



THE ASSEMBLY
STATE OF NEW YORK
ALBANY

RICHARD N. GOTTFRIED
75th Assembly District

CHAIR
Committee on Health

COMMITTEES
Rules
Higher Education
Judiciary
Insurance
Social Services
Majority Steering Committee

Legislative Office Building, Room 822
Albany, New York 12248
(518) 455-4941
FAX (518) 455-5939

250 Broadway, Room 2232
New York, New York 10007
(212) 312-1492
FAX (212) 312-1494

242 West 27th Street
New York, New York 10001
(212) 807-7900
FAX (212) 243-2035

GottfrR@assembly.state.ny.us

December 12, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

BY FAX AND BY MAIL - 301-827-6776

To the Division of Dockets Management:

We are writing in support of over-the-counter status of Plan B, an emergency contraceptive pill. Scientific research and the Food and Drug Administration itself have confirmed emergency contraception (EC) as a safe and effective way of preventing unintended pregnancy, and it is an appropriate candidate for over-the-counter use.

Plan B meets the Food and Drug Administration's criteria for determining whether drugs are suitable for over-the-counter availability. It treats a condition that is self-diagnosed, it is safe and effective when used without direct prescriber supervision, and the drug's label adequately explains potential adverse effects and conditions of use. Plan B is easy to use, has no known health hazards, has no contraindications, and has minor and temporary side effects. There is no compelling medical rationale for barring its use over-the-counter. The prescription requirement delays access, thus diminishing the effectiveness of EC and exposing the patient to an unwanted pregnancy.

It is noteworthy that the American College of Obstetricians and Gynecologists has endorsed the switch to over-the-counter status of EC. It is striking and unusual for an organization of physicians to endorse access to a treatment without physician intervention. This speaks powerfully to the safety and benefit of over-the-counter use of EC.

Unintended pregnancy is a major public health issue that has negative consequences for both individuals and society as a whole. Nearly half of all pregnancies in the United

03 DEC 15 19:12

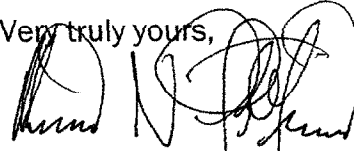
OIP-0075

C319

States are unintended. It has been estimated that greater access to EC could reduce the rate of unintended pregnancy nearly by half.

Over-the-counter status for Plan B is appropriate and will advance the greater public health of the entire country.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Richard N. Gottfried', written over a circular stamp or seal.

Richard N. Gottfried
Chair
Assembly Committee on Health

THE FOLLOWING NEW YORK STATE ASSEMBLY MEMBERS JOIN IN SIGNING THIS LETTER:

Adele Cohen
Jeffrey Dinowitz
Patricia Eddington
Deborah Glick
Pete Grannis
Rhoda Jacobs

Jeffrey Klein
John W. Lavelle
Nettie Mayersohn
Scott Stringer
Keith Wright