E.C.

* mtg w/ WH counsel + HHS counsel + Jeanne don't involve [redacted] Mack Reed (OMB) later

ask Liz Fike → re: PACE

Morgan's Commerce contact person -- legislative counsel to do Commerce

Amy - WHAC - 55688

learn what everyone's doing - what a good program is good connection.

Healthy People 2020 —
goal to ↑ providers providing EC

* Medicaid - States decide what drugs cover
27 + DC cover EC's encourage to cover
49 + DC ~~EC~~ cover birth control pills
also invite CHC, Indian HS, etc. - other grantees

* OPM - FEHBP - make sure cover EC - under Fed - law you are required to cover all FDA approved EC's

RU-486 - urge states to cover under Hyde amendment

* states + Medicaid r medical ~~surgical~~ abortion
treat same as surgical

FAX

THE ALAN GUTTMACHER INSTITUTE
NEW YORK & WASHINGTON
1120 Connecticut Avenue, NW
Suite 460
Washington, DC 20036
Phone: 202 296-4012
Fax: 202 223-5756
E-mail: policyinfo@usa.org
Web site: www.agi-usa.org

Date: 11/30

Number of pages including cover sheet: 10

To: Heather Howard

@ 456-2878

From: Cynthia

* ____Original will not follow
____Original will follow, via _____

MESSAGE:

To: Heather Howard

From: Cynthia Dailard
Marilyn Keefe

Date: November 29, 2000

Re: Potential Clinton Administration Action on Emergency Contraception

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In 1997, the FDA announced that high doses of birth control pills taken within 72 hours of unprotected sex are safe and effective in preventing unintended pregnancy. The notice was intended to encourage manufacturers to package and market birth controls pills in dosages appropriate for use as emergency contraceptives. In 1998, the FDA approved "Preven," the first separately packaged pills for use as emergency contraceptives, which was followed by the approval of another dedicated product, "Plan B" in 1999.

Emergency contraception is highly effective in preventing unintended pregnancy, reducing the risk by 75 percent. It is not a method of abortion, as some anti-choice advocates have claimed, because it does not disrupt an already established pregnancy. Instead, it prevents the establishment of a pregnancy before it occurs. As a result, it has enormous potential to help reduce this country's extremely high rate of unintended pregnancy (half of all pregnancies in this country are unintended).

Nonetheless, use of emergency contraception in this country remains low. This is in part due to a lack of physician and patient awareness of the method. Several organizations are working to change this – in particular, the American College of Obstetricians and Gynecologists recently issued practice guidelines for emergency contraception. In addition, *Healthy People 2010*, published by the Surgeon General this year, established a 10-year national public health goal of increasing the proportion of health care providers who provide emergency contraception (see attached). Taking steps to increase awareness of the method by health care providers would go a long way toward achieving this important goal.

Here are a few steps that the Clinton Administration should take to increase awareness of emergency contraception and reduce unintended pregnancy:

- The Secretary of HHS should write a letter to entities that provide family planning services through federal public health grants, such as Title X clinics, community health centers, and state MCH programs, urging them to offer emergency contraceptives to women at risk of unintended pregnancy. There is a precedent for such action: in 1997, the Office of Population Affairs sent a policy guidance to Title X regional health administrators urging Title X grantees to consider offering emergency contraceptives (see attached). The Secretary should send similar letters to the directors of state health departments and state family planning administrators

urging a similar stance. The Indian Health Service and CHAMPUS are other areas worth exploring.

- The Secretary of HHS should write a letter to state Medicaid directors encouraging them to cover emergency contraception under state Medicaid plans. (States decide which prescription drugs they want to cover; currently, 47 states cover oral contraceptives but only 27 states cover emergency contraceptives.

- The revised Title X guidelines for service providers that are currently awaiting final clearance within HHS should require Title X providers to offer emergency contraceptives. The existing guidelines, last revised in 1980, require Title X projects to a broad range of acceptable and effective family planning methods. We do not know what the revised guidelines will say with regard to emergency contraception, and may even be silent on the subject. (Note that we would not want to encourage any action that would prevent the revised guidelines from being published before the end of this Administration.)

- OPM should write a letter to plans participating in FEHBP, reminding them that the statutory requirement for FEHBP plans to cover the full range of FDA-approved prescription contraceptives includes coverage of emergency contraceptives.

HEALTHY PEOPLE 2010

Volume I

Includes

- Understanding and Improving Health
- Objectives for Improving Health (Part A: Focus Areas 1–15)

Females Aged 15 to 44 Years Using Reversible Contraception, 1995	Experienced Pregnancy Percent
Select populations	
Marital/cohabiting status	
Married	10
Cohabiting	22
Unmarried, not cohabiting	14

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

The public health benefits of improved contraceptive practices are potentially enormous. Whether fertile females who are sexually active and do not want to get pregnant experience an unintended pregnancy is a function of their choice—and their partners' choice—of contraceptive methods and how effectively they use them. The efficacy of reversible contraceptive methods depends on consistent and appropriate usage. Unintended pregnancies experienced by females using reversible methods are primarily a result of inconsistent and/or inappropriate use.[30] Ideally, an objective would focus on consistent and correct use of a particular method. The data, however, cannot address the role that method switching may play in unintended pregnancy.

9-5. (Developmental) Increase the proportion of health care providers who provide emergency contraception.

Potential data source: Alan Guttmacher Institute.

The *U.S. Guide to Clinical Preventive Services*[6] identifies postcoital administration of emergency contraceptive pills (ECP) after unprotected intercourse as an effective means of reducing subsequent pregnancy. ECP is estimated to reduce the risk of subsequent pregnancy by 75 percent. Yet, this method, which has the public health potential of significantly reducing unintended pregnancy, is not well known and not yet widely available to the public. Surveys indicate that knowledge and use of postcoital contraception remains low among patients and clinicians alike.[29] In 1995, less than 1 percent of females in the United States reported ever having used ECP.[31]

Several developments, however, have formalized recognition within the medical community of ECP as an effective means of preventing pregnancy, including the American College of Obstetrics and Gynecology issuance of practice guidelines for emergency oral contraception. Barriers to the more frequent use of ECP include a lack of physician awareness of the method, a lack of public awareness of the method's availability, and a lack of access by patients to a physician who will prescribe the method.[32] Increased public awareness, including culturally and linguistically competent education about ECP, as well as direct access to and insur-

ance reimbursement for ECP, would contribute significantly toward attainment of this objective.

In February 1997, the Food and Drug Administration (FDA) announced that certain regimens of combined oral contraceptives are safe and effective for ECP when initiated within 72 hours after unprotected intercourse.[33] The FDA notice was intended to encourage manufacturers to make this additional contraceptive option available.[33] One product, an emergency contraceptive kit, has been approved by FDA and is being marketed. On July 28, 1999, FDA approved the first progestin-only emergency contraceptive.

9-6. (Developmental) Increase male involvement in pregnancy prevention and family planning efforts.

Potential data source: National Survey of Family Growth (NSFG), CDC, NCHS.

There is increasing recognition of the value of male involvement in pregnancy prevention and family planning. Several related developments in public health and welfare demonstrate that male involvement is key, including culturally and linguistically appropriate programs promoting condom use and addressing HIV and STD prevention, culturally and linguistically competent services targeting men as part of managed care marketing strategies, emphasis on male responsibility in welfare, child support enforcement, and pregnancy prevention efforts. Concern about the spread of HIV and other STDs and the recognition of condoms as the most effective way of preventing transmission during intercourse have accentuated the need to change the sexual behavior of males. The need for rapid treatment of male partners of females testing positive for bacterial STDs is a critical element in slowing not only STD spread but also that of HIV.

Yet, information about how males could and should participate in pregnancy prevention programs is lacking. For many years, reproductive policy in the United States concentrated almost entirely on females. The National Survey of Adolescent Males (NSAM), begun in 1988 by the Urban Institute and repeated again in 1995, collected the first national trend data on the reproductive behavior of male teens. An Urban Institute survey of publicly funded family planning clinics found that males make up more than 10 percent of the total clientele in only 13 percent of clinics. An average of 6 percent of clients are males. Males represent an even smaller share of clients who receive family planning services subsidized by the Title X program (2 percent in 1991) or by Medicaid (2 percent in 1990).[34] Even though males do not actually get pregnant, integrating them in prevention programs makes sense. Males must be included in any efforts to address unintended pregnancy.[35]

The next National Survey of Family Growth (NSFG) is being expanded to include males, providing an avenue for institutionalizing data collection about male fertility that will be reflected in the Healthy People 2010 objectives. Over the course of

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date APR 23 1997

From Acting Deputy Assistant Secretary for Population Affairs

Subject OPA Program Instruction Series, OPA 97-2: Emergency Contraception

To Regional Health Administrators
Regions I-X

On February 25, 1997, the Food and Drug Administration (FDA) issued a notice in the Federal Register announcing that certain regimens of combined oral contraceptives are safe and effective for postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. This action is based on the FDA's review of the published literature concerning postcoital use of currently available oral contraceptives, knowledge of the safety of oral contraceptives as currently labeled, and on the unanimous conclusion of the FDA Advisory Committee on Reproductive Health Drugs, which met on June 28, 1996, to consider the safety and efficacy of this contraceptive option.

According to Section 1001(a) of the Title X statute and Section 59.5(a)(1) of the Title X regulations, family planning projects must offer a broad range of acceptable and effective family planning methods. In considering the range of methods that will be offered in a specific family planning project, Title X grantees should consider the availability of emergency contraception the same as any other method which has been established as safe and effective.

As with all other prescriptive contraceptive methods, emergency contraception must be prescribed in accordance with medically accepted protocol, and in accordance with a sliding fee scale that is based on the actual cost of providing the service. Resources attached may be helpful in developing protocols for providing emergency contraception.

Thomas C. Kring

Attachments (3)

(1) ACOG Practice Patterns on Emergency Oral Contraception, Number 2, October 1996.

(2) Federal Register, Vol. 62, No. 37, Tuesday, February 25, 1997, "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception."

(3) Gynetics Announcement of Intent to Market "Yuzpe Method" of Emergency Contraception in 1998.