

5/18/93

Kaiser Family Foundation Forum
OVER-THE-COUNTER ORAL CONTRACEPTIVES
Quadrus Conference Center, Menlo Park, CA
July 8-9, 1993

DRAFT AGENDA

THURSDAY, JULY 8

7:45 - 8:30 Continental Breakfast

8:30 WELCOME & INTRODUCTIONS

Drew Altman, Ph.D.
Kaiser Family Foundation

Mark Smith, M.D., M.B.A.
Kaiser Family Foundation

[PRO]

Morning Session: Sarah E. Samuels, Dr.P.H. (Moderator)
Kaiser Family Foundation

9:00 - 9:30 OVERVIEW: OVER-THE-COUNTER ORAL CONTRACEPTIVES

Felicia Stewart, M.D.
Sacramento Planned Parenthood

[PRO]

9:30-10:00 HISTORY OF ORAL CONTRACEPTIVES IN THE U.S.

Vanessa Northington Gamble, M.D.
University of Wisconsin

10:00 - 10:30 INTERNATIONAL EXPERIENCE

Francine Coeytaux
Population Council

[probably pro, but UNSURE
WHAT INTERNATIONAL EXPERIENCE
to be PRESENTED - ONLY
(SWEDEN) AND NOT POSITIVE
FOR OTC] -> DR. GORAN SKANSJÖ

10:30-11:00 Discussion

11:00-11:15 Break

11:15-12:15 SAFETY OF ORAL CONTRACEPTIVES

Diana Pettiti, M.D., M.P.H.
University of California, San Francisco

[~ PRO
- PILLS ARE VERY SAFE -
SAFETY NOT ISSUE]

Discussion

12:15 LUNCH

THURSDAY, JULY 8 (Continued)

Afternoon Session: Mark D. Smith, M.D. (Moderator)

1:30-2:00 USE AND ACCESS TO ORAL CONTRACEPTIVES

Jacqueline D. Forrest, Ph.D.
The Alan Guttmacher Institute

*[CON - PILLS
KRE SAFER BUT WHAT
KRE OTHER RAMIFICATIONS?]*

2:00-2:30 RESULTS OF SURVEY OF WOMEN'S VIEWS

Sarah E. Samuels, Dr.P.H.

*[PROGRAM COORDINATOR -
MOST LIKELY NEUTRAL]*

2:30-3:00 EFFICACY OF ORAL CONTRACEPTIVES

James Trussell, Ph.D.
Princeton University

*[PRO -
Economics of
OIC]*

3:00 - 3:30 Discussion

3:30 - 3:45 Break

3:45 - 5:00 CURRENT PROGRAMS AND POLICIES (invited)

Planned Parenthood: Mike Policar, M.D.
Planned Parenthood Federation of America

Teens: Vanessa Cullins, M.D.
Francis Scott Key Medical Center

Title X Programs: Joan Henneberry
Colorado Department of Family Planning

*[PRO, BUT STAYS -
NEUTRAL UNTIL NEW
P.P. ROLE WITHOUT
CHEAP OCS IRONED
OUT]*

*[ESTROGEN NO PLANT
SUPPORTER -
PROBABLY PRO]*

[PRO]

6:30 Reception

7:00 Dinner

Speaker: Jocelyn Elders, M.D. (invited)
Surgeon General designate

FRIDAY, JULY 9TH

Morning Session: Sarah E. Samuels, Dr.P.H. (Moderator)

8:30 - 9:00 LAWS AND REGULATIONS

Nancy Buc, Esq.
Weil, Gotschal, and Manges

[pro - but will focus on liability considerations]

9:00 - 9:30 FDA POLICY OPTIONS

Carol Scheman, Deputy Commissioner for
External Affairs
Food and Drug Administration

Ezra Davidson, M.D.
King-Drew Medical Center

[pro]

Randy Juhl, Ph.D. ^(?)
University of Pittsburgh

9:30 - 10:15 COST AND COVERAGE

Stephen Schondelmeyer, Pharm.D., Ph.D.
University of Minnesota

[focused on cost/covrable issues - economics of DTC - position?]

Discussion

10:15 - 10:30 Break

10:30 - 11:15 INDUSTRY PERSPECTIVES PANEL (invited)

11:15 - 12:30 SUMMARY AND DISCUSSION OF POLICY AND RESEARCH RECOMMENDATIONS

12:30 Lunch

OVER-THE-COUNTER ORAL CONTRACEPTIVES FORUM

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SUMMARY OF ISSUES
REGARDING NON-PRESCRIPTION ORAL CONTRACEPTIVES

A. THEORETICAL BENEFITS :

- 1. Decrease in the number of unintended pregnancies by increasing the access to a safe and highly effective form of contraception.**
 - Women, particularly teens, who may fear the doctor visit, cannot afford it or cannot get to a low cost clinic today, could now get the pill at a drugstore without that visit.
 - This could result in fewer pregnancies, abortions and cost the healthcare system less.

B. THEORETICAL DRAWBACKS :

- 1. Probability of sparking major controversy on an issue that is already highly polarized and controversial.**
 - Healthcare community currently split 50/50 on issue with high emotion on both sides.
- 2. Possibility of increasing unintended pregnancies due to improper usage of the pill among consumers who would no longer receive personal instruction on how to use it.**
 - Possibility of increased abortions.
 - Possibility of increased costs to the healthcare system.
- 3. Possibility of increase in STDs because of loss of doctor counseling regarding responsible sexual behavior and protection methods.**
- 4. Increase in other health risks in women who choose to take the pill but should not.**
 - Although contraindications, such as smoking, high blood pressure and heart disease, are listed in the labeling, consumers, in some cases, cannot and, in many cases, do not read the labels.
- 5. Possibility for misuse of the pill as 'morning after'.**
- 6. Possibility of increase in unintended pregnancies due to the premise that access is not, in fact, the major barrier to more widespread use of the pill.**
 - Dramatically increased access to condoms has not caused a dramatic increase in its use for HIV protection, particularly in teens.
 - Psychological factors may play more of a role in lack of contraceptive use than access.
- 7. Possibility of increase in cost of the pill to consumers.**
 - Most healthcare plans do not cover OTC medications, which may actually result in decreased access.
- 8. Possible delay in diagnosis of STDs, breast cancer and other gynecological disorders due to the delay or avoidance of the annual physical exam.**

HEALTH

Talks Canceled On Making 'Pill' Nonprescription

By ELYSE TANOUYS
And ROSE GUTTFELD

Staff Reporters of THE WALL STREET JOURNAL

The Food and Drug Administration abruptly canceled a special meeting on the potentially explosive issue of allowing birth control pills to be sold without a prescription.

The unusual retreat, which was ordered directly by the FDA's top brass, came after the officials realized the issue has much further-reaching social consequences than they contemplated. Opponents also had complained that the meeting was hastily planned and that the agency hadn't given them enough time to prepare.

Carol Scheman, FDA deputy commissioner for external affairs, rejects the notion that the FDA was backing away from a controversy. But she says, "It's not clear why the issue is being addressed at this time and this narrowly." The meeting of outside advisers to the agency was canceled after FDA officials decided that the agenda wasn't broad enough and that the agency hadn't consulted with a wide enough range of groups, she says.

The meeting was being organized by Johnson & Johnson, which sells the top-selling oral contraceptive brand, Ortho-Novum. The company has a huge stake in the outcome of any FDA decision on the issue. By some estimates, sales of J&J's birth control pill sales could double to \$500 million if it's sold without a prescription, a growth opportunity the company doesn't have in the sluggish prescription drug market.

"This would be a truly historical decision, if it ever happens," says Heinnant Shah, an independent drug analyst.

But for now, the issue sharply divides family-planning advocates. Supporters say making the pills more easily available will reduce unwanted births and abortions, and increase women's reproductive autonomy. Opponents say a switch could increase the risk of side effects and out-of-pocket costs of the pills for many women, and reduce medical services for women.

"It's too potent a drug for over-the-counter," says Sidney Wolfe, director of Public Citizen's Health Research Group. Mr. Wolfe contends that removing the prescription requirement would increase the use of the pills by women for whom they pose dangers.

Although the pill has been proven safe and effective for the vast major-

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ity of women of childbearing age, it does pose risks for women with high blood pressure, certain cancers or diabetes, and for smokers over 35 years old. In addition to J&J, oral contraceptives are sold by units of American Home Products Corp., Monsanto Co., Warner-Lambert Co. and Bristol-Myers Squibb Co.

Other opponents argue that the only time many women see a physician is to obtain a birth control prescription. During those visits, other problems such as sexually transmitted diseases, high blood pressure and cancer are often detected, they say. "A birth control prescription is the poor woman's ticket to health care," says Cynthia Pearson, program director for the National Women's Health Network, which opposes switching the pill's status.

Physicians also would lose the opportunity to counsel adolescent patients about side effects, says Daniel Riddick, president of the American Fertility Society and head of an American College of Obstetricians and Gynecologists' practice committee. Without counsel, women may stop taking the pill when the side effects make them uncomfortable, which would lead to more unwanted pregnancies, he says.

Although physicians are expected to oppose a pill switch, because it might reduce patient visits and doctors' incomes, Dr. Riddick argues such a move may result in more physician visits. Women may rush to emergency rooms or doctors' offices because of vaginal bleeding or other common side effects that wouldn't have alarmed women who were counseled before starting the pill, he says.

Condom use also may decline if birth control pills are readily available on drug-store counters, opponents argue. That could lead to an increase in sexually transmitted diseases, including AIDS.

The opponents also argue that making birth control pills available without a prescription may reduce options for poor women, who currently receive them free or at a low cost. Medicaid won't cover nonprescription birth control pills, forcing poor women to pay \$20 to \$25 a month out of their own pockets.

Michael Poticar, medical director of the Planned Parenthood Federation of America, notes that what makes some family planning providers balk at the idea of over-the-counter sales is the possibility of losing valuable income from selling birth control pills, which they buy at a discount.