilms L, Tseng AL, Wighardt S, Einarson TR, Koren G. Fetal genital effects of first-trimester sex hormone exposure: a meta- analysis. Obstet Gynecol 1995;85: 141-9.

22. ACOG practice patterns. Emergency oral contraception. Number 3, December 1996. American College of Obstetricians and Gynecologists. Int J Gynaecol Obstet 1997;56:290-7.

23. Consortium for emergency contraception. Expanding global access to emergency contraception. Seattle, WA: Program for Appropriate Technology in Health, 2000.

24. Goldzieher JW. Pharmacokinetics and metabolism of ethynyl estrogens. In: Goldzieher JW, Fotherby K, eds. Pharmacology of the Contraceptive Steroids. New York: Raven Press, 1994.

25. Obach RS. Inhibition of human cytochrome P450 enzymes by constituents of St. John's Wort, an herbal preparation used in the treatment of depression. J Pharmacol Exp Ther 2000;294:88-95.

26. Guerts TBP, Goorissen EM, Sitsen JMA. Summary of drug interactions with oral contraceptives. Camforth, England: Parthenon Publishing Group, Ltd., 1993.

27. Webb A. Deregulating emergency contraception. The alternative may be unwanted pregnancies. BMJ 1994;308:135.

Table 1. Side effects associated with two ECP regimens

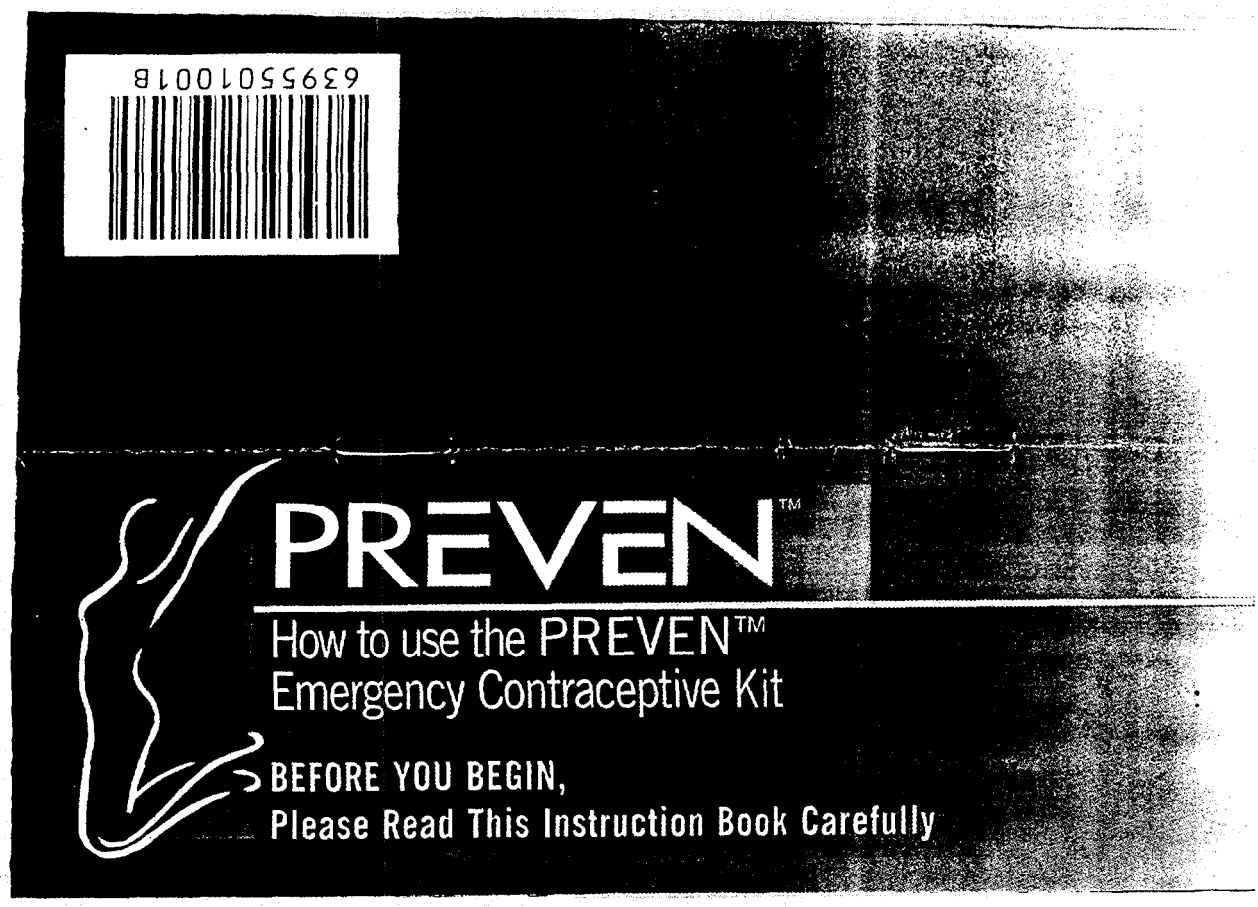
	% with symptom (95% CI)	
	Yuzpe (n=979)	Levonorgestrel (n=977)
Nausea	50.5 (47.3 – 53.6)	23.1 (20.5 – 25.9)
Vomiting	18.8 (16.4-21.4)	5.6 (4.3 – 7.3)
Dizziness	16.7 (14.4 – 19.1)	11.2 (9.3 – 13.3)
Fatigue	28.5 (25.7 – 31.4)	16.9 (14.6 – 19.4)
Headache	20.2 (17.8 – 22.9)	16.8 (14.5 – 19.3)
Breast tenderness	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.

2

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.**

3

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.

4

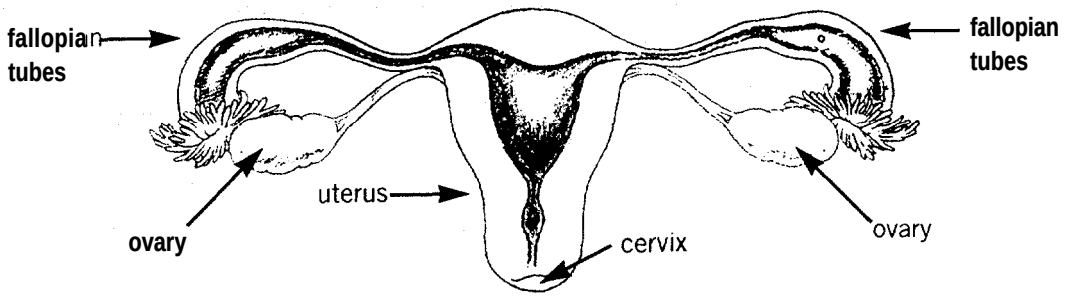
How do the pills in the PREVEN" Emergency Contraceptive Kit prevent pregnancy?

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).

5

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

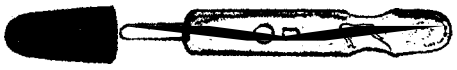
Step 1. Please finish reading this patient book in full before using the Kit.

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.

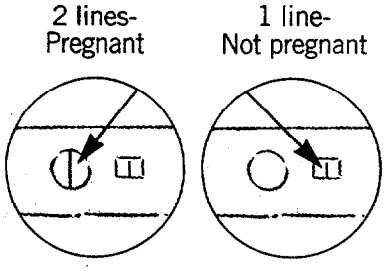
How to read the pregnancy test:

- 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.

14

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.

15

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.

16

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).

17

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
Print Code: 0891-098
PREVEN™ Emergency Contraceptive Kit is made in the USA
Printed in USA

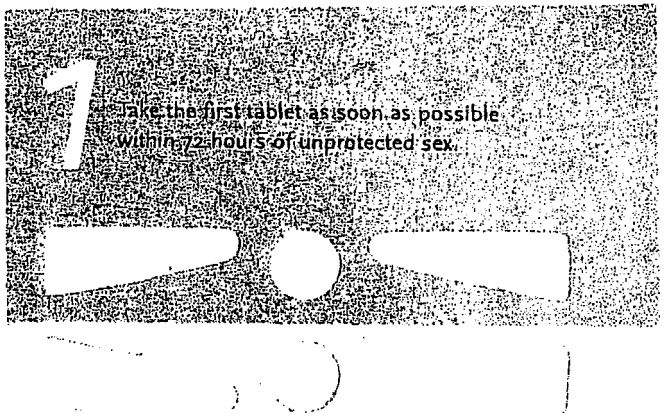
INTRODUCTION

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 nor work. iiowever, 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 Capitol 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, LNOR.

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

CAUTION: Rx Only.

Curricula Vitae

January, 200 1

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:

19651969	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:

19751977	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 197 1
- 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, 198 1
- 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, 199 1
- 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, 199 1
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

36. Grimes DA, Hulka JF, McCutchen ME: Midtrimester abortion by dilatation and evacuation versus intraamniotic instillation ofprostaglandin F2a: A randomized clinical trial. Am J Obstet Gynecol 1980;137:785-790

37. Grimes DA: Routine circumcision reconsidered. Am J Nurs 1980; 80:108-109

3 8. Grimes DA, Cates W Jr: Fatal myocarditis associated with abortion in early pregnancy. South Med J 1980;73:236-238

39. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr: Local versus general anesthesia: Which is safer for performing suction curettage abortions? Am J Obstet Gynecol 1979;135:1030-1035

40. Grimes DA, Fowler WC Jr: Adenosquamous carcinoma of the cecum arising in endometriosis. Gynecol Oncol 1980;9:254-255

41. Grimes DA, Hulka JF: Midtrimester dilatation and evacuation abortion. South Med J 1980; 73:448-451

42. Grimes DA, Ekbladh LE, McCartney WH: 'Cortical blindness in preeclampsia. Int J Gynaecol Obstet 1 9 8 0 ; 17:601-603

43. Grimes DA, Cates W Jr, Selik RM: Abortion facilities and the risk of death. Fam Plann Perspect 1981;13:30-32

44. Grimes DA, Cates W Jr, Selik RM: Fatal septic abortion in the United States, 1975-1977. Obstet Gynecol 1981;57:739-744

45. Grimes DA, Geary FH Jr, Hatcher RA: Rh immunoglobulin utilization after ectopic pregnancy. Am J Obstet Gynecol 1981;140:246-249

46. Grimes DA, Gross GK: Pregnancy outcomes in black women aged 35 and older. Obstet Gynecol 1981;58:614-620

47. Guidotti RJ, Grimes DA, Cates W Jr: Fatal amniotic fluid embolism during legally induced abortion, United States, 1972-1978. Am J Obstet Gynecol 1981;141:257-261

48. Cates W Jr, Grimes DA: Deaths from second-trimester abortion by dilatation and evacuation: Causes, prevention, facilities, Obstet Gynecol 1981;58:401-408

49. Peterson HB, Grimes DA, Cates W Jr, Rubin GL: Comparative risk of death from induced abortion at < 12 weeks' gestation performed with local versus general anesthesia. Am J Obstet Gynecol 1981; 141:763-768

50. Atrash HK, Peterson HB, Cates W Jr, Grimes DA: The risk of death from combined abortion-sterilization procedures: Can hysterotomy or hysterectomy be justified? Am J Obstet Gynecol 1982; 142:269-276

5 1. Grimes DA: Diagnostic dilation and curettage: A reappraisal. Am J Obstet Gynecol. 1982; 142: l-6

52. Grimes DA, Peterson HB: Should dilation and curettage be performed routinely at the time of laparoscopy? J Reprod Med 1982; 27:213-216

53. Grimes DA, Peterson HB, Rosenberg MJ, Fishburne JI Jr, Rochat RW, Khan AR, Islam R: Sterilization-attributable deaths in Bangladesh. Int J Gynaecol Obstet 1982; 20:149-154

54. Lebolt SA, Grimes DA, Cates W Jr: Mortality from abortion and childbirth. Are the populations comparable? JAMA 1982; 248:188-191

55. Cates W Jr, Smith JC, Rochat RW, Grimes DA: Mortality from abortion and childbirth. Are the statistics biased? JAMA 1982; 248:192-196

56. Cates W Jr, Schulz KF, Grimes DA, Horowitz AJ, Lyon FA, Kravitz FH, Frisch MJ: D&E procedures and second trimester abortions: The role of physician skill and hospital setting. JAMA 1982;248:559-563

57. Grimes DA, Satterthwaite AP, Rochat RW, Akhter N: Deaths from contraceptive sterilization in Bangladesh: Rates, causes, and prevention. Obstet Gynecol 1982; 60:635-640

58. Schulz KF, Cates W Jr, Grimes DA, Selik RM, Tyler CW Jr: Reducing classification errors in cohort studies: The approach and practical application. Stat Med 1983; 2:25-3 1

59. Spitz AM, Lee NC, Grimes DA, Schoenbucher AK, Lavoie M: Third-trimester induced abortion in Georgia, 1979 and 1980. Am J Public Health 1983; 73:594-595

60. Suarez RA, Grimes DA, Majmudar B, Benigno BB: Diagnostic endometrial aspiration with Karman cannula. J Reprod Med 1983; 28:41-44

6 1. Schutterman EB, Grimes DA: Comparative safety of the low transverse versus the low vertical uterine incision for cesarean delivery of breech infants. Obstet Gynecol 1983; 61:593-597

62. Grimes DA, Steele AO, Hatcher RA: Rh immunoglobulin utilization with placenta previa and abruptio placentae. South Med J 1983; 76:743-749

63. Dorfman SF, Grimes DA, Cates W Jr: Maternal deaths associated with antepartum fetal death in utero, United States, 1972-1978. South Med J 1983; 76:838-843

64. Grimes DA, Kafrissen ME, O'Reilly KR, Binkin NJ: Fatal hemorrhage from legal abortion in the United States. Surg Gynecol Obstet 1983; 157:46 l-466

65. Easterday CL, Grimes DA, Riggs JA: Hysterectomy in the United States. Obstet Gynecol 1983; 62:203-212

66. Binkin NJ, Schulz KF, Grimes DA, Cates W Jr: Urea-prostaglandin versus hypertonic saline for instillation abortion. Am J Obstet Gynecol 1983; 146:947-952

67. Kafrissen ME, Barke MW, Workman P, Schulz KF, Grimes DA: Coagulopathy and induced abortion methods: Rates and relative risks. Am J Obstet Gynecol 1983; 147:344-345

68. Cates W Jr, Schulz KF, Grimes DA: The risks associated with teenage abortion. N Engl J Med 1983; 3 09:62 l-624

69. Richards FO Jr, Grimes DA, Wilson M: The question of a helminthic cause of preeclampsia. JAMA 1983;250:2970-2972

70. Cates W Jr, Schulz KF, Grimes DA, Ezzard NV: Teenage abortion in the United States. Public Health Rev 1983; 11:291-3 10

71. Kafrissen ME, Schulz KF, Grimes DA, Cates W Jr: Midtrimester abortion. Intra-amniotic instillation of hyperosmolar urea and prostaglandin F2a versus dilatation and evacuation. JAMA 1984;251:916-919

72. Grimes DA, Flock ML, Schulz KF, Cates W Jr: Hysterectomy as treatment for complications of legal abortion. Obstet Gynecol 1984; 63:457-462

73. Grimes DA, Schulz KF, Cates W Jr: Prevention of uterine perforation during curettage abortion. JAMA 1984; 251:2108-2111

74. Grimes DA, Techman T: Legal abortion and placenta previa. Am J Obstet Gynecoll984; 149:501-504

75. Kaunitz AM, Spence C, Danielson TS, Rochat RW, Grimes DA: Perinatal and maternal mortality in a religious group avoiding obstetric care. Am J Obstet Gynecol 1984; 150:826-83 1

76. Dorfman SF, Grimes DA, Cates W Jr, Binkin NJ, Kafrissen ME, O'Reilly KR: Ectopic pregnancy mortality, United States, 1979-80: Clinical aspects. Obstet Gynecol 1984; 64:386-390

77. Grimes DA, Schulz KF, Cates W Jr: Prophylactic antibiotics for curettage abortion Am J Obstet Gynecol 1984;150:689-694

78. Grimes DA: Second-trimester abortions in the United States. Fam Plann Perspect 1984;16:260-266

79. Kaunitz AM, Grimes DA, Hughes JM, Smith JC, Hogue CJR: Maternal deaths in the United States by size of hospital. Obstet Gynecol 1984; 64:3 1 l-3 14

80. Grimes DA: The epidemiology of gestational trophoblastic disease. Am J Obstet Gynecol 1984; 150:309-318

8 1. Kaunitz AM, Hughes JM, Grimes DA, Smith JC, Rochat RW, Kafrissen ME: Causes of maternal mortality in the United States. Obstet Gynecol 1985; 65:605-612

82. Park TK, Flock M, Schulz KF, Grimes DA: Preventing febrile complications of suction curettage abortion. Am J Obstet Gynecol 1985; 152:252-255

83. Grimes DA, Schulz KF: The morbidity and mortality of second-trimester abortions. J Reprod Med 1985; 30:505-5 14

84. Berman SM, MacKay HT, Grimes DA, Binkin NJ: Deaths from spontaneous abortion in the United States. JAMA 1985; 253:3119-3123

85. Grimes DA, LeBolt SA, Grimes KR, Wingo PA: Systemic lupus erythematosus and reproductive function: A case-control study. Am J Obstet Gynecol 1985; 153: 179-186

86. Buehler JW, Schulz KF, Grimes DA, Hogue CJR: The risk of serious complications from induced abortion: Do personal characteristics make a difference? Am J Obstet Gynecol 1985;153:14-20

87. Kaunitz AM, Rovira EZ, Grimes DA, Schulz KF: Abortions that fail. Obstet Gynecol 1985; 66:533-537

88. MacKay HT, Schulz KF, Grimes DA: Safety of local versus general anesthesia for second trimester dilatation and evacuation abortion. Obstet Gynecol 1985; 66:66 l-665

89. Grimes DA: Reversible contraception for the 1980s. JAMA 1986; 255:69-75; Reprinted in JAMA Southeast Asia 1986;2:37-44

90. Grimes DA: Unplanned pregnancies in the United States. Obstet Gynecol 1986; 67:438-442

9 1. Grimes DA: Deaths from sexually transmitted diseases: The forgotten component of reproductive mortality. JAMA 1986; 255:1727-1729; Reprinted in Japanese JAMA, 1986 October 10, pp 74-79

92. Atrash HK, Hogue CJR, Grimes DA: Epidemiology of hydatidiform mole during early gestation. Am J Obstet Gynecol 1986;154:906-909

93. Stone KM, Grimes DA, Magder LS: Primary prevention of sexually transmitted diseases: A primer for clinicians. JAMA 1986; 255:1763-1766

94. Grimes DA: Declining surgical case-load of the obstetrician-gynecologist. Obstet Gynecol 1986; 67:760-762

95. Grimes DA: How can we translate good science into good perinatal care? Birth 1986; 13:83-90

96. Stone KM, Grimes DA, Magder LS: Personal protection against sexually transmitted diseases. Am J Obstet Gynecol 1986;155:180-188

97. Kafrissen ME, Grimes DA, Hogue CJR, Sacks JJ: Cluster of abortion deaths at a single facility. Obstet Gynecoll986; 68:387-389

98. Grimes DA, Blount JH, Patrick J, Washington AE: Antibiotic treatment of pelvic inflammatory disease: trends among private physicians in the United States, 1966-1983. JAMA 1986; 256:3223-3226 ; Reprinted in Japanese JAMA 1987 May 5, pp 56-60

99. Roongpisuthipong A, Grimes DA, Hadgu A: Is the Papanicolaou smear useful for diagnosing sexually transmitted diseases? Obstet Gynecol 1987;69:820-824

100. Grimes DA, Ray IG, Middleton CJ: Lamicel vs. laminaria for cervical dilation before early midtrimester abortion: a randomized clinical trial. Obstet Gynecol 1987; 69:887-890

101. Grimes DA: Reversible contraception for women at high risk of fetal anomalies. J Am Acad Dermatol 1987; 17:148-155

102. Grimes DA: Intrauterine devices and pelvic inflammatory disease: recent developments. Contraception 1987; 36:97-109. Reprinted in Infectious and Medical Disease Letters for Obstetrics and Gynecology 1989; XI(3):72-77, and in Perez-Palacios G, Garza-Flores J, Rowe PJ (eds).

119. Grimes DA. Evaluating triphasic oral contraceptives: The rationale for a randomized trial. Am J Obstet Gynecol 1989;161:1390-1392

120. Koonings PP, Moyer DL, Grimes DA: A randomized clinical trial comparing Pipelle and Tis-U-Trap for endometrial biopsy. Obstet Gynecol 1990;75:293-295

121. Koonings PP, Grimes DA, Campbell K, Sommerville M: Bilateral ovarian neoplasms and the risk of malignancy. Am J Obstet Gynecol 1990;162:167-169

122. Griffith CS, Grimes DA: The validity of the postcoital test. Am J Obstet Gynecol 1990; 162:615-620

123. Grimes DA, Bernstein L, Lacarra M, Shoupe D, Mishell DR Jr: Predictors of failed attempted abortion with the antiprogestin mifepristone (RU 486). Am J Obstet Gynecol 1990;162:910-917

124. Grimes DA: New therapies for genital warts. West J Med 1990;152:410-411

125. Stein AL, Koonings PP, Schlaerth JB, Grimes DA, d'Ablaing G III: Relative frequency of malignant par-ovarian tumors: should parovarian tumors be aspirated? Obstet Gynecol 1990; 75:1029-1031

126. Sinei SKA, Schulz KF, Lamptey PR, Grimes DA, Mati JKG, Rosenthal SM, Rosenberg MJ, Riara G, Njage PN, Bhullar VB, Ogembo HV. Preventing IUCD-related pelvic infection: The efficacy of prophylactic doxycycline at insertion. Br J Obstet Gynaecol 1990;97:412-419

127. Levin JH, Lacarra M, d'Ablaing G, Grimes DA, Vermesh M: Mifepristone (RU 486) failure in an ovarian heterotopic pregnancy. Am J Obstet Gynecol 1990; 163:543-544

128. Lee NC, Rubin GL, Grimes DA: Measures of sexual behavior and the risk of pelvic inflammatory disease. Obstet Gynecol 1991;77:425-430

129. Sommerville M, Grimes DA, Koonings PP, Campbell K: Ovarian neoplasms and the risk of adnexal torsion. Am J Obstet Gynecol 1991;164:577-578

130. Expert Committee on Pelvic Inflammatory Disease: Pelvic inflammatory disease. Research directions in the 1990s. Sex Transm Dis 1991; 18:46-64

131. Grimes DA: Editorial re: "An epidemiologic study of contraception and preeclampsia." Obstet Gynecol Surv 1991;46:350-351

132. Yu J, Grimes DA: Ascites and pleural effusions associated with endometriosis. Obstet Gynecol 1991;78:533-534

133. Grimes DA: Randomized clinical trials: "It ain't necessarily so." Obstet Gynecol 199 1; 78:703-704

134. MacMillan MC, Grimes DA: The limited usefulness of urine and blood cultures in treating pyelonephritis in pregnancy. Obstet Gynecol 1991;78:745-748

135. Aghajanian A, Grimes DA: Routine prothrombin time determination before elective gynecologic operations. Obstet Gynecol 1991; 78:837-839

136. Washington AE, Aral SO, Wolner-Hanssen P, Grimes DA, Holmes KK: Assessing risk for pelvic inflammatory disease and its sequelae. JAMA 1991; 266:2581-2586

137. Grimes DA, Forrest JD, Kirkman AL, Radford B: An epidemic of anti-abortion violence in the United States. Am J Obstet Gynecol 1991; 165:1263-1268

138. Grimes DA: Neoplastic effects of oral contraceptives. Int J Fertil 1991; 36(suppl):19-24

139. Grimes DA, Schulz KF: Randomized controlled trials of home uterine activity monitoring. A review and critique. Obstet Gynecol 1992; 79: 13 7- 142

140. Grimes DA: Progestins, breast cancer, and the limitations of epidemiology. Fertil Steril 1992; 57:492-494

141. Romo MS, Grimes DA, Strassle PO: Infarction of the uterus from subacute incomplete inversion. Am J Obstet Gynecol 1992; 166:878-879

142. Grimes DA: Frontiers of operative laparoscopy: A review and critique of the evidence. Am J Obstet Gynecol 1992; 166: 1062- 107 1 Reprinted in Transactions of the American Gynecological and Obstetrical Society 1992;X:202-211

143. Grimes DA: RU 486 (Mifepristone). West J Med 1992; 156:648

144. Grimes DA: Safety of oral contraceptives: Epidemiologic insights from the first thirty years. Am J Obstet Gynecol 1992; 166:1950-1954

145. Grimes DA, Mishell DR Jr, David HP: A randomized clinical trial of mifepristone (RU486) for induction of delayed menses: Efficacy and acceptability. Contraception 1992;46:1-10

146. Grimes DA: Other health benefits of oral contraceptives. Advances in Contraception 1991; 7(suppl 1):39-48

147. Grimes DA: Clinicians who provide abortions: The thinning ranks. Obstet Gynecol 1992; 80:719-723

148. Grimes DA, Cook R: Mifepristone (RU486): an abortifacient to prevent abortion? N Engl J Med 1992; 327:1088-1089

149. Grimes DA: The intrauterine device, pelvic inflammatory disease, and infertility: The confusion between hypothesis and knowledge. Fertil Sterill992; 58:670-673

150. Grimes DA: The case for confidence intervals. Obstet Gynecoll992; 80:865-866

151. Karamardian LM, Grimes DA: Luteal phase defect: The effect of treatment on pregnancy rates. Am J Obstet Gynecol 1992; 167:1391-1398

152. Cook RJ, Grimes DA: Antiprogestin drugs: Ethical, legal and medical issues. Law, Medicine and Health Care 1992; 20:149-153

153. US. Preventive Services Task Force: Screening for adolescent idiopathic scoliosis. Review article. JAMA 1993; 269:2667-2672

154. U.S. Preventive Services Task Force: Screening for adolescent idiopathic scoliosis. Policy statement. JAMA 1993; 269:2664-2666

155. Grimes, DA: Technology follies. The uncritical acceptance of medical innovation. JAMA 1993; 269:3030-3033

156. Speroff L, DeCherney A, and the Advisory Board for the New Progestins: Evaluation of a new generation of oral contraceptives. Obstet Gynecol 1993; 81:1034-1047

157. Grimes DA, Mishell DR Jr, Speroff L: Introduction. Am J Obstet Gynecol 1993; 168: 1979

158. U.S. Preventive Services Task Force: Home uterine activity monitoring for preterm labor. Policy statement. JAMA 1993; 270:369-370

159. U.S. Preventive Services Task Force: Home uterine activity monitoring for preterm labor. Review article. JAMA 1993; 270:371-376

160. Grimes DA: Over-the-counter oral contraceptives-an immodest proposal? Am J Public Health 1993; 83:1092-1094

161. Fraser EJ, Grimes DA, Schulz KF. Immunization as therapy for recurrent spontaneous abortion: a review and meta-analysis. Obstet Gynecol 1993; 82:854-859

162. Grimes DA: Mifepristone (RU 486) for induced abortion. Women's Health Issues 1993; 3: 171-l 75

163. U.S. Preventive Services Task Force: Routine iron supplementation during pregnancy. Policy statement. JAMA 1993; 270:2846-2848

164. U.S. Preventive Services Task Force: Routine iron supplementation during pregnancy. Review article. JAMA 1993; 270:2848-2854

165. Grimes DA: Primary prevention of ovarian cancer. JAMA 1993; 270:2855-2856

166. Grimes DA, Godwin AJ, Rubin A, Smith JA, Lacarra M: Ovulation and follicular development associated with three low-dose oral contraceptives: a randomized controlled trial. Obstet Gynecol 1994; 83:29-34

167. Aghajanian A, Bernstein L, Grimes DA: Bartholin's duct abscess and cysts: a casecontrol study. South Med J 1994; 87:26-29

168. Grimes DA: The morbidity and mortality of pregnancy: still risky business. Am J Obstet Gynecol 1994; 170:1489-1494

169. Peipert JF, Grimes DA: The case-control study: A primer for the obstetrician-gynecologist. Obstet Gynecol 1994;84:140-145

170. Schulz KF, Chalmers I, Grimes DA, Altman DG: Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynecology journals. JAMA 1994;272:125-128

171. Stubblefield PG, Grimes DA: Septic abortion. N Engl J Med 1994;331:310-314

172. U.S. Preventive Services Task Force: Screening for prostate cancer: a commentary on the prostate cancer screening recommendations of the Canadian Task Force on the Periodic Health Examination. Am J Prev Med 1994;10:187-193.

173. Walsh TL, Bernstein GS, Grimes DA, Frezieres R, Bernstein L, Coulson AH, and the IUD Study Group: Effect of prophylactic antibiotics on morbidity associated with IUD insertion: a pilot randomized controlled trial. Contraception 1994;50:319-327

174. Grimes DA: Shifting indications for hysterectomy: nature, nurture, or neither? Lancet 1994;344:1652-1653

175. Grimes DA, Economy KE. Primary prevention of gynecologic cancers. Am J Obstet Gynecol 1995;172:227-235

176. NIH Consensus Development Committee. Effect of corticosteroids for fetal maturation on perinatal outcomes. JAMA 1995;273:413-418; Reprinted in Am J Obstet Gynecol 1995;173:246-252

177. Slaughter JL, Grimes DA: Methotrexate therapy: non-surgical management of ectopic pregnancy. West J Med 1995; 16:225-228

178. Adolph C, Ramos DE, Linton KLP, Grimes DA: Pregnancy among Hispanic teenagers: is good parental communication a deterrent? Contraception 1995; 51:303-306

179. Grimes DA: Over-the-counter oral contraceptives: an idea whose time has not quite come! Obstet Gynecol Surv 1995; 50:411-412

180. Arona AJ, Al-Marayati L, Grimes DA, Ballard CA: Early secondary repair of third- and fourth-degree perineal lacerations after outpatient wound preparation. Obstet Gynecol 1995;86:294-296

181. Grimes DA: Introducing evidence-based medicine into a department of obstetrics and gynecology. Obstet Gynecol 1995;86:451-457

182. Cates W Jr, Grimes DA, Hogue LL: Justice Blackmun and legal abortion: a besieged legacy to women's reproductive health. Am J Public Health 1995;85:1204-1206

183. Rosenberg MJ, Burnhill MS, Waugh MS, Grimes DA, Hillard PJA: Compliance and oral contraceptives: a review. Contraception 1995;52: 137-141

184. Millar LK, Wing DA, Paul RH, Grimes DA: Outpatient treatment of pyelonephritis in pregnancy: a randomized controlled trial. Obstet Gynecol 1995;86:560-564

185. Schulz KF, Chalmers I, Altman DG, Grimes DA, Dore CJ: The methodologic quality of randomization as assessed from reports of trials in specialist and general medical journals. Online Journal of Current Clinical Trials 1995; No. 197

186. Grimes DA: Clinical research in ancient Babylon: methodologic insights from the Book of Daniel. Obstet Gynecol 1995;86:1031-1034

187. Chatwani A, Martens M, Grimes DA, Chatterjee M, Noah M, Stamp-Cole MM, Perry KT, and the Cefmetazole Study Group: A singleblind, prospective, randomized study of cefmetazole and cefoxitin in the treatment of post-cesarean section endometritis. Infectious Diseases in Obstetrics and Gynecol 1995;3:28-33

188. Schulz KF, Grimes DA, Altman DG, Hayes RJ: Blinding and exclusions after allocation in randomized controlled trials in obstetrics and gynecology. BMJ 1996;312:742-744

189. Sawaya GF, Grady D, Kerlikowske IS, Grimes DA: Antibiotics at the time of induced abortion: the case for universal prophylaxis based on meta-analysis. Obstet Gynecol 1996;87:884-890;

190. Grimes DA: Discussion of the risk of pregnancy after tubal sterilization: fmdings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol 1996; 174: 1168-l 169

191. Grimes DA, Schulz KF: Methodology references and the quality of randomized controlled trials in obstetrics and gynecology. Am J Obstet Gynecol 1996;174:1312-1315

192. Grimes DA: Spontaneous perforation of the gallbladder from cholecystitis with acute appendicitis in pregnancy. J Reprod Med 1996;41:450-452

193. Grimes DA: Stress, work, and pregnancy complications. Epidemiology 1996;7:337-338

194. Grimes DA: A 17-year-old mother seeking contraception. JAMA 1996; 276: 1163-1170

195. Waetjen LE, Grimes DA: Oral contraceptives and primary liver cancer: temporal trends in three countries. Obstet Gynecol 1996; 88:945-9

196. Grimes DA, Learman LA: .Evidence-based medicine: theory into practice within a department. Bailliere's Clin Obstet Gynaecol 1996; 10:697-714

197. Grimes DA: Medical abortion in early pregnancy: A review of the evidence. Obstet Gynecol 1997;89:790-796

198. Grimes DA: Emergency contraception: effect on abortion rates and cost-effectiveness. J Reprod Med (Beijing) 1996;5(suppl1):79-8 1

199. Rosenberg L, Palmer JR, Sands MI, Grimes DA, Bergman U, Daling J, Mills A. Modern oral contraceptives and cardiovascular disease. Am J Obstet Gynecol 1997; 177:707-715

200. Learman LA, Grimes DA: Rapid hospital discharge following laparoscopy for ectopic pregnancy: a promise unfulfilled? West J Med 1997;167:145-148

201. Grimes DA: Emergency contraception - expanding opportunities for primary prevention. N Engl J Med 1997; 337:1078-1079

202. Grullon KE, Grimes DA: The safety of early postpartum discharge: a review and critique. Obstet Gynecol 1997; 90:860-865

203. Amersi S, Grimes DA: The case against using ordinal numbers for gestational age. Obstet Gynecol 1998;91:623-625

204. Walsh T, Grimes DA, Frezieres R, Nelson A, Bernstein L, Coulson A, Bernstein G, for the IUD Study Group: Randomised controlled trial of prophylactic antibiotics before insertion of intrauterine devices. Lancet 1998;351:1005-1008

205. Grimes DA: Discussion of impaired growth and risk of fetal death: is the tenth percentile the appropriate standard? Am J Obstet Gynecol 1998; 178:667-668

206. 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;352:428-433

207. Grimes DA: The continuing need for late abortions. JAMA 1998;280:747-750

208. Grimes DA, Bachicha JA, Learman LA: Teaching critical appraisal to medical students in obstetrics and gynecology. Obstet Gynecol 1998;92:877-882

209. Bartholomew L, Grimes DA: The alleged association between induced abortion and breast cancer: biology or bias? Obstet Gynecol Surv 1998;53:708-714

210. Grimes DA, Hubacher D: IUDs: time for a renaissance. Am Fam Phys 1998;58:1963-1964

211. The Population Council: Medical methods of early abortion in developing countries. Consensus statement. Contraception 1999;58:257-259

212. Stanback J, Grimes D: Can intrauterine device removals for bleeding or pain be predicted at a one month follow-up visit? A multivariate analysis. Contraception 1999;58:357-360

213. WHO Task Force on Postovulatory Methods of Fertility Regulation. Comparison of three single doses of mifepristone as emergency contraception: a randomised trial. Lancet 1999;353:697-702

214. Piaggio G, von Hertzen H, Grimes DA, Van Look PFA, on behalf of the Task Force on Postovulatory Methods of Fertility Regulation: Timing of emergency contraception with levonorgestrel or the Yuzpe regimen. Lancet 1999;353:721

215. Grimes DA, Snively GR: Patients' understanding of medical risks: Implications for genetic counseling. Obstet Gynecol 1999;93:9 1 O-9 14

216. Sawaya GF, Grimes DA: New technologies in cervical cytology screening: a word of caution. Obstet Gynecol 1999;94:307-310

217. Grimes DA, Raymond EG: Bundling a pregnancy test with the Yuzpe regimen of emergency contraception. Obstet Gynecol 1999;94:47 1-473

218. Grimes DA: A 26-year-old woman seeking an abortion. JAMA 1999;282: 1169-75

219. Grimes DA, Schulz KF: Antibiotic prophylaxis for intrauterine contraceptive device insertion. Cochrane Database Syst Rev 2000;2:CD00 1327

220. Rivera R, Yacobson I, Grimes D. The mechanism of action of hormonal contraceptives and intrauterine contraceptive devices. Am J Obstet Gynecol 1999;181:1263-1269

221. Grimes DA, Schulz KF: Prophylactic antibiotics for intrauterine device insertion: a metaanalysis of the randomized controlled trials. Contraception 1999;60:57-63

222. Grimes DA: Emergency contraceptives over the counter. West J Med 2000;172: 148-9

223. WHO Task Force on Post-ovulatory Methods of Fertility Regulation. Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: a randomised trial. Br J Obstet Gynaecol 2000;107:524-30

224. Grimes D, Schulz K, Stanwood N. Immediate post-abortal insertion of intrauterine devices. Cochrane Database Syst Rev 2000;2:CD 00 1777

225. Cates W Jr, Grimes DA, Schulz KF: Abortion surveillance at CDC: creating public health light out of political heat. Am J Prev Medicine 2000;19(1S):12-17

226. Grimes DA: Medical abortion: public health and private lives. Am J Obstet Gynecol 2000; 183 : S 1-S2

227. World Health Organization Task Force on Post-Ovulatory Methods for Fertility Regulation: Efficacy and side effects of immediate postcoital levonorgestrel used repeatedly for contraception. Contraception 2000;61:303-308

228. Grimes DA: Intrauterine device and upper-genital-tract infection. Lancet 2000;3 56: 10 13 - 19

229. Grimes DA, Schulz KF, Droegemueller W, Munsick RA, Lisanti L. A faculty development course in obstetrics and gynecology. Am J Obstet Gynecol 2000;183:1041-4

PUBLICATIONS IN PRESS:

1. Grimes DA: Commentary. Evidence Based Obstetrics and Gynecology

2. Grimes DA: Evidence-based family planning: the paradigm for the third millennium. Eur J Contracept Reprod Health Care

PUBLICATIONS: (Non-Peer Review Journals)

1. Center for Disease Control: Surveillance summary: Abortion - United States, 1974. Morbidity Mortality Weekly Rep 1976; 25:179-180

2. Center for Disease Control: Comparative risks of three methods of midtrimester abortion. Morbidity Mortality Weekly Rep 1976; 25:370-375

3. Center for Disease Control: Abortion surveillance - United States, 1975. Morbidity Mortality Weekly Rep 1977; July 29

4. Center for Disease Control: Fatal ectopic pregnancy after sterilization or abortion - New York, California. Morbidity Mortality Weekly Rep 1977;26:75

5. Grimes DA: Should your newborn son be circumcised? Mother's Manual 1978;14(6):17-23

6. Grimes DA, Cates W Jr: The brief for hypertonic saline. Contemp OB/GYN 1980; 15(6):29-38

7. Grimes DA: Nongonococcal pelvic inflammatory disease. Clin Obstet Gynecol 1981; 24:1227-1243

8. Grimes DA: Assessing risks of tampon use. Contemp OB/GYN 1981; 18(Suppl):91-96

9. Grimes DA: Discussion of hormone therapy for endometrial hyperplasia. Bulletin of the Department of Gynecology and Obstetrics of Emory University School of Medicine 1981; 3:137-138

10. Grimes DA: Life after the (population) bomb. Medical Alumni Bulletin, University of North Carolina 1982;28:6-8

11. Grimes DA: Birth control pills: A reappraisal of the pros and cons. Med Asp Hum Sexual 1982; 16:32J-32Y

12. Grimes DA: Screening tests: what they are and what they aren't. Contemp OB/GYN 1982; 20:69-80

13. Schulz KF, Grimes DA, Cates W Jr: Measures to prevent cervical injury during suction curettage abortion. Lancet 1983; 1:1 182-1184

14. Grimes DA: Cause and effect - or coincidence? Contemp OB/GYN 1984; 23: 109-l 15

15. Grimes DA: Common mistakes patients make regarding contraception. Med Asp Hum Sexual 1984; 18(6):154-168

16. Kaunitz AM, Grimes DA: Childbirth without OB care: The bad old days revisited. Contemp OB/GYN 1985; 26(1):165-171

17. Schulz KF, Grimes DA, Christensen DD: Vasopressin reduces blood loss from second-trimester dilatation and evacuation abortion. Lancet 1985; 2:353-356

18. Grimes DA: Diagnostic office curettage: heresy no longer. Contemp OB/GYN 1986; 27(1):96-103

19. Speroff L, Grimes DA, Mishell DR Jr, Quagliarello J: Prescribing OCs for safety (Symposium). Contemp OB/GYN 1986; 27(3):128-148

20. Kaunitz AM, Grimes DA: Good news about contraceptives and PID. Contemp OB/GYN 1986; 27(3):153-158

2 1. Grimes DA: How to offer advice on avoiding STDs. Contemp OB/GYN 1987; 29:25-36

22. Grimes DA: The safety of mid-trimester abortion. Medical Digest, Planned Parenthood Federation of America Summer, 1987, pp l-3

23. Report of a WHO Scientific Group: Mechanism of Action, Safety and Efficacy of Intrauterine Devices. Technical Report Series 753. Geneva, World Health Organization, 1987

24. Johnson J, Grimes D, Minkoff HL, Repke J: AIDS in women: The latest findings (forum). Female Patient 1987; 12(10):68-79

25. Grimes DA: The preventive role of contraceptives in STDs. Clinical Advances in the Treatment of Infections 1987; 1(2):6-7

26. Grimes DA: An incidental finding. Female Patient 1988; 13:8

27. Grimes DA: Ectopic pregnancy. Masters in Obstetrics and Gynecology 1988; 4(1): 17-20

28. Kaunitz AM, Grimes DA: Endometrial sampling in older women. Contemp Ob/Gyn 1988; 31:85-97

29. Grimes DA: Multiphasic oral contraceptives and functional ovarian cysts. Contemp Ob/Gyn 1988; 32:103-112

30. Grimes DA: IUD insertion: a clinical refresher. Female Patient 1989; 14:51-54

3 1. Grimes DA: Whither the intrauterine device? Clin Obstet Gynecol 1989; 32:369-376

32. Grimes DA: Foreword. Clin Obstet Gynecol 1989; 32:305-6

33. Connell EB, Grimes DA, Tatum HJ, Tyrer LB: Contraceptive advances: Part I: Hormonal methods. (Symposium) The Female Patient 1989; 14(12):29-36

34. Grimes DA: Mifepristone (RU 486) for early abortion. Obstetrics/Gynecology Report 1990; 2(1):91-95

35. Connell EB, Grimes DA, Tatum HJ, Tyrer LB: Contraceptive advances: Part II: IUDs and barrier methods. (Symposium). The Female Patient 1990; 15(1): 14-28

36. Grimes DA: Oral contraceptives: Trial by media. Fertility News 1990; 24(2): 10

37. Grimes DA: The sperm penetration assay. A biologic phenomenon in search of a clinical use. Obstetrics/Gynecology Report 1990; 2(4):4 13 -424

38. Grimes DA: An introduction to classifying the scientific literature. Key Obstetrics and Gynecology 1991; 4(1):25-35

39. Chez RA, Grimes DA, Tatum H: IUDs: Underused and misunderstood. (Symposium) Contemp Ob/Gyn 1991; 36(10):73-92

40. Grimes DA: Biases: The saboteurs of science. Key Obstetrics and Gynecology 1991; 4(2): preface

41. Grimes DA: Sample size and power: How big is big enough? Key Obstetrics and Gynecology 1991; 4(3): preface. Reprinted in Sheld HH: Obstetrics and Gynecology Review 1995. New York, McGraw-Hill, 1995: l-2

42. Grimes DA: Making sense of research findings. Key Obstetrics and Gynecology 199 1; 4(4): preface

43. Grimes DA: Risky business: measuring associations in clinical research. Key Obstetrics and Gynecology 1993; 6(1): preface

44. Grimes DA: Meta-analysis: mega-trend or mega-silliness? Key Obstetrics and Gynecology 1993; 6(2):preface

45. Grimes DA: Randomized controlled trials: truth in advertising? Key Obstetrics and Gynecology 1993; 6(3): ii-iii

46. Grimes DA: The confidence game: hypothesis testing vs. confidence intervals. Key Obstetrics and Gynecology 1993; 6(4):ii-iii

47. Creinin MD, Grimes DA: Medical options for early abortion. Contemp Ob/Gyn 1994; 39(4):85-90

48. Sawaya GF, Grimes DA: Preventing postabortal infection. Contemp Ob/Gyn 1994;39: 53-60

49. Grimes DA: Evidence-based medicine: the new clinical wave. Talbert Journal of Health Care 1996;1:37-41

50. Grimes DA, Schulz KF: Determining sample size and power in clinical trials: the forgotten essential. Sem Reprod Endocrinol 1996;14:125-131

5 1. Chez RA, Grimes DA, Stewart F, Trussell J, Zinberg S: Emergency contraception: practical considerations. OBG Management 1997;October:23-26

52. Grimes DA, Atkins D: The U.S. Preventive Services Task Force: putting evidence-based medicine to work. Clin Obstet Gynecol 1998;41:332-342

53. Grimes DA: Evidence-based medicine: keeping your practice from getting stale. Contemp Ob/Gyn 1999, January: 41-54

54. Grimes DA: On the road. Lancet 1999;354:962

55. Grimes DA: Role of the cervix in sexual response: evidence for and against. Clin Obstet Gynecol 1999;42:972-978

56. Grimes DA: Commentary: Increased monitoring of women at risk for preterm labour did not decrease the rate of preterm birth. Evidence-based Obstetrics and Gynecology 1999;1:106.

57. Grimes DA: Understanding screening tests: the key to avoiding pitfalls in interpretation. Contemp Ob/Gyn 2000, June: 46-68

ABSTRACTS:

1. Grimes DA, Romm FJ: Fertility and family planning among white teenagers in metropolitan Atlanta. Pediatrics Digest 1975; 17(10):28

2. Grimes DA, Cates W Jr: Deaths from paracervical anesthesia used for first-trimester abortion, 1972-1975. Surv Ophthalmol 1977; 22:149-150

3. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr: Midtrimester abortion by dilatation and evacuation. Ob/Gyn Digest, 1978 April, pp 33 -34

4. Grimes DA, et al: Maternal death at term as late sequela of failed attempted abortion. Medilex Digest Ob-Gyn, 1980 December, p 111

5. Grimes DA, Geary FH Jr, Hatcher RA: Rh immunoglobulin utilization after ectopic pregnancy. OB/GYN Digest, 1981 December, p 4

6. Grimes DA: Diagnostic dilatation and curettage. OB/GYN Digest, 1982, p 9

7. Koonings PP, Grimes DA: Adnexal torsion in postmenopausal women. Ob/Gyn Digest 1989; 5:25

8. Griffith CS, Grimes DA: The validity of the postcoital test. Fertility Digest 1990; 2:28-29

9. Grimes DA: A simplified device for intraoperative autotransfusion. In: Miller RD, Kirby RR, Ostheimer GW, et al, eds. The Year Book of Anesthesia. St. Louis, Mosby Year Book, 1990:280-281

10. Grimes DA: Prophylactic antibiotics at IUD insertion. Contraception 1992; 45:283

11. Grimes DA: The prevention of gynecological cancer by contraception. Adv Contraception 1995;1 l:l-2

LETTERS TO EDITOR:

1. Grimes DA: Use of Lomotil. Obstet Gynecol 1975; 45:115

2. Cates W Jr, Grimes DA: Maternal mortality and abortions, Hospital Practice 1975; 10(10): 19

3. Cates W Jr, Grimes DA: The IUD revisited. Fam Plann Perspect 1975; 7(6):244-245

4. Cates W Jr, Grimes DA: On seeking abortion counseling. Am J Public Health 1977; 67:780-781

5. Grimes DA, Cates W Jr: Risks of paracervical anesthesia. N Engl J Med 1977; 296:760

6. Cates W Jr, Grimes DA: And the poor get buried Fam Plann Perspect 1977; 9(1):2

7. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr: Midtrimester abortions. N Engl J Med 1977; 297:511-512

8. Cates W Jr, Grimes DA, Smith JC, Tyler CW Jr: Safety of abortion. JAMA 1977; 237:2601-2602

9. Grimes DA, Cates W Jr, Schulz KF: Midtrimester abortion by dilatation and evacuation. Am J Obstet Gynecol 1978; 13 1:23 1

10. Cates W Jr, Schulz KF, Grimes DA: Effect of liberalized abortion on maternal mortality rates. Am J Obstet Gynecol 1978; 130:372-374

31. Grimes DA: The CDC and abortion in HIV-positive women. JAMA 1988; 259:2 17-2 18

32. Grimes DA: D&C discussed. Contemp Ob/Gyn 1986; 27(4): 18

33. Grimes DA, Mishell DR, Jr: Congenital limb reduction deformities and oral contraceptives. Am J Obstet Gynecol 1988; 158:439

34. Settlage RH, Grimes DA: The HIV clade. Am J Public Health 1988; 78:1367-1368.

35. Kaunitz AM, Grimes DA, Kaunitz KK: A physician's guide to adoption. JAMA 1988; 259:2405

36. Grimes DA: Reversible contraception for women at high risk of fetal anomalies. J Am Acad Dermatol 1988; 18:150

37. Grimes DA, Mishell DR Jr: Bad rap for IUDs? Contemp Ob/Gyn 1990; 35(2): 14

38. Mao C, Grimes DA: Value of hamster egg penetration assay. Am J Obstet Gynecol 1990; 162:865

39. Grimes DA, Mishell DR Jr: Oral contraceptives and infection rates. Am J Obstet Gynecol 1990; 162:1121-l 122

40. Grimes DA: Support for the abortion pill. Issues in Science and Technology 1990; 7:13-14

41. Koonings PP, Grimes DA, Schlaerth JB: Acronym-associated illness (Letter) Crit Care Med 1990; 18:1187

42. Grimes DA, Griffith CS: The importance of the postcoital test. Am J Obstet Gynecol 1991; 164:932-933

43. Grimes DA, Schulz KF: Randomized controlled trials of home uterine activity monitoring: A review and critique. Obstet Gynecol 1992; 79: 1053

44. Grimes DA: Reply to Dr. Willke. Am J Obstet Gynecol 1992; 167:1485

45. Grimes DA: Clinicians who provide abortions: The thinning ranks. Obstet Gynecoll993; 81:3 19-320

46. Grimes DA, Cook RJ: Mifepristone (RU 486)-An abortifacient to prevent abortion? N Engl J Med 1993; 328:354-355

47. Grimes DA: Laparoscopic surgery: experiment or expedient? Am J Obstet Gynecol 1993; 168:1333-1334

48. Grimes DA: "Technology follies": curtain call. JAMA 1993; 270:2299

49. Grimes DA, Karamardian LM: Corpus luteum dysfunction-is the treatment really ineffective? Am J Obstet Gynecol 1994; 170:958-959

50. Grimes DA, Fraser EJ, Schulz KF: Immunization as therapy for recurrent spontaneous abortion: a review and meta-analysis. Obstet Gynecol 1994; 83:637-638

51. Grimes DA: Implantable hormonal contraceptives: emerging controversy. Obstet Gynecol 1995;85:641-642

52. Grimes DA: Validity of thepostcoital test. Am J Obstet Gynecol 1995; 172:1327

53. Schulz KF, Altman DG, Grimes DA: Restricted randomization in randomized controlled trials. JAMA 1995;274:1835-1836

54. Grimes DA: Clinical research in ancient Babylon: methodologic insights from the Book of Daniel. Obstet Gynecol1996;87:157-158

55. Grimes DA: Introducing evidence-based medicine into a department of obstetrics and gynecology. Obstet Gynecol 1996;87: 160

56. Johannisson E for the International Committee for Research in Reproduction: Safety of modern oral contraceptives. Lancet 1996;347:258.

57. Rosenberg L, Begaud B, Bergman U, Brown B, Buist AS, Cramer D, Daling J, Grimes D, Kemper F, Mills A: What are the risks of third-generation oral contraceptives? Hum Reprod 1996;11:687-688

58. Grimes DA, Schulz KF: A "randomized" controlled trial without randomization. Am J Obstet Gynecol 1996;175:240-241

59. Grimes DA: Stress, work and pregnancy complications. Epidemiology 1997; 8:113-114

60. Grimes DA: The best measure of uncertainty - hypothesis tests or tests of estimation? Fertil Steril 1997;68:177-8

61. Grimes DA: The law, the AMA, and partial-birth abortion. JAMA 1999;282:26

62. Grimes DA: Abortion and unplanned pregnancy. JAMA 2000;283: 1566-7

63. Grimes DA: Pregnancy saves lives: author's response. West J Med 2000;173: 12-13

CHAPTERS:

1. Kumarasamy T, Brenner WE, Hulka JF, Mercer JP, Fishburne JI, Dingfelder JR, Omran KF, Grimes DA, Hendricks CH, Staurovsky LG: Research programs in sterilization and post conceptive regulation. Proceedings of Seminar on Voluntary Sterilization and Post Conceptive Regulation, 1974 pp 79-85, (Bangkok, Thailand)

2. Staurovsky LG, Brenner WE, Dingfelder JR, Kumarasamy T, Grimes DA, Ogburn P: The effect of meperidine analgesia in PGF2a induced midtrimester abortions. Proceedings of the VIIIth World Congress on Fertility and Sterility, 1974 (Buenos Aires)

3. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr: The Joint Program for the Study of Abortion/CDC: A preliminary report. In: Abortion in the Seventies. (Hern W, Andrikopoulos B, Eds.). New York, National Abortion Federation, 1977

4. Cates W Jr, Grimes DA, Smith JC: Surveillance of abortion mortality in the United States. In: Abortion in the Seventies. (Hern W, Andrikopoulos B, Eds.). New York, National Abortion Federation, 1977

5. Tyler CW Jr, Cates W Jr, Grimes DA: The benefits, risks, and controversies in pregnancy termination: An overview. In: Risks, Benefits, and Controversies in Fertility Control. (Sciarra JJ, Zatuchni GI, Speidel JJ Eds.). Hagerstown, Maryland, Harper and Row, 1978, pp 390-400

6. Cates W Jr, Schulz KF, Grimes DA, Tyler CW Jr: Short-term complications of uterine evacuation techniques for abortion at 12 weeks' gestation or earlier. In: Pregnancy Termination. Procedures, Safety, and New Developments. (Zatuchni GI, Sciarra JJ, Speidel JJ, Eds.). Hagerstown, Maryland, Harper and Row, 1979, pp 127-135

7. Grimes DA: Premature rupture of membranes: antenatal steroid therapy to increase fetal pulmonary maturity; and induction of labor. In: Obstetric Technology. (Randall HW Jr, Ed). Atlanta, Emory University School of Medicine, 1980

8. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr: The safety of midtrimester abortion. In: The Safety of Fertility Control. (Keith LG, Kent DR, Berger GS, Brittain JR. Eds.). New York, Springer Publishing Company, 1980, pp 198-210

9. Grimes DA, Cates W Jr: Abortion: Methods and complications. In: Human Reproduction: Conception and Contraception. (Hafez ESE, Ed.). New York, Harper and Row, 1980, pp 796-813

10. Gray MJ, Grimes DA: Birth control, abortion, and sterilization. In: Gynecology and Obstetrics. The Health Care of Women. 2nd Ed. (Romney SL, Gray MJ, Little AB, et al., Eds.). New York, McGraw-Hill Book Company, 1980

11. Cates W Jr, Grimes DA: Morbidity and mortality of abortion in the United States. In: Abortion and Sterilization. Medical and Social Aspects. (Hodgson JE, Ed.). New York, Grune and Stratton, 1981, pp 155-180

12. Grimes DA, Cates W Jr: Midtrimester abortion by dilatation and evacuation. In: Second Trimester Abortion. Perspectives after a Decade of Experience. (Berger GS, Brenner WE, Keith L, Eds.). Littleton, Massachusetts, PSG Publishing Company, Inc., 198 1

13. Cates W Jr, Grimes DA: Morbidity and mortality. In: Second Trimester Abortion.. Perspectives after a Decade of Experience. (Berger GS, Brenner WE, Keith L, Eds.). Littleton, Massachusetts, PSG Publishing Company, Inc., 1981

14. Grimes DA, Cates W Jr: Instrumental abortion in the second trimester: An overview. In: Second Trimester Pregnancy Termination. (Keirse MJNC, et al, Eds.). The Hague, University of Leiden Press, 1982, pp 65-79

15. Cates W Jr, Grimes DA: The trimester threshold for pregnancy termination: Myth or truth? In: Second Trimester Pregnancy Termination, (Keirse MJNC, et al, Eds.). The Hague, University of Leiden Press, 1982, pp 41-51

16. Grimes DA, Cates W Jr, Selik RM: Abortion facilities and the risk of death. In: Proceedings of the Third International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination, and Sterilization. (Hingorani V, Pandit RD, Bhargava VL, Eds.). New Delhi, Federation of Obstetrics and Gynaecological Societies of India, 1982, pp 610-614

17. Grimes DA, Tyler CW Jr: Controversies concerning midtrimester dilatation and evacuation abortion. In: Reid's Controversies in Obstetrics and Gynecology. (Zuspan FP, Christian CD, Eds.). New York, WB Saunders, 1983, pp 386-392

18. Kafrissen ME, Binkin NJ, Grimes DA, Cates W Jr: Abortion incidence, mortality, and morbidity. In: Perspectives on Abortion. (Sachdev P, Ed.). Metuchen, New Jersey. Scarecrow Press, 1984, pp 130-140

19. Grimes DA: Surgical management of abortion. In: TeLinde's Operative Gynecology, 6th Ed. (Mattingly RF, Thompson JD, Eds.). Philadelphia, Lippincott, 1985, pp 5 13-539

20. Kaunitz AM, Grimes DA: First-trimester abortion technology. In: Fertility Control. (Corson SL, Derman RJ, Tyrer LB, Eds.) Boston, Little Brown and Co, 1985, pp 64-76

21. Grimes DA, Schulz KF: The comparative safety of second-trimester abortion methods. In: Abortion: Medical Progress and Social Implications. (Porter R, O'Connor M, Eds.). London, Pitman Books Ltd., 1985, pp 83-96

22. Grimes DA: The provision of abortion services in the United States. In: Abortion: Medical Progress and Social Implications. (Porter R, O'Connor M, Eds.). London, Pitman Books Ltd, 1985, pp 26-3 1

23. Grimes DA: Non-contraceptive benefits of oral contraceptives--Good news for a change. In: Medical Education in the Field of Primary Maternal Child Health Care. (Fayad MM, Abdalla MI, Eds.). Proceedings of International Conference, Cairo Egypt, 1986, pp 85-91

24. Grimes DA: The epidemiology of gestational trophoblastic disease: A global view. In: Medical Education in the Field of Primary Maternal Child Health Care. (Fayad MM, Abdalla MI, Eds.). Proceedings of International Conference, Cairo, Egypt, 1986, pp 340-344

25. Grimes DA, Kafrissen ME: Hematologic aspects of contraception, abortion, and sterilization. In: Hematologic Problems in Pregnancy (Kitay DZ, Ed) Oradell, New Jersey, Medical Economics Books, 1987, pp 386401

26. Grimes DA: Genital herpes infections. In: Management of Common Problems in Obstetrics and Gynecology. (Mishell DR, Jr, Brenner PF, Eds.) Oradell, New Jersey, Medical Economics Books, 1988, pp 295-299

27. Grimes DA: Human immunodeficiency virus infections in women. In: Management of Common Problems in Obstetrics and Gynecology. (Mishell DR, Jr, Brenner PF, Eds.) Oradell, New Jersey, Medical Economics Books, 1988, pp 291-294

28. Grimes DA: Sexually transmitted diseases. In Wallace HM, Ryan G Jr, Oglesby AC (eds): Maternal and Child Health Practices, 3rd ed. Oakland, Third Party Publishing Co., 1988; pp 347-355

29. Grimes DA, Cates W Jr: Family planning and sexually transmitted diseases. In Holmes KK, Mardh P-A, Sparling PF, Wiesner PJ (eds). Sexually Transmitted Diseases, 2nd edition. New York, McGraw-Hill Book Company, 1990, pp 1087-1094

30. Grimes DA Breast cancer, the pill, and the press. In Mann RD (ed): Oral contraceptives and breast cancer. Carnforth, England, Parthenon Publishing Group, 1990; pp 309-322

3 1. Grimes DA: Surgical management of abortion. In: TeLinde's Operative Gynecology, 7th Ed. (Thompson JD, Rock J, Eds). Philadelphia, J.B. Lippincott, Co. 1991; pp 3 17-342

32. Grimes DA: Safety and efficacy of the IUD. In: Contraception. (Shoupe D, Haseltine FP, Eds). New York, Springer-Verlag 1993; pp 123-130

33. Grimes DA: Comments on Session II. In: Clinical applications of mifepristone RU 486 and other antiprogestins. (Donaldson MS, Dorflinger L, Brown SS, and Benet L, Eds). Washington, D.C., National Academy Press, 1993; pp 183-188

34. Grimes DA: Genital Herpes. In: Management of Common Problems in Obstetrics and Gynecology. (Mishell DR, Jr, Brenner PF, Eds), 3rd edition. Boston, Blackwell Scientific Publications, 1994; pp 386-390

35. Grimes DA: Human Immunodeficiency Virus Infection. In: Management of Common Problems in Obstetrics and Gynecology. (Mishell DR, Jr, Brenner PF, Eds), 3rd edition. Boston, Blackwell Scientific Publications, 1994; pp 3 8 l-3 85

36. Grimes DA, Schulz KF: Prophylactic antibiotics at IUD insertion. In: Bardin CW, Mishell DR Jr (eds): Proceedings from the Fourth International Conference on IUDs. Boston, Butterworth-Heinemann, 1994; pp 164- 170

37. Stubblefield PG, Grimes DA: Septic abortion: epidemiology and complications. In: Sciarra JJ (ed): Gynecology & Obstetrics, 6th ed. Chicago, J.B. Lippincott, 1995; pp l-8

38. Grimes DA: Sequelae of abortion. In: Baird DT, Grimes DA, Van Look PFA (eds): Modern methods of inducing abortion. Oxford, Blackwell Science, 1995; pp 95-l 11

39. Grimes DA: Family planning through reversible contraception. In: Woolf, Jonas and Lawrence, eds. Health Promotion and Disease Prevention in Clinical Practice. Baltimore, Williams and Wilkins, 1996; pp 258-272

40. Grimes DA: Risks and benefits of oral contraceptives. In: Li JJ, Li SA, Gustafsson J-A, et al., eds. Hormonal Carcinogenesis II. New York, Springer, 1996; pp 3 12-320

41. Grimes DA: Management of abortion. In: Rock JA, Thompson JD, eds. Te Linde's Operative Gynecology, 8th ed. Philadelphia, Lippincott-Raven, 1996; pp 477-500

42. Grimes DA, The application of evidence-based medicine to the care of the breast. In: Hindle WH, ed. Breast care. A clinical guidebook for women's primary health care providers. New York: Springer, 1998; pp 20-27

43. Lichtenberg ES, Grimes DA, Paul M: Abortion complications. Prevention and management. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, eds. A clinician's guide to medical and surgical abortion. New York: Churchill Livingstone, 1999; pp 197-Z 16

44. Grimes DA: Communicating research: working with the media. In: O'Brien PMS, Pipkin FB, eds. Introduction to research methodology for specialists and trainees. London: Royal College of Obstetricians and Gynaecologists, 1999; pp 210-217

BOOKS:

1. Withington AM, Grimes DA, Hatcher RA: Teenage Sexual Health. New York, Irvington Publishers, 1983

2. Brautigam HH, Grimes DA: Arztliche Aspekte des Legalen Schwangerschaftsabbruchs. Stuttgart, Ferdinand Enke Verlag, 1984

3. Baird DT, Grimes DA, Van Look PFA (eds). Modern Methods of Inducing Abortion, Oxford, Blackwell Science, 1995

4. U.S. Preventive Services Task Force. Guide to Clinical Preventive Services, 2nd ed. Baltimore, Williams & Wilkins, 1995

5. Grimes DA, Wallach M, Chaney EJ, Connell EB, Emans SJ, Goldzieher JW, Hillard PJA, Mastroianni L, Jr. Modern Contraception. Updates from the Contraception Report, Totowa, NJ, Emron, 1997

6. Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, eds. A Clinician's Guide to Medical and Surgical Abortion. New York: Churchill Livingstone, 1999

7. Knijff SCM, Goorissen EM, Velthuis-te Wierik EJM, Korver T, Grimes DA: Summary of contraindications to oral contraceptives, New York: Parthenon Publishing, 2000

8. Wallach M, Grimes DA, Chaney EJ, Connell EB, Creinin MD, Emans SJ, Goldzieher JW, Hillard PJA, Mastroianni L Jr. Modern Oral Contraception. Updates from the Contraception Report. Totowa, NJ, Emron, 2000

MISCELLANY:

1. Grimes DA: Oral contraceptives. Published by University of North Carolina, 1974. Revised 1977

2. Grimes DA: Intrauterine contraceptive devices. Published by University of North Carolina, 1974. Revised 1977

3. Grimes DA: A contraceptive potpourri. Published by University of North Carolina, 1974. Revised 1977

4. Grimes DA: Permanent female sterilization. Published by University of North Carolina, 1974. Revised 1977

5. Center for Disease Control: Abortion Surveillance: 1974, issued 1976 April

6. Cates W Jr, Grimes DA: The comparative safety of intraamniotic prostaglandin F2a and saline for abortion. In "Special Question," Sexual Medicine Today, 1977 April, p.33

7. Center for Disease Control: Abortion Surveillance: 1975, issued 1977 April

8. Grimes DA: D + E for abortions in: Q + A patient problems. Sexual Medicine Today 1978 October P 24

9. Grimes DA: Amount of blood shed in menses. Med Asp Hum Sexual 1980 14(3):143

10. Grimes DA: Discussion in: Bishop EH: Three Women with Suspected Gonorrhea. Clinical Simulations in Ob-Gyn, Series 4, Number two. Pleasantville, N.Y., Docent Corporation, 1978

11. Grimes DA, Brenner WE: Methods of midtrimester abortion. ACOG Technical Bulletin #56, 1979 December

12. Grimes DA: Toxicshockandcoitus. Med Asp Hum Sexual 1981; 15(11):114

13. Centers for Disease Control: Ectopic Pregnancy Surveillance 1970-1978, issued 1982 July

14. Report of a WHO Scientific Group: Gestational Trophoblastic Diseases. Technical Report Series 692. Geneva, World Health Organization, 1983

15. Grimes DA: What percentage of women who have a tubal sterilization nonetheless conceive? (Q&A) Med Asp Hum Sexual 1984; 18(7):95

16. Grimes DA: Gonorrhea and Chlamydial Infections. ACOG Technical Bulletin No. 89, 1985 November

17. Grimes DA: Can donor insemination cause toxic shock syndrome? International Correspondence Society of Obstetricians and Gynecologists Collected Letters 1986; 27(7):7

18. Grimes DA: Sexually transmitted diseases. Precis III. Washington, D.C., American College of Obstetricians and Gynecologists, 1986

19, Grimes DA, Becker TM: Herpes Simplex virus infections. ACOG Technical Bulletin No. 102, 1987 March

20. Grimes DA: Introduction. In : Fertility Regulation and the Public Health: Selected Papers of Christopher Tietze, M.D. (Tietze SL, Lincoln R, Eds.) New York, Springer-Verlag, 1987, pp 137-138

21. Grimes DA: Contraceptive choices for teenagers. Questions and Answers JAMA 1987; 257:3419

22. Grimes DA, Becker TM: Genital human papillomavirus infections, ACOG Technical Bulletin No. 105, 1987 June

23. Grimes DA: Editorial note. Contraception 1987; 36:IV

24. Report of a WHO Scientific Group: Mechanism of Action, Safety and Efficacy of Intrauterine Devices. Technical Report Series 753. Geneva, World Health Association, 1987

25. Grimes DA: What are the main benefits (other than contraception) of OCs in disease prevention? (Q&A) Med Asp Hum Sexual 1989;23(5):21

26. Grimes DA: A device for transfusing autologous blood. Contemp Ob/Gyn 1989; 31:51-55

27. Grimes DA: Sexually transmitted diseases. Precis VI. Washington, D.C., American College of Obstetricians and Gynecologists, 1990

28. Grimes DA et al. Who will provide abortions? Ensuring the availability of qualified practitioners. Washington, D.C., National Abortion Federation, 199 1

29. Grimes DA: Preinsertion antibiotics help prevent IUD complications. Med Asp Hum Sexual 1991; 25(11):12

30. PROLOG Task Force: Patient Management in the office. Washington, D.C. American College of Obstetricians and Gynecologists, 199 1

3 1. Darney PD, Grimes DA, Speroff L: Long acting contraception. ACOG Update 1992;17(7):1-10

32. National Commission on America without Roe: Facing a future without choice. A report on reproductive liberty in America. Washington, D.C., National Abortion Rights Action League, 1992

33. Grimes DA: Gonorrhea and chlamydial infections. ACOG Technical Bulletin No. 190, 1994 March

34. Shulman LP, Grimes DA, Stubblefield PG: Abortion. ACOG UPDATE 1996, volume 22, number 7

35. Grimes DA: Foreword. In Hulka JF, Reich H, eds. Textbook of Laparoscopy, Third Edition New York, WB Saunders, 1997

36. Grimes DA: Sense and sensuality: contraceptives. Audio-Digest Obstetrics/Gynecology 1997, 44, number 2

3 7. Report of a WHO Scientific Group. Medical methods for termination of pregnancy. Technical Report Series 871. Geneva, World Health Organization, 1997.

38. Grimes DA: Foreword. In: Hulka JF, Reich H. Textbook of laparoscopy. Third ed. Philadelphia: W. B. Saunders Co., 1998:xiii-xiv

39. Family Health International: Mechanisms of the contraceptive action of hormonal methods and intrauterine devices. Research Triangle Park, NC: Family Health International, 1998

40. Grimes DA: Epidemiologic insights: The safety of oral contraceptives. Consults in Oral Contraception 1998;1(3):1-12.

41. Grimes DA: Commentary on: Use of the intrauterine device by inner-city women JAMA Women's Health Web Site, Contraception Information Center, May 4, 1998.

42. Grimes D: A research agenda emphasizing clinical outcomes in OB/GYN. In: Gabbe S, Mueller-Heubach E, eds. Blueprint for academic obstetrics and gynecology. A consensus conference convened by the Council of University Chairs of Obstetrics and Gynecology (CUCOG). Washington, DC: CUCOG, 1997.

43. Grimes D: DMPA good choice for women with sickle cell. Network 1999; 19(2): 1 O-l 1.

44. Grimes D: Hormonal methods may affect headaches. Network 1999;19(2):1l-13.

ELIZABETH GRAY RAYMOND

OFFICE
Clinical Research Division
Family Health International
P. 0. Box 13950
Research Triangle Park, NC 27709
Phone: (919) 544-7040
Fax: (208) 2756440
Email: eraymond@fhi.org

RESIDENCE
7301 Caliber Park, #206
Durham, NC 27701
Phone: (919) 489-0462

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

1. Kane AB, Stanton RP, Raymond EG, et al. Dissociation of intracellular lysosomal rupture from the cell death caused by silica. J Cell Biol 1980; 87:643-651.

2. Hunter V, Raymond EG, et al. Efficacy of the metastatic survey in the staging of gestational trophoblastic disease. Cancer 1990; 651647-I 650.

3. Raymond E, Clemens JD. Prospective risk of stillbirth [letter]. Obstet Gynecol 1992; 80:473-4.

4. Levine RJ, Raymond E, DerSimonian R, Clemens J. Preeclampsia prevention with calcium supplementation. Clin Applied Nutrit 1992; 2:30-38.

5. Raymond EG, Mills JL. Placental abruption: risk factors and associated fetal conditions. Acta Obstet Gynecol Scand 1992; 72:633-639.

6. Mills JL, Raymond E. Effects of recent research on recommendations for periconceptional folate supplement use. Ann N Y Acad Sci 1993; 678:137-145.

7. Raymond EG, Cnattingius S, Kiely JL. Effects of maternal age, parity, and smoking on the risk of stillbirth. British J Obstet Gynaecol 1994; 101:301-306.

8. Raymond EG, Tafari N, Troendle J, Clemens JD. Development of a practical screening tool to identify preterm, low birthweight neonates in Ethiopia. Lancet 1994; 344:520-523.

9. Levine RJ, Esterlitz JR, Raymond EG, et al. The trial of calcium for preeclampsia prevention (CPEP): rationale, design, and methods. Controlled Clinical Trials 1996; 17:442-469.

10. Raymond EG, Singh M, Archer DF, Saxena BB, Baker J, Cole D. Contraceptive efficacy, pharmacokinetics, and safety of Annuelle® biodegradable norethindrone pellet implants. Fertil Steril 1996; 66:954-61.

11. Olson BR, Forman MR, Lanza E, et al. Relation between sodium balance and menstrual cycle symptoms in normal women. Ann Intern Med 1996; 125:564-567.

12. Levine RJ, Hauth JC, Curet LB et al. Trial of calcium to prevent preeclampsia. New Engl J Med 1997; 337:69-76.

13. Cates W, Raymond EG. Emergency contraception – parsimony and prevention in the medicine cabinet. Am J Public Health 1997; 87:909-910.

14. Cates W, Raymond EG. Vaginal Spermicides. In: Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Guest F, Kowal D.et al., eds. Contraceptive Technology. 17th edition. New York: Irvington Publishers, Inc., 1998: 357-370.

15. Trussell J, Ellertson C, Stewart F, Koenig J, Raymond EG. Emergency contraception: a cost effective approach to preventing unintended pregnancy. Women Health Primary Care 1998; 1:52-69.

16. Fortney JA, Feldblum PJ, Raymond EG. Intrauterine devices: the optimal long-term contraceptive method? J Reprod Med 1999; 44:269-274.

17. Trussell J, Raymond EG. Statistical evidence about the mechanism of action of the Yuzpe regimen of emergency contraception. Obstet and Gynecol 1999; 93:872-876.

18. Grimes DA, Raymond EG. Bundling a pregnancy test with the Yuzpe regimen of emergency contraception. Obstet Gynecol 1999; 94:471-473.

19. Raymond EG, Dominik R, Spermicide Trial Group. Contraceptive efficacy of two spermicides: a randomized trial. Obstet Gynecol 1999;93:896-903.

20. Raymond E, Alvarado G, Ledesma L, Diaz S, Bassol S, Morales E, Femandez V, Carlos G. Acceptability of two spermicides in five countries. Contraception, 1999;60:45-50.

21. Steiner MJ, Hertz-Picciotto I, Raymond E, Trussell J, Wheeless A, Schoenbach V, Influence of cycle variability and coital frequency on the risk of pregnancy. Contraception 1999;60:137-43.

22. Mills JL, DerSimonian R, Raymond E, Morrow JD, Roberts LJ 2nd, Clemens JD, et al. Prostacyclin and thromboxane changes predating clinical onset of preeclampsia: a multicenter prospective study. JAMA 1999;282:356-362.

23. Steiner MJ, Raymond E, Attafuah JD, Hays M. Provider knowledge about emergency contraception in Ghana. J Biosoc Sci 2000;32:99-106.

24. Raymond EG, Creinin MD, Barnhart KT, Lovvorn AE, Rountree RW, Trussell J. Meclizine for prevention of nausea associated with emergency contraceptive pills: a randomized trial. Obstet Gynecol 2000;95:271-277.

25. Lovvorn A, Nerquaye-Tetteh J, Glover EK, Amankwah-Poku A, Hays M, Raymond E. Provision of emergency contraceptive pills to spermicide users in Ghana. Contraception. 2000;61:287-93.

26. Raymond EG, Lovely LP, Chen-Mok M, Seppälä M, Kurman RJ, Lessey BA. Effect of the Yuzpe Regimen of Emergency Contraception on Markers of Endometrial Receptivity. Hum Reprod 2000;15:2351-5

Align top of FedEx PowerShip Label or Astra Label here.

PRISCILLA SMITH
CRLP
126 WALL STREET
NEW YORK NV 10005
(9171637-3600

SHIP DATE: 13FEB01
ACC# 158450739
ACTUAL WGT: 4 LBS MAN Wt

TO: Dockets Management Branch
FDA Dep't of Health & Human Svcs
Room 10-61
5630 Fiskers Lane
Rockville MD 20857

(301)827-6860

4654 4388 9833

FedEx.

4654 4388 9833

REF: 236

PRIORITY OVERNIGHT WED

CAD# 0633934 13FEB01

Deliver by:
14FEB01

TRK# 4654 4388 9833 Form 0201

IAD AA

20857 -MD-US 19 GAIA --

3077-077.SP G.T.I. 7/99

'd Overnight®