

To Whom This May Concern

I am enclosing my
Concerns about ~~permitted~~
the sale of oral contra-
ceptives without a
prescription.

I can't believe a
woman can not get
their ears pierced

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without permission
and yet you consider
oral contraception without
a prescription considering
all the contraindications
worthy of consideration.
I am in shock. Please
consider the enclosed.

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In view of the multitude of

- > harms of hormonal contraceptives, many of which have now been firmly
- > established 1,2, and others where a causal link is strongly evident, if
- > not finally proven, it would have been more to the point to hold hearings
- > on whether to revoke the licensure for sale of all chemical
- > contraceptives; whether administered orally or by injection.
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- > It was not clear from the announcement whether the proposal is to include
- > the "morning after" abortifacient, Preven, as well as standard low-dose
- > combined oral contraceptives and the progestin only "mini-pill."
- >
- > 1) Allowing the sale of oral contraceptives over the counter sends the
- > wrong message, namely, that oral contraceptives are completely safe and
- > acceptable. It is well established that legalization of any drug is taken
- > by the public to be an endorsement not only of its safety, but of its
- > acceptability. This has been repeatedly demonstrated with "leisure drugs"
- > such as alcohol, smoke and smokeless tobacco, and marijuana, through
- > alternate periods of relative restriction and legalization.
- >
- > The prescription of oral contraceptives was illegal until the early
- > nineteen-sixties. Nearly forty years of experience with oral
- > contraceptives have linked their use to the breakdown of marriage and
- > family life,3,4 exactly as was predicted by Pope Paul VI in the classical
- > 1968 document Humane Vitae. The explosion of divorce and unplanned
- > pregnancies exactly coincided with increased use of the pill. Today, we
- > are being pressured to accept the complete separation of the sexual act
- > from family life in movements to legalize homosexual unions, and in the
- > use of in vitro fertilization. It was "the pill" that first effected this
- > separation, and is now threatening the moral foundation of our society.
- >
- > 2) Oral contraceptives are medically harmful. Based on an overall death
- > rate of 7.9 per 100,000 users, it has been estimated that over a thousand
- > American women die every year from strokes, heart attacks and other direct
- > complications from the use of oral contraceptives.2 This estimate excludes
- > more than 30,000 deaths per year from cancer of the breast, liver and
- > cervix linked to the use of oral contraceptives. Hormonal contraceptives,
- > whether taken orally or by implantation, are abortifacient,5,6 cause
- > breast cancer (overall 40% or greater increase in risk); blood clots
- > (3-11X greater risk), strokes (1.4X greater risk of fatal brain
- > hemorrhage, 3X greater for smokers) and heart attacks (2X greater risk of
- > fatal heart attacks, 12X greater if the woman also smokes).2 In addition,
- > chemical contraceptives suppress the immune system, causing a significant
- > increased risk of sexually transmitted disease.7 Half of the women who
- > take the pill discontinue it within the first year due to side effects
- > such as headache and depression.2 The "morning after pill," is even more
- > dangerous, with a 50% higher risk of strokes.8
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- > It is no coincidence that insurance companies have been reluctant to cover
- > the use of oral contraceptives. This amounts to independent verification
- > of the harms of contraceptives, based only on a single measure of harm;
- > that of increased medical costs resulting from their use.
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- > 3) Approving this proposal could effectively eliminate age restrictions,
- > and parental consent. A twelve-year-old could possibly buy contraceptives
- > along with her bubble gum. A child molester could just pick up some to
- > force on his victim, no questions asked. I have no doubt at all that
- > approving this proposal would result in increased sexual predation on
- > young girls, and earlier sexual experiences for young women.

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> 4) Making oral contraceptives available over the counter places on a woman
> the responsibility to make medical judgments about her risks that few
> women are qualified to make. The package inserts on ordinary oral
> contraceptives list nine major contraindications for use. My experience as
> a medical interviewer is that physicians often fail to check a woman's
> medical history before prescribing these drugs. It is not uncommon to
> discover that a woman with contraindications placing her at a high risk
> for adverse effects has been prescribed oral contraceptives by her
> physician. When even doctors have failed to properly assess and warn their
> patients, letting women assess the risks by themselves is a prescription
> for disaster.

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> The website of the Food and Drug Administration (www.fda.gov) proclaims
> that it is "the nation's foremost consumer protection agency." Citizens
> have a right to expect the FDA to live up to that promise. The public must
> be protected from dangerous drugs such as oral contraceptives. Bubble gum
> should be available over the counter. Minor pain relievers and cold
> medicine, if they have few risks, which are well announced in labeling and
> advertising, should be available without a prescription. Oral
> contraceptives should NOT be available without a prescription.

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> Sincerely,
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