type of test used).[27] Where access to radioimmunoassay pregnancy tests is available pregnancy can be determined at about the time that implantation begins.

In places where the laboratory-dependent tests are not available, a woman generally must wait one to two weeks after her missed menses in order to determine if she is pregnant. In these circumstances it would be impossible for any provider or acceptor of RU 486/PG to know with certainty, in the six weeks between the LMP and pregnancy test results, whether the woman was in fact pregnant. Significantly, this time span of "unknown condition" is almost identical to the period of time recommended for use of RU 486/PG. A crucial question is whether the use of RU 486/PG during this time violates a prohibition on abortion.

The legal status of menstrual regulation techniques, a term used to denote other early fertility regulation procedures that do not neatly fit into the abortion/contraception dichotomy, was first undertaken by Lee and Paxman in 1975.[4] They point out that, historically, restrictive criminal abortion statutes around the world generally follow one of two legislative models:

(1) Statutes that expressly or implicitly require proof of pregnancy as an element of the criminal offense; and

(2) Statutes that make it a crime to act with the intent of interrupting a pregnancy whether or not the woman is pregnant.[4]

Some countries, for example many of the African Commonwealth nations, have a dual scheme for punishment under which women who are prosecuted for procuring an abortion upon themselves must have been pregnant in fact, but doctors who perform the abortion can be prosecuted for merely intending to induce abortion. This produces the possibility of a doctor, or other person, who administers RU 486/PG to a woman with the intent of interrupting a "supposed" pregnancy, being found on the illegal side of abortion legislation, whereas the woman, if never proved to have been pregnant, would not be.

Statutes Requiring Proof of Pregnancy

Statutes that require proof of pregnancy are worded in many ways, including "causing an abortion upon a pregnant woman" (Dominican Republic),[28] procuring the "abortion of a pregnant woman" (Libya),[29] causing a "woman with child to miscarry" (Malaysia),[30] or simply make the act

of causing "abortion" illegal. For instance, Argentinean law criminalizes the causing of "abortion"[31] and Mexican law prohibits the performing of "an abortion on a woman."[32] Mexican law is unusual in one significant respect. Most abortion laws do not define abortion per se, but Mexican law states that "abortion is the killing of the product of conception at any time during pregnancy".[32]

The Mexican example illustrates an uncertainty with respect to biologic fact that is inherent in many abortion laws. Where there is no legal directive delineating when pregnancy begins, it is difficult to say with any certainty what acts constitute "abortion." If Mexican law were to be interpreted to mean that pregnancy begins at implantation and the "killing" of the "product of conception" after that point is abortion, then the use of RU 486/PG prior to implantation would not be a criminal act. If, however, the Mexican laws is interpreted to mean that pregnancy begins at conception, then the post-coital use of RU 486/PG is technically abortion, though the proof requirement that the "fetus" either be produced or proved to have existed makes successful prosecution for abortion resulting from RU 486 near impossible.[4] (Technically, RU 486 is recommended for use before a "fetus," as medically defined, exists at all.) Yet, proof of a violation of the abortion law and the legality of the use of a technique, like RU 486/PG, are not the same thing. It is important to look at the language of various abortion laws to determine whether the use of RU 486/PG would be legal.

Discussions of when pregnancy begins tend to wander into efforts to define when life itself begins. In Honduras a 1983 law states: "Abortion is the interruption of a pregnancy by the premature and violent expulsion of the product of the gestation or its interruption in the mother's womb."[33] In 1985 Honduras repealed articles of the Penal Code that had legalized abortion in the case of rape, in the case where the pregnancy posed a serious threat to the health or life of the women, or where the child would be born "defective."[34] The reasoning behind the narrowing of the law was that abortion was a "flagrant violation" of the principles in the Honduran Constitution which state that the "unborn shall be considered as born for all rights accorded within the limits established by law" and the "right to life is inviolable."[34] The interpretation of Honduran law depends on the definition of pregnancy applied. If the medical definition is used, then RU 486/PG could be legally available for use before implantation was complete; such use would be

prior to pregnancy. If , however, pregnancy is deemed to begin at conception, RU 486/PG would be treated as an abortifacient (as would, presumably, the IUD) on the grounds that it interrupts gestation in the "mother's womb." The use of the language "product of the gestation" offers an interesting distinction from the Mexican notion of "product of conception." Did Honduras intend that gestation begins only after implantation?

The laws of some other Latin American jurisdictions are more explicit on this point. For example, the Costa Rica National Population Programme of 1987 guarantees respect for the family and acknowledges the right to control fertility through access to birth control. However, it also states that "[e]very human being has the right to life from the moment of conception. . . ." Consequently, Costa Rica rejects abortion as a method of birth control within the meaning of its policy on population growth.[35] Though there remains an argument that when the conflicting considerations of a woman's life or health are threatened by ~~unwanted~~ pregnancy abortion should be legally available notwithstanding the above language, it appears that legal access to RU 486/PG in Costa Rica is unlikely.[36]

Yet, absent positive proof of pregnancy, Latin American jurisprudence indicates that the crime of abortion has not been committed. In Argentina, for example, a woman went to her doctor and, suspecting that she had conceived, sought an abortion. Because she was too near in time to her LMP, no procedure existed to test her suspicion of conception. The doctor performed a procedure that resulted in bleeding. They were tried and convicted of criminal abortion.[37] On appeal, however, the court held that the abortion statute had not been violated due to the lack of proof of pregnancy, an essential element of the crime. The law, the court said, did not apply to attempted non-abortions.[37] As there was no proven pregnancy, there was no abortion. This rule has been applied in other Latin American jurisdictions.[4] The same jurisprudential approach is applied in a few francophone countries that follow the basic provision of the French Penal Code of 1810, which spoke, like legislation in Latin American countries, of "a pregnant woman."[38] Absent proof of actual pregnancy there is neither abortion nor attempted abortion.[39]

The inability to prove pregnancy with certainty renders abortion statutes that require proof of pregnancy impossible to apply to the use of RU 486/PG except where the most sophisticated

pregnancy tests are used. Where, of course, accurate pregnancy tests can detect fertilization very early, a positive result would mean that RU 486/PG would be subject to the requirements of abortion legislation, if "pregnancy" is legally defined as beginning at the moment of conception or fertilization. If pregnancy legally begins at implantation, however, there would be no need to do a "pregnancy" test prior to implantation.

Statutes Requiring Only Intent to Terminate Pregnancy

Many countries have abortion laws that focus on the intent of the woman and the person performing the procedure, not whether the woman is in fact "pregnant" within the meaning of the law. Most of these laws descend from nineteenth-century French and English legislation.[39] As we have seen, Article 317 of the Penal Code of 1810 made it a crime to provoke the abortion of a "pregnant woman" (d'une femme enceinte) in France. But in 1939 the law was broadened to make criminal the acts of

> any person who causes or attempts to cause an abortion on a pregnant or supposedly pregnant woman, regardless of her consent, by means of food, beverages, prescriptions, manipulations, force or by any other means whatsoever. . . . (emphasis added) [40]

The law also made it a crime for a woman to induce or attempt to induce her own abortion. The Decree-law of 1939 expanded the reach of Article 317, making it criminal to employ any means whatsoever intended to induce an abortion. It was sufficient that a mere "belief" existed that the woman might be pregnant. For all intents and purposes the pregnancy of the woman was presumed, so no proof of pregnancy was required. Furthermore, it was unimportant whether an abortion actually occurred. The mere attempt was a criminal act.[41] Many of the African countries that were formerly French colonies, as well as others, have retained this restrictive abortion code introduced by the French.[42] In France, however, the abortion law was liberalized to allow abortion in the first trimester in 1975.

In the United Kingdom, abortion was liberalized with the passage of the Abortion Act of 1967, which permits abortion on wide health and social grounds. However, save for Barbados, Belize, Bermuda, Hong Kong, India, Singapore, the Seychelles, Zambia, Ghana and Zimbabwe, the new abortion law has not influenced the statutes of former British colonies.[43] The latter

continue to adhere to nineteenth-century statutes, many of which are patterned after the Offences Against the Person Act of 1861, which is similar in many respects to the restrictive French abortion law of 1939. The Offences Against the Person Act defined the crime of abortion as "unlawfully using any instrument or other means with the intent to procure the miscarriage of any woman," (emphasis added) with no specific exceptions for therapeutic abortion.[44] Additional gloss was put on the statutory language in colonial settings. For example, section 228 of the Nigerian Federal Criminal Code reads:

> Any person who, with intent to procure the miscarriage of a woman whether she is or is not with child, unlawfully administers to her or causes her to take any poison or other noxious thing of any kind, or uses any means whatsoever, is guilty of a felony.[45] (emphasis added)

Similar statutes are in force in Jamaica, Kenya, Tanzania, Trinidad and Tobago, and many other former British colonies.

At first glance, statutes that follow the intent only English or French models pose rather formidable barriers to the use of RU 486/PG because they forbid medical intervention regardless of actual pregnancy. However, criminal intent requires that the person using the medical procedure provide the service with the desire that an abortion result. If the doctor was treating the woman for other medical reasons, in theory s/he would not be culpable under the law.

A two-decades old English case involving the use of the IUD may square with the issues raised by RU 486/PG. (The post-coital insertion of an IUD ostensibly works the same as RU 486/PG --it creates a uterine environment that is inhospitable to implantation.) Sachs L.J. presented the basic question:

> Did the appellant at the time he inserted the [IUD] know or believe that the patient was pregnant and accordingly, introduce the instrument with intent to produce a miscarriage, or did he, as it was his case for defence, think that she was not pregnant and introduce it for the purpose of allaying anxieties on her behalf as regards her future.[46]

The woman in question in Price appeared to be in the second trimester of pregnancy, and Doctor Price was convicted. (His conviction was overturned on appeal on an unrelated point.) However, the question presented raises the possibility that early use of RU 486/PG could be detremined to have been taken to allay anxieties on behalf of a woman as regarding her future, and therefor not to be in contravention of abortion legislation.[4 46]

Prior to the US Supreme Court decisions legalizing abortion[47] several state courts had ruled that one could prove the defendant's state of mind by introducing evidence that the woman sought a physician for the purpose of abortion, and that even though she was subsequently shown not to have been pregnant, the defendant had performed an act that was designed to terminate pregnancy. Such rulings were similar to those followed by French courts before liberalization of abortion law there, where the presumption of pregnancy and a correlating attempt to perform an abortion were punishable even though totally ineffective means were used.

The issue of intent is resolved on the basis of the facts of each case. We can speculate about what would happen under these "intent" type statutes if a woman sought medical advice immediately upon missing her menstrual period and her doctor induced a menses using RU 486/PG. Whether the law has been violated depends on which of four basic situations is found to have existed: (1) If at the time that RU 486/PG was administered, the doctor only intended to medically resolve the problem of delayed menses, or some other medical problem, and not to terminate a pregnancy, then the law has not been violated; (2) If the woman being treated for a menstrual delay had in fact conceived and the doctor knew it, whether a violation has occurred may depend on the defintion of "pregnancy" employed; (3) If the doctor possesses the intent to abort but does not succeed because there was in fact no pregnancy, such attempted non-abortion appears to be punishable; and (4) If the woman was indeed pregnant (post-implantation) and the doctor intended to terminate her pregnancy, then a violation of criminal abortion law has, barring application of an exception to the abortion law, taken place. Finally, we note that it has long been an established rule of jurisprudence in Civil Law jurisdictions that a doctor who knowingly interrupts a pregnancy while providing other treatment is not guilty of abortion because the intent to abort was lacking.[48]

RU 486/PG and Traditional Islamic Law

Islamic countries commonly tend to outlaw abortion under statutes inherited from colonial systems, like that of Mauritania, that state "[w]hoever, by means of food, drink, medication, ploy, violence or any other means procures or tries to procure the abortion of a woman pregnant or supposed to be pregnant, whether or not she has consented thereto, will be punished.

(emphasis added).[49] The Mauritania law also punishes the woman for procuring abortion upon herself, but the sentence is less harsh.[49] No exceptions to this law are stated.

Though abortion laws in the Islamic countries are generally considered restrictive, the principles of traditional Moslem law itself may have a greater impact on the legal availability of RU 486/PG in some Islamic countries. The traditional Moslem view is that abortion is not a socially repugnant act until after "quickening" takes place. In December 1964, the Grand Mufti of Jordan stated that it is permissible to take medicine to interrupt a pregnancy so long as the "embryo is not formed in human shape (a period defined as up to 120 days from the LMP)".[4] Islamic law forbids the killing of the soul, but the traditional position is that the soul is not created until the fetus has taken human shape.[4] For instance, Iran has a detailed system for payment of the "diyat", a penalty or fine, to the family or individual by a person "for causing miscarriage." Section 194 of the Iran Islamic Penal Code provides:

> The *diyat* for causing a miscarriage shall be as follows:
>
> 1. The *diyat* for the sperm that has settled in the womb: twenty Dinars.
> 2. The *diyat* for a clot (*'alaqah*) which has formed into blood: forty Dinars.
> 3. The *diyat* for a shapeless lump (or tissue, *mudghah*) which has formed into flesh: sixty Dinars.
> 4. The *diyat* for a foetus in a stage when it has formed into a bone but no flesh has grown on it: eighty Dinars.
> 5. The *diyat* for a foetus whose form of flesh and bones has been complete, but who has no soul (or Life): one hundred Dinars.
> 6. For a foetus in whom soul is produced (or who is animate), in case it is a boy (or male) its *diyat* shall be full, and if it is a girl (or female) its diyat shall be half of a full *diyat*.[50]

Section 200 of the Penal Code adds: "There shall be no criminal punishment (*kaftarah*) for a miscarriage prior to the period the foetus becomes animate. There shall, however, be criminal penalty as well as a full *diyat* subsequent to its becoming animate.[50] Under the Iranian Penal Code, then, the concept of ensoulment as described by the Grand Mufti of Jordan is incorporated into the *diyat* scheme at the sixth level, where the full *diyat* for the taking of human life is available. (Under Iranian law, the penalty for taking the life of a woman is half that for taking the life of a man.) Similarly, criminal punishment, the more serious penalty, is only exacted after

ensoulment. Ensoulment is parenthetically defined as life, reflecting the traditional belief that prior to ensoulment there is no human "life." Though it is not all that easy to fit the use of RU 486/PG neatly into the time frame delineated by the Iranian code, it appears that abortion legislation in Iran could tolerate the use of RU 486, albeit with a "fine" for its use.

Conclusion

RU 486/PG will not end the abortion debate, vociferous as it is. It does, though, make an important contribution to reproductive technology. Labelling RU 486 the "death pill" threatens to curtail the availability of this important method that offers some women a new method for managing their reproductive health. The WHO estimates that somewhere between 200,000 and 350,000 women die annually due to complications of illegal abortion.[51] The addition of another safe, legal, alternative could save many lives.

On the other hand, promoting widespread access to RU 486/PG as the answer to the abortion debate might also threaten women's health. Many questions remain as to the safety and efficacy of RU 486/PG if it is not used with strict adherence to the French manufacturer's protocol. What prospect for access to RU 486/PG exists in countries where sophisticated medical services, including the recommended access to a physician, are unavailable? Should RU 486/PG be made available without medical supervision? What chance of safeguards can be expected as long as RU 486/PG remains officially unavailable in most of the world's countries, and it trickles into the black market? What of the woman that takes RU 486/PG later in gestation than the recommended eight week limit? What of the woman (and her fetus) that fails to undergo surgical abortion in the event that RU 486/PG fails? How does the RU 486 /PG therapy compare with other early techniques for interrupting pregnancy, like menstrual regulation? These questions lend themselves not to immediate answer, but to further thought, research and discussion.[52] As access to RU 486/PG expands, as it is bound to do, the necessity for dispassionate education of health and legal professionals, as well as the general public, becomes increasingly urgent.

Research continues in the hope of discovering a "one step" process allowing a woman to take RU 486 and a time-release dose of prostaglandin together or, similarly, in finding an effective orally administered prostaglandin. Theoretically, both would allow a woman to

administer the regimen to herself in the privacy of her home, then go for a checkup after the process is complete. Important issues arise in the context of such a developments, however. First, though either option would arguably enhance the accessibility of RU 486/PG for women in the developing world, where it is often very difficult to get to a doctor or clinic, the physician-based process used in France ensures, and we would say correctly, that the woman is under medical supervision when bleeding is expected to be most heavy, when complications are likely to present themselves, and when expert opinion is needed to ascertain that the therapy has been successfully completed. The second issue arises from the first: Roussel Uclaf will distribute RU 486 only to countries that are equipped to administer it according to the manufacturer's protocol, those that have liberal abortion laws like that of France. In the developing world India, Liberia, Turkey and Zambia are likely candidates. Yet, the reasons a self-administered or one-step process would be of particular benefit to women in most developing countries are precisely the same reasons–lack of medical supervision--why those countries are less likely to have legal access to RU 486.

The introduction of RU 486/PG may precipitate moves to resolve some of the issues they raise in relation to abortion legislation. Four basic approaches can be anticipated. First, one can expect that the major trend will be to accommodate the technology within the law on abortion itself. Approximately 63% of the world's population live in countries with relatively liberal abortion legislation. If one were aiming to make RU 486/PG as widely available as possible, the place to begin would be in these countries. This, in fact, is the marketing strategy of Roussel Uclaf. In most of these settings, the fact that the law has the capacity to accommodate RU 486/PG will not be as important as the impact of the politics of abortion on the decision whether to approve its use.

The second approach is to liberalize the narrow, restrictive abortion statutes in place in many countries, because, as appealing and practical as it may be to focus on the liberal legal settings, the real challenge will be to consider whether to make this technology available in countries where abortion practice is legally restricted. It is in these countries, most of which are in the developing world, where the introduction of RU 486/PG (and other modern methods of

abortion) could have the largest impact on the health of women, as major portions of maternal mortality there can be traced to the practice of illegal, unsafe abortion. It is also in these countries where it is least likely that RU 486/PG can be legally introduced, raising the question of whether it will be necessary to liberalize abortion laws before RU 486/PG can be accommodated. (Most of the more restrictive laws accept the interruption of pregnancy for a narrow set of reasons, usually including threat to the life of the mother or pregnancy resulting from rape or incest. The possibility exists that RU 486/PG could be allowed for use as an abortifacient in these narrow instances.) Reform is one way to ensure that the law will be receptive to RU 486/PG but, as we have shown, a liberalized abortion law is no guarantee that RU 486/PG will be made available. Most countries with restrictive abortion laws--many of which are in Latin America and Africa-- have steadfastly refused to seriously discuss the liberalization of those laws (though the advent of RU 486/PG may provide impetus for renewed discussion about the need for reform). And, if one is thinking of expediency, legal reform is the long way around despite the large number of countries that have liberalized their abortion laws in the last 20 years. So, legal reform itself is a tactic that is unlikely to produce much immediate result.

That brings us to the third approach. As we have shown, because of the ambiguous language employed in many abortion statutes, often coupled with rather stringent proof requirements (particularly in many Latin American countries) the use of RU 486/PG prior to implantation would arguably not be abortion under many restrictive abortion laws. This approach, as appealing as it might be, is a very technical, legal, one, and therefore may also have limited application. It may, however, create some space for the use of RU 486/PG just as it has for menstrual regulation in some jurisdictions.

Fourth, some countries have explicitly defined the IUD as a contraceptive, thereby exempting it from abortion laws. Because RU 486/PG is, like the IUD, designed for very early use, it too could be treated as a contraceptive and be exempted from abortion law. Yet due to the French initiative, questions about the abortifacient properties of RU 486/PG are likely to linger. Still, the Bangladesh experience shows that even a country with restrictive abortion laws can accommodate methods of menstrual regulation without confronting the penal law on abortion.[53] In

Bangladesh menstrual regulation is part of the national family planning program and is widely available at health facilities. There "menstrual regulation is now recognized as an interim method of establishing non-pregnancy for the woman who is at risk of being pregnant. Whether or not she is in fact pregnant is no longer an issue" according to the legal opinion that authorized the use of menstrual regulation.[54] Were this approach more widely adopted, RU 486/PG could be accommodated without resort to legal reform. However, authorities in Bangladesh have apparently begun to weigh whether RU 486/PG can be made available under the menstrual regulation rubric, and seem to be leaning toward disallowing the procedure because of "limited health service capacities, strong personal, social and cultural taboos associated with bleeding patterns, and the several clinic visits required" by the RU 486/PG regimen.[55]

Finally, the Bangladesh example illustrates a long nagging issue of reproductive jurisprudence which arises yet again in the context of RU 486/PG: Should the law be called upon to weigh in with criminal sanctions in areas of fine medical distinction so well illustrated by the physiology of the reproductive process? We believe the answer is "no" for several reasons. First, issues of reproductive health are a complicated mix of medical, cultural, social and personal elements, and simply do not lend themselves to the relatively rigid framework of criminal law. Second, as the legislative examples cited throughout this article show, the criminal law is ill equipped to keep pace with an ever evolving field of medicine such as fertility control. Finally, and perhaps of the greatest importance, the intent of criminalizing certain fertility control measures has never been realized. As the experience of Brazil and other countries with restrictive abortion laws illustrate, abortion rates are virtually unaffected (and may even go up) in jurisdictions where abortion is criminalized. There is, however, a very positive role for the law to play in the area of fertility control technology regulation. In this arena the law can and must lead the way toward ensuring the safety and efficacy of fertility control technologies as they are developed and introduced. As the example of RU 486/PG reveals, those technologies that hold the greatest hope of advancing women's ability to control their fertility in a safe and effective manner require particularly close supervision and regulation.

ENDNOTES

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29. Penal Code art. 392.

30. Penal Code art. 312. *See also* Penal Code of Pakistan sec. 312.

31. Penal Code art. 85.

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36. Similarly, the Constitution of Ecuador declares in Article 25: "The child will be protected from conception." Ecuador, however, also guarantees constitutional support for the family (Art. 22) and guarantees to all individuals the rights enunciated in all other laws, national and international (Article 44). The argument persists, therefore, that when the protection of the child from conception is balanced against the life or health of the mother, protection of the fetus might give way. Such niceties of argument, however, probably have little effect on the future of RU 486 in these jurisdictions unless pregnancy is deemed to begin after implantation, an argument harder to make when protection is stated as beginning at conception.

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38. These include the Congo, Ivory Coast, Haiti, Chad and Mali. In Mali it is a crime to "employ any means or substance for the purpose of provoking the premature expulsion of the foetus" on a woman who is "pregnant" at the "moment expulsion takes place." Penal Code, art. 170.

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44. The no-exception aspect of the Offences Against the Person Act as softened in England formed the foundation upon which rests the generally accepted legality of the defense of therapeutic abortion in the United Kingdom, and hence in former British colonies. *R. v. Edgal*, (1948) 4 W.A.C.A. 133 (Nigeria), citing *Bourne* (1939) K. B. 687; (1938) 3 A11

E.R. 615. The precedent is followed to a lesser extent in Britain's former colonies, however.

45. The Criminal Code Act, Act. no. 15 of 1916, as amended in 1964.

46. R. v. Price, (1969) 1 Q.B. 544 (1968) 2 All E.R. 283 (C.A.).

47. *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton*, 410 U.S. 170 (1973).

48. Cour de Cassation Francaise, Cass, 27 June 1806 (Napoleonic Code, Article 2).

49. Code Penal (Ordinance No. 83-162) 9 July 1983 (Journal Officiel de la Republique Islamique de Mauritanie, Nos. 608-609, 29 Feb. 19844 at 112.) *Reprinted in* Ann. Rev. Pop. Law; June 1988; 12(app. 240):317.

50. Islamic Penal Code, Diyat Section. 15 Dec. 1982. (*Official Gazette*, no. 11030, 1 Dec. 1982. Translated in *Islamic Penal Code of Iran*, Islamabad, Pakistan, Iran Pakistan Institute of Persian Studies (1986).

51. Mahler, H. 1987: The safe motherhood initiative: a call to action! Lancet i: 668.; Royston, E; Armstrong, S. eds. preventing maternal deaths Geneva: World Health Organization (1987).

52. For a provocative critique of RU 486/PG and some of these unanswered questions, see Raymond JG, Klein, R., Dumble, LJ: RU 486 - misconceptions, myths and morals. Cambridge: Institute on Women and Technology (1991).

53. Dixon-Mueller, R: Innovations in reproductive health care: Menstrual regulation policies and programs in Bangladesh. Studies in Family Planning, 1988; 19(3):129-140.

54. Tietze, C, Henshaw, SK: Induced abortion: a world review. 6th ed. New York: Alan Guttmacher Institute (1986) at 14.

55. Abortion Research Notes Dec. 1991 20 (3-4):2

American Life League, Inc.
National Headquarters: P.O. Box 1350, Stafford, VA 22554
(703) 659-4171 • Metro D.C. 690-2049 • Fax (703) 659-2586

July 15, 1992

David A. Kessler, M.D., Ph.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler,

We staunchly defend the Import Alert for RU-486 currently on appeal from the ill-conceived and illogical District Court order that RU-486 must be released to Ms. Leona Benten.

In his ruling, Federal District Court Judge Charles P. Sifton contends that the RU-486 was seized illegally from Ms. Benten because the FDA issued its Import Alert for RU-486 but did not provide for published notice and comment in the Federal Register.

But, if the FDA does not have the authority to issue an Import Alert unless there is a published notice and comment (or an FDA statement accompanying the alert saying why notice is not needed), the RU-486 pills still should not be released because Federal law states at 21 USC 381 (A)(3) that no new unapproved drug may be imported into the United States.

The FDA has issued many Import Alert orders without public notice and comment (including the original Personal Importation Policy). If public notice and comment must precede the publishing of Import Alerts, how will the FDA be able to protect the American public from dangerous foods and drugs imported from overseas?

In order to procure their novel, chemical abortions, Judge Sifton, the Abortion Rights Mobilization and the Center for Reproductive Law and Policy appear to have no problem with virtually abolishing the present ability of the FDA to protect the American public from importation of harmful foods and drugs.

9205600

Will the FDA be forced to reissue all of its Import Alerts on harmful foods and drugs since the initiation of the Personal Import Policy, or perhaps even before? A very real danger exists that unless you defend the FDA's RU-486 ban, some women will seek to obtain RU-486 through the mail with frightful medical and moral consequences.

Judge Sifton's peculiar order represents a real threat to the health and well-being of all Americans.

Sincerely,

(Mrs.) Judie Brown, President
American Life League

APPEARS THIS WAY
ON ORIGINAL

national RIGHT TO LIFE committee, inc.

Suite 500, 419 7th Street, N.W.
Washington, D.C. 20004-2293 — (202) 626-8800 (FAX) 737-0189 or 347-3668

To: Interested Parties

From: Douglas Johnson, NRLC Legislative Director
(202) 626-8820, fax (202) 347-3668

Re: Bogus *ABC News* Report on Administration Position on RU 486 Breast Cancer Research

Date: October 8, 1992

ABC NEWS CLAIM

The Oct. 8 edition of the *New England Journal of Medicine* contains a report on a study that purports to show that the French abortion pill, RU 486, has been proven useful as a "morning-after pill." The same issue contained an editorial by Dr. David Grimes, criticizing the Bush Administration for not creating a "receptive climate" for RU 486 to be marketed in the U.S.[1]

The October 7 *ABC Evening News* carried a report on the article by *ABC News* medical correspondent Dr. Timothy Johnson, who concluded with this statement:

> The Bush Administration has been openly hostile to further research with RU 486, *even for non-reproductive uses, such as breast cancer treatment.* But Dr. Grimes and other experts say that a new Administration, and a new political climate, could open the doors previously closed to RU 486 in this country. [emphasis added]

There is no factual basis for Johnson's statement that the Bush Administration is hostile to research on RU 486 for purposes unrelated to reproduction, such as breast cancer.

THE F.D.A. POSITION

Human studies on unapproved drugs are the province of the FDA, which receives applications for "Investigatory New Drug" permits and grants those applications that meet statutory standards for safety. There is no evidence, or even an allegation as far as we know, that the FDA has disapproved any research applications on RU 486. In a May 15, 1991 memo, the FDA's Director of the Division of Metabolism and Endocrine Drug Products stated, "This Division currently has 10 'active' IND's for RU 486."

THE N.I.H. POSITION

Moreover, the National Institutes of Health has itself conducted studies on RU 486 for purposes other than abortion. In an appearance before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, on April 15, 1991, N.I.H. Director Dr. Bernadine Healy testified:

(continued)

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> It is my understanding that NIH has complete freedom to do research on RU 486 that does not involve its use as an abortifacient. And in fact, some of the research is extremely promising. For example, RU 486 in a low dose has been treating endometriosis, which in fact is a cause of infertility in in many women, such as women who delay childbearing. Its use in endometrial cancer. Its use in certain hormonal problems, such as Cushing's disease. *NIH has not banned, or is it restricted, from pursuing this investigation.* [emphasis added]

THE F.D.A. "IMPORT ALERT" AND THE A.M.A. POSITION

If challenged, *ABC News* may cite as evidence of Administration "hostility" to RU 486 research, the 1989 FDA action placing the drug on the "import alert" list. Congressman Wyden and other pro-abortion polemicists have persuaded some careless journalists that the FDA's "import alert" on RU 486 somehow prevents researchers from obtaining the drug.

There is no factual basis for this claim. The "import alert" merely advises customs agents to prevent private citizens-- not researchers-- from bringing RU 486 into the country for "personal use." The "import alert" in no way applies to researchers who have received IND permits from the FDA.

The American Medical Association, which supports the testing of RU 486 for abortion and for other purposes, also strongly supports the FDA "import alert." The AMA testified in support of the import alert at a 1990 hearing chaired by Rep. Wyden:

> Rumors exist that the FDA, due to political pressure, is standing in the way of research on RU 486. We do not believe this to be true. On the contrary, it is the FDA's responsibility to ban a drug that has not met legal and regulatory requirements for importation into the United States... From our understanding of the current situation, the FDA has acted responsibly in issuing import restrictions for RU 486.[2]

THE POLICY OF ROUSSEL UCLAF

Some pro-abortion sources have alleged that the manufacturer of RU 486, the French company Roussel Uclaf, refuses to make the drug available to researchers in the U.S. because of the "hostility" of the Bush Administration. This claim, too, is a distortion.

Because of pro-life strength in the U.S., including a pro-life President, Roussel Uclaf chooses not to make the drug available in the U.S. for research on abortion-- which is a prudent corporate decision, in view of the threat of product boycotts by religious and pro-life groups representing millions of citizens.

However, the National Right to Life Committee has consistently stated that it is not opposed to research on RU 486 for purposes unrelated to abortion, such as breast cancer. We are aware of no other pro-life group that has expressed opposition to RU 486 research unrelated to abortion.

(continued)

Moreover, Roussel has repeatedly stated its willingness to supply U.S. researchers with RU 486 for appropriate studies on applications unrelated to abortion.

Roussel's director of clinical research, Dr. Andre Ulmann, denies that the company had interrupted any U.S. non-abortion research because of the import ban. He said that Roussel does not approve all "individual demands made by doctors who proposed to do trials," but does provide the drug for studies involving what it regards as suitable protocols (*Le Figaro*, November 28, 1990).

Roussel's international marketing director, Ariel Mouttet, said in *Nature* (Nov. 29, 1990), "so long as the protocol appears interesting to our scientific committee and fits into with our own developments, we will supply the drug."

At the December 6, 1991 "Antiprogestin Drugs" conference, Dr. Ulmann reiterated Roussel's policy:

> We are funding, or we are providing, investigators with RU 486 for various indications, which include meningioma, Cushing's Syndrome, endometriosis, some physiological studies. So we have a lot of studies for which either we provide the drug, or we provide funding. *So it is not wise to say that we do not do studies in the United States. It is not true.* [emphasis added]

In December, 1991, Roussel decided to begin clinical studies on RU 486 as a breast cancer treatment in Canada. In a December 10, 1991 *Washington Post* article, Ariel Mouttet, Roussel Uclaf's director of marketing for hormonal drugs, stated that "the decision to work with the National Cancer Institute of Canada, rather than with an American institution, had 'nothing to do with the abortion issue.'"

---

[1] Dr. Grimes was connected with the abortion surveillance office at the Centers for Disease Control during the 1980s. He left under pressure, related in part to the revelation that he was (as Dr. C. Everett Koop put it) "moonlighting" doing late-term abortions at an Atlanta abortion clinic.

[2] "RE RU 486," Statement of the American Medical Association to the Subcommittee on Regulation, House Committee on Small Business, November 19, 1990.

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Statement of the American Medical Association

to the

Subcommittee on Regulation, Business Opportunities, and Energy

Committee on Small Business

U.S. House of Representatives

Presented by:
P. John Seward, M.D.

RE: RU 486

November 19, 1990

American Medical Association
515 N. State Street
Chicago, Illinois 60610

Department of Federal Legislation
Division of Legislative Activities
(312) 464-4775

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Regulation, Business Opportunities, and Energy

Committee on Small Business

U.S. House of Representatives

Presented by:
P. John Seward, M.D.

RE: RU 486

November 19, 1990

Mr. Chairman and Members of the Subcommittee:

My name is P. John Seward, M.D., and I am a physician in family practice in Rockford, Illinois. I also am a member of the Board of Trustees of the American Medical Association. Accompanying me is Dave Heidorn of the Association's Division of Legislative Activities. The AMA appreciates this opportunity to appear today to discuss the issue of RU 486 availability in the United States.

In the Subcommittee's letter of invitation to appear, you asked that the AMA respond to a number of special questions regarding the drug. In addressing those inquiries, I want there to be a clear understanding of the AMA's policy regarding RU 486 and what we believe to be the current legal status of that drug within the United States.

At its June 1990 meeting, the AMA's House of Delegates adopted the following resolution:

> RESOLVED, That the American Medical Association support the legal availability of RU 486 for appropriate research and, if indicated, clinical practice.

The reason that the Association took this position was our very real concern that politics or ideology could interfere with a well established, legal decision-making process that is and must always be based on good science and proper medical practice, nothing more.

As you well know, RU 486, or mifepristone, which is a steroidal agent being used as an early abortifacient in some countries, has raised deep feelings among both the proponents and opponents of abortion and the prospective use of RU 486 in the United States. It is the AMA's position that any governmental decision regarding this drug, as with all other drugs, must not be influenced by political debates or social issues such as this one. This must not be taken to mean that the AMA supports the widespread availability of RU 486. We do not believe that there has been adequate research to establish that this drug is a safe and effective therapeutic modality. In fact, the central difficulty in evaluating this drug is that no research is being conducted in the United States to determine whether RU 486 has a role in medical practice, and the reason no research is going forward is its manufacturer's decision not to pursue clinical testing of the drug here.

As we understand the current situation, no Investigational New Drug (IND) applications (the legal precondition for a drug to be transported in interstate commerce for the purpose of clinical research) either are pending or have been approved by the Food and Drug Administration (FDA) for RU 486. Since the Federal Food, Drug and Cosmetic Act requires that a drug be proven safe and effective for its intended purpose through well controlled clinical investigations, there is no basis for approval of a New Drug Application to allow the drug to be marketed. Therefore, no

legal basis exists for this drug to be used in the United States for research or in marketing.

The only other basis for allowing importation of RU 486 would be for individual compassionate use. However, it is the AMA's understanding that RU 486 poses a severe risk to patients unless the drug is administered as part of a complete treatment plan under the supervision of a physician. During an appropriate course of treatment with the drug, it is common that three or four visits to a physician are necessary to avoid hemorrhaging and to ensure that a complete abortion has taken place. It also must be taken with a prostaglandin to increase the probability that a complete abortion occurs. Clearly, the importation of RU 486 for personal compassionate use would not be medically desirable given alternative available care methodologies.

These difficulties do not mean that research on RU 486 should not be conducted. On the contrary, we believe that if this drug can be shown to be a safe and effective medical treatment, it should be available for the appropriate care and treatment of patients. There has been some published conjecture that RU 486 may be an effective treatment for other indications besides its use as a contraceptive or abortifacient, including treatment of breast cancer, gynecological malignancies, glaucoma, infertility, and labor induction. While we do not believe this conjecture to be based on any substantiated tests of the drug, RU 486's application to these conditions is certainly possible, although adequate drugs for these conditions already exist. It may even be possible that this drug is useful in treatments about which we have no current knowledge. No one, at this time, can say.

The only way to make these determinations and to establish the safety and efficacy of RU 486, as all other drugs, is to conduct the necessary research and clinical trials required by the FDA to market drugs in the United States. This is a highly effective process established to protect the health, safety, and welfare of the American people. For the same reasons drugs proven to be safe and effective should not be kept out of the United States for political reasons, so also should the high standards we have for drugs not be contravened for political purposes.

Rumors exist that the FDA, due to political pressure, is standing in the way of research on RU 486. We do not believe this to be true. On the contrary, it is the FDA's responsibility to ban a drug that has not met legal and regulatory requirements for importation into the United States. Because RU 486 has not met these requirements, the FDA complied with its charge and acted well within its authority in issuing its June 9, 1989, automatic detention import alert concerning the drug.

As we understand the situation, the actual impediment to research on RU 486 is the manufacturer's unwillingness to make the drug available in the United States. Without the drug, it is impossible to apply for an IND. The manufacturer is reportedly unwilling to allow clinical testing in the United States because of its concerns over the political controversy that has followed this drug and is sure to intensify if research begins in this country. While the French government compelled the French manufacturer to make the drug available in that country, we do not believe that this is a problem that can be easily addressed under our current law.

Conclusion

The AMA stands by the FDA's appropriate application of its legal responsibilities in protecting the health and well being of the American people from unsafe drugs. From our understanding of the current situation, the FDA has acted responsibly in issuing import restrictions for RU 486. At the same time, we would expect that, if an acceptable IND is submitted, the IND would be approved and importation allowed. We hope that the drug can be made available and research eventually can be conducted in this country to determine if the drug is safe and effective for its known uses and whether its use may be appropriate for other medical treatments. It is our primary concern that patients have every opportunity to receive the best possible medical treatment. When possible research into drug therapies does not occur, for whatever reason, the likelihood that the best possible care will not someday be available is greatly increased.

Frankly, we have no answer for this Subcommittee on how to ensure that all appropriate research occurs. Under our current system, which is the world's standard for the development of drugs, the manufacturer is well within its rights to hold the drug from distribution. We can only hope that the political climate will somehow not influence any future consideration of the introduction of RU 486 into the United States.

4239s

national RIGHT TO LIFE committee, inc.

Suite 500, 419 7th Street, N.W.
Washington, D.C. 20004-2293 (202) 626-8800 (FAX) 737-9189 or 347-3668

To: Interested Parties

From: Douglas Johnson, NRLC Legislative Director
(202) 626-8820, fax (202) 347-3668

Re: New claims by Rep. Wyden regarding purported Administration disinterest in breast cancer research on RU 486

Date: October 8, 1992, 1 p.m.

This is a followup to the memo I faxed around this morning regarding the Oct. 7 *ABC News* report on RU 486.

I am faxing herewith a press release put out today by Congressman Wyden, who claims to have a communication from Roussel Uclaf stating that Roussel offered the National Cancer Institute the first opportunity to do a big breast cancer study with RU 486, but that NCI "did not want to be immediately involved in this study." The study subsequently was taken on by the National Cancer Institute of Canada.

We have no knowledge of whether the U.S. National Cancer Institute in fact turned down the study, or if so, why. However, as noted in my earlier memo, there is nothing in NIH policy or other Administration policy to discourage pursuit of such a study.

Also, Roussel said in December, 1991, that "the decision to work with the National Cancer Institute of Canada, rather than with an American institution, had 'nothing to do with the abortion issue'." (December 10, 1991, *Washington Post*.

#######

APPEARS THIS WAY
ON ORIGINAL

News From Congressman RON WYDEN

THIRD DISTRICT OREGON

2452 Rayburn House Office Building • Washington • DC • 20515 • (202) 225-4811

FOR IMMEDIATE RELEASE
OCTOBER 8, 1992

CONTACT: WENDY MORWITZ
(202)225-4811
ANDREA CAMP
(202)225-4431

WYDEN, SCHROEDER SAY NEW DOCUMENTS SHOW NIH TURNED DOWN OPPORTUNITY TO TEST RU 486 TO FIGHT BREAST CANCER

LEGISLATORS INTRODUCE BILL TO FORCE COMPREHENSIVE RESEARCH AND TESTING OF CONTROVERSIAL FRENCH DRUG

WASHINGTON, D.C. -- Oregon Congressman Ron Wyden and Colorado Congresswoman Patricia Schroeder today said they have obtained documents showing the National Institutes of Health denied a major breast cancer research trial using RU 486, even though agency researchers said the drug held promise for fighting breast cancer. In addition, Wyden and Schroeder said the agency's claim that U.S. researchers are disinterested in this drug's potential for fighting breast cancer is simply false.

The two members of Congress said the major research trial went to Canada instead of our National Cancer Institute (NCI) even though the French manufacturer of RU 486, Roussel Uclaf, offered the Institute the opportunity for the research trial.

In a January 10, 1992 letter from Dr. Edouard Sakis of Roussel Uclaf to Dr. E.E. Drew of Hoechst Celanese Corporation, Sakis said "Roussel Uclaf contacted the NCI with the project to make a study on breast cancer. The American NCI having other promising compounds to be tested did not want to be immediately involved in this study." Subsequently, the breast cancer trial went to Canada.

At about the same time, according to NCI documents, federal researchers stated, "theoretically, progesterone-receptor positive breast cancer should respond to an antiprogestin," the RU 486 category of drugs. "This concept," said the researchers, "has been supported by limited clinical trials, and is currently being tested in larger trials."

In addition, NCI officials have said that cancer researchers have shown little interest in using the drug in tests to fight breast cancer. Specifically, in the September 4, 1992 edition of The Cancer Letter, Dr. Michael Friedman, Director of the Division of Cancer Treatments Therapy Program at NCI said, "We have not received any mailings from our grantees on RU 486 in breast cancer. The investigative community on their own has not put in any requests for trials."

Wyden noted, however, that in communications with his Subcommittee on Regulation and Business Opportunities, research interest had been demonstrated by clinicians at the Memorial Sloan Kettering Cancer Center in New York, the Lombardi Cancer Center in Washington, D.C., and the Virginia Commonwealth Medical School in Richmond, Virginia.

In sworn testimony before the Subcommittee, Dr. William Regelson of the Medical College of Virginia said that an early, limited trial with breast cancer patients in France yielded real promise.

"There was a significant clinical response in this population of advanced breast cancer patients...We need to find the means of getting this drug out into the clinic for testing," said Regelson.

In the face of continuing reluctance by the NIH to thoroughly test the drug, Wyden and Schroeder said they are "forced to conclude that the only way to break the political logjam is through legislation which requires these trials." The two legislators introduced legislation on Monday mandating comprehensive testing by the Federal government of anti-progestin drugs including RU 486.

The bill, H.R. 6178, requires the Department of Health and Human Services to obtain RU 486, evaluate it for its safety and effectiveness in government-sponsored clinical trials as both an abortifacient and for treating other illnesses and conditions. Under the legislation, results of these tests would have to reported publicly annually. These tests are especially important given the new evidence reported in this week's New England Journal of Medicine indicating a recent study in Scotland showing that RU 486 to have considerable promise as a "morning after" pill.

The legislation follows a series of congressional hearings chaired by Wyden, investigating actions by the Bush Administration to keep the abortion-inducing drug out of the United States. The hearings found that in substantial clinical use in Europe, RU 486 was a safe and effective alternative to surgical abortion.

Additionally, the drug shows promise as a treatment for a variety of other illnesses and conditions ranging from brain cancer to endometriosis. U.S. scientists, however, have complained that the Administration's anti-abortion stance effectively has dried up opportunities for research in the United States using the unapproved drug.

In an October 2, 1992 letter to Wyden, Dr. Bruce A. Chabner, Director of Cancer Treatment at NCI, contended that small foreign research trials using RU 486 against breast cancer had shown limited potential. Chabner also said that Roussel Uclaf had been invited to an October 19th NIH meeting to discuss RU 486 in breast cancer trials.

# # #

WISDOM MATURITY EXPERIENCE

DU PAGE SENIOR CITIZENS COUNCIL

1 S 132 Summit Avenue, Suite #202 • Oakbrook Terrace, Illinois 60181-3940 • (708) 620-0804

November 4, 1992

Dr. David Kessler, Director
Federal Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Research and testing of RU486.

Dear Dr. Kessler:

The DuPage Senior Citizens Council supports efforts to ensure medical research and testing for use of RU486 on breast cancer and diseases relating to aging.

We are aware that lab studies show it affects several diseases, breast cancer, endometrioses, prostate cancer, brain tumors, hypertension, and alzheimers to name a few.

Its anti-cortizone property is beneficial to patients with Cushings Disease and brain tumor.

This drug could ultimately be very beneficial to senior citizens in improving quality of life, and lengthening life.

It is essential that a climate of acceptance be achieved for increased research, testing, and ultimately availability and use of this life enhancing and life saving drug.

The Import Alert ban imposed on RU486 in 1989 by the Food and Drug Administration has had the effect of bringing research to a near stand still. Senate Bill 2268 and HR 875 are bills which would lift the ban. Please support improving the opportunities for research and testing.

Sincerely,

Joan Taylor

Joan Taylor
Executive Director

The same letter was sent to Senator Paul Simon, and Congressmen Dennis Hastert, Henry Hyde and Harris Fawell of Illinois.

9207511
9207511

MIF 003731

HARVARD UNIVERSITY

ALAN A. STONE, M.D.
PROFESSOR OF LAW AND PSYCHIATRY
IN THE FACULTY OF LAW AND
THE FACULTY OF MEDICINE

LANGDELL HALL
HARVARD LAW SCHOOL
CAMBRIDGE, MASS. 02138
617 495-3124

November 6, 1992

Dr. David Kessler
Commissioner, Food & Drug Administration
5600 Fisher's Lane
Room 2
Rockville, MD

Dear David:

My research assistant, _____, is writing her third-year paper (a requirement at Harvard akin to a thesis) on the legal issues surrounding the antiprogestin RV-486. Specifically, she is looking at the drug approval process and the restrictions on importation of unapproved drugs as they relate to this drug.

I would appreciate your sending me any materials that would help her in her research, including position-statements by FDA on RV-486, briefs from the Benten case, and any other articles of interest.

Thanks for your help.

Sincerely,

Alan

Alan A. Stone, M.D.

You are doing a great job.

9207612

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

January 21, 1993

Alan A. Stone, M.D.
Harvard University
Langdell Hall
Harvard Law School
Cambridge, MA 02138

Dear Alan:

Thank you for your letter of November 6, 1992, your note of support, and your follow-up note of January 6. Please excuse the long delay in responding.

I am enclosing materials that discuss the drug approval process and the RU-486 import restrictions. I am also enclosing copies of the court memoranda and related documents. These materials should be helpful to your research assistant.

It was good hearing from you, Alan. Very best wishes for the new year.

Sincerely yours,

David A. Kessler, M.D.
Commissioner of Food and Drugs

Enclosures

1/21/93
92070172

AJ Congress

American Jewish Congress
Stephen Wise Congress House
15 East 84th Street
New York, NY 10028-0458
212 360 1560 • Fax 212 249 3672

♀ Commission for Women's Equality ♀
Ann F. Lewis, Chair
Hanita Blumfield, Director

December 8, 1992

Commissioner David Kessler
United States Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

Dear Commissioner Kessler;

Enclosed are petitions gathered across the country by members of the Commission for Women's Equality of American Jewish Congress. In August I sent you a number of petitions. Our members feel strongly about this issue and have continued to circulate the petitions. The over 300 new signatories urge you, as I do, to test RU 486 in the United States to see if it is safe for widespread use. As you know, RU 486 is not only beneficial as a non-surgical alternative to abortion but may also have benefits for curing breast cancer and other types of diseases. How can you deny women the best health care available to them?

Although President-elect Clinton has already promised to approve testing of RU 486 soon after taking office, I am forwarding these petitions to emphasize to you and the new administration that women should have all available options when making health care decisions.

American Jewish Congress, a national social action organization with membership of over 50,000, has already passed a resolution supporting the testing and marketing of RU 486 and will continue to monitor the situation to ensure that progress is made in a timely manner.

Sincerely,

Dr. Hanita Blumfield

Dr. Hanita Blumfield

Enc.

92080911

A PETITION ON BEHALF OF WOMEN'S HEALTH

AMERICAN JEWISH CONGRESS
COMMISSION FOR WOMEN'S EQUALITY
15 East 84th Street
New York, New York 10028

To: Commissioner David Kessler
U.S. Food and Drug Administration
Washington, D.C.

The undersigned citizens believe that the French pharmaceutical, RU 486, is urgently needed in our country as a treatment for a wide variety of diseases and conditions.

It is unconsionable for our government to withold from the people of this country a drug that is a safe, non-invasive, and effective abortifacent, as well as a known cure for Cushing's Syndrome...and a possible treatment for endometriosis, for complications associated with childbirth, and for as many as 40 percent of known breast cancers.

Therefore, we ask you to fulfill your duty to provide the best health care possible to all Americans by doing everything in your power to bring RU 486 to this country.

Name	Address	City, State, Zip

NATIONAL CATHOLIC PRO-LIFE PROGRAM
Our Lady's Chapel, Inc.
P.O. Box 2065 65 Walden Street
New Bedford, MA 02741-2065
(508) 992-7357 FAX (508) 992-7357

December 18, 1992

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear [redacted]

We are interested in learning why the FDA is interested in aborting Unborn Babies by supporting RU-486, a antiprogestin that prevents a fertilized egg from attaching to the uterine wall of the Host-Mother.

Why should the Taxpayers - especially the 58 Million Catholics - many who pay Federal Taxes to support the Budget at FDA - support with their dollars a Drug which aborts potential babies - one of which could become a future U.S. Senator - President of the United States, etc., etc., etc., if this drug is allowed to be sold in America someday.

Copies of this correspondence will be sent to members of the U.S. Congress for their interest in it and to the Governor of Arkansas - Bill Clinton - President-Elect - United States of America.

We request an early response to this letter of correspondence between us.

Faithfully in the Sacred Name - JESUS CHRIST,

Bro Ronald A.J. DeMello, OR NRS

Bro. Ronald A.J. DeMello, OR, NRS
National Pro-Life President
Servant of GOD

RAJD/dal
cc: Governor Bill Clinton
David Kessler, Commissioner
Rep. Jamie L. Whitten, D-Miss.
Chairman, Sub-Committee
Sen. Quentin N. Burdick, D-N. Dakota
Chairman, Sub-Committee
Files

9208287

PRO-LIFE REPRESENTS GOD - Pro-Choice Represents Evil

MIF 003736

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CMKUN
9208287

February 2, 1993

Bro. Ronald A. J. DeMello, OR, NRS
National Pro-Life President
National Catholic Pro-Life Program
Our Lady's Chapel, Inc.
Post Office Box 2065, 65 Walden Street
New Bedford, Massachusetts 02741-2065

Dear Brother DeMello:

This is in response to your letter of December 18, 1992, regarding the drug RU-486 (mifepristone). We appreciate your writing to let us know of your concerns related to the possible marketing of RU-486 in this country.

As you may know, the new administration has taken steps to study the issues surrounding RU-486. As we are a part of the Executive Branch, we will be a participant in this evaluation. In addition, by law, we are required to review a marketing application for a new drug, if one is submitted to us, based on its scientific merits.

We appreciate hearing your concerns, and we hope you understand our legal responsibilities in this regard. Thank you for taking the time to write and to express your views on this issue.

Sincerely yours,

Carol R. Scheman

Carol R. Scheman
Deputy Commissioner
for External Affairs

9208287

MIF 003737

pharmacists planning service inc.

200 GATE FIVE ROAD P.O. BOX 1336 SAUSALITO, CA 94966 (415) 332-4066

December 29, 1992

David Kessler, M.D., J.D.
Commissioner, FDA
5600 Fishers Lane
Rockville, MD 20857

RE: RU 486

Dear Dr. Kessler:

Enclosed please find November 8, 1989 letter from FDA's Division of Federal-State Relations regarding PPSI's request to have the FDA release RU 486 for use in the United States.

In his response he says that an NDA, as required by Section 505(a) of the FDA Act, or a similar type application must be made in order to permit RU 486 to be imported, distributed and produced in the USA.

Would you be kind enough to send us the application forms that must be filled out in order for PPSI to obtain approval for RU 486 sales.

I am also sending along a San Francisco Chronicle from December 17, 1992 article "FDA Clearing Way for French Abortion Pill" in which this article quotes, "In a letter to a leading congressional advocate of the drug the FDA said clinical trials already conducted in Europe may well be sufficient to permit an adequate review of the drug by the federal agency."

PPSI has negotiated with a national pharmaceutical company for the distribution of RU 486 and this major company already has been licensed by the FDA.

Enclosed also please find letters to Roussel-Uclaf (Paris, France) and Hoechst-Roussel (USA) along with past correspondence over the last four years, in order to release RU 486 in the USA.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H.
President

encls.
cc: Senator Barbara Boxer
Congressman Ron Wyden
Congresswoman Nancy Pelosi
Edouard Sakiz, Roussel-Uclaf
Hoechst-Roussel

Q300037

MIF 003738

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 8, 1989

Marcel Laventurier, R.Ph.
Vice President, Professional Affairs
Pharmacists Planning Service, Inc.
200 Gate Road
P.O. Box 1336
Sausalito, California 94966

Dear Mr. Laventurier:

Your letter of September 21 to Ronald G. Chesemore, Acting Associate Commissioner for Regulatory Affairs, on the subject of RU 486 importation for personal use via the mail has been referred to me for reply.

As requested, enclosed is a copy of "Pilot Guidance for Release of Mail Importations", which reflects current FDA policy in this area. Please note the first sentence in the first paragraph - "Because of the desire to acquire articles for treatment of serious and life-threatening conditions like AIDS and cancer, individuals have been purchasing unapproved products from foreign sources" (underlining added for emphasis). RU 486, a powerful abortifacient drug, does not meet this requirement.

FDA has determined that RU 486 appears to be a new drug without an effective new drug application (NDA) as required by Section 505(a) of the FD&C Act and that it would be inappropriate for release under the personal importation policy. THE INTENDED USE OF SUCH DRUGS COULD POSE A RISK TO THE SAFETY OF THE USER. (See enclosed copy of Import Alert #66-47). Therefore, we must again deny PPSI's request to import, via the mail, the drug RU 486 for subsequent disbursement to patients.

Sincerely yours,

/S/

Division of Federal-State Relations

Enclosures (2)

MIF 003739

pharmacists planning service inc.

200 GATE FIVE ROAD P.O. BOX 1336 SAUSALITO, CA 94966 (415) 332-4066

December 29, 1992

President/CEO
Hoechst-Roussel
Route 202-206 North
Somerville, NJ 08876

RE: RU-486

Dear ———

Enclosed please find the September 27, 1989 letter from ——— of Hoechst-Roussel regarding RU-486 and your response letter from 1989.

We would like to apply for distribution rights in the USA of RU-486 and am sending along correspondence to keep you informed as to our progress.

Please let me hear from you regarding any change in policy. In your letter to us you said, "...Hoechst-Roussel Pharmaceuticals Incorporated has not been involved with the development of this compound. In addition, we have no rights to this drug." Has your position changed?

Please let us hear from you.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H.
President

encls.
cc: Senator Barbara Boxer
Congressman Ron Wyden
Edouard Sakiz, Chairman, Roussel Uclaf
Congresswoman Nancy Pelosi
David Kessler, MD, FDA

APPEARS THIS WAY
ON ORIGINAL

DIRECTION DES ACCORDS
BUSINESS DEVELOPMENT

JO/jg

Paris, September 26, 1989

Mr. M. LAVENTURIER, R.Ph.
Vice President, Director,
Professional and Public Affairs
PHARMACISTS PLANNING SERVICE INC.

Dear Sir,

Thank you for your letter dated September 11, 1989.

As I told you in my letter of August 25, we are far from a possible introduction of RU 486 outside of France, especially in the USA, and we would certainly not be able to elaborate much in a meeting at this time. However, if you are coming to France anyway, we could meet you so that you can tell us more about your organization and your ideas.

As you may understand, our Chairman would not directly be involved. As for myself, who is in charge of handling this kind of contact, I will be in Japan at the beginning of October, but my associate, ____ . Director of Licensing will be pleased to meet you ; he is available at the following dates :

- September 29th, am
- October 3rd, am
- October 4th, am / early pm
- October 6th, am

Could you please contact him at the same address. His direct phone number is : 33 / 1. 40.62.44.06.

Best regards.

(S)

Business Development

35 [illegible] des Invalides, 75007 Paris - Tél. (1) 40 62 40 62 - FAX . 33 (1) 40 62 49 49 - Télex Grups 200675 F
[illegible]

pharmacists planning service inc.

200 GATE FIVE ROAD P.O. BOX 1336 SAUSALITO, CA 94966 (415) 332-4066

December 29, 1992

Edouard Sakiz, Chairman
Roussel-Uclaf
35 Boulevard
Des Invadides
POB BP 12007 75323
Paris, France Cedex 07

RE: RU-486

Dear Mr. Sakiz:

Thank you for allowing ——— Director, Business Development, Roussel Uclaf, to meet with our Vice President, Marcel Laventurier, Vice President, PPSI. I also thank you for your follow up letters of August 25 and September 26, 1989 which we are enclosing regarding PPSI's interest in the distribution rights for RU-486 for the United States.

We have had a new change in administration with the election of President-Elect Clinton and the FDA has made statements that they will release RU-486.

As a member of the National Health Leadership Council Clinton-Gore '92 (who has endorsed the use of RU-486) we urge you to apply to FDA to market RU-486.

We are enclosing letters to FDA Commissioner Kessler and ——— President/CEO Hoechst-Roussel current letters regarding our desire to distribute RU-486 in the United States.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H.
President

encls.
cc: Senator Barbara Boxer Congresswoman Nancy Pelosi
Congressman Ron Wyden David Kessler
——— Hoechst-Roussel

pharmacists planning service inc.

200 GATE FIVE ROAD P.O. BOX 1336 SAUSALITO, CA 94966 (415) 332-4066

August 10, 1989

Edouard Sakiz, Chairman
Roussel-Uclaf
35 Boulevard
Des Invadides
POB BP 12007 75323
PARIS, FRANCE CEDEX 07

Dear Mr. Sakiz:

PPSI would like to request information on becoming a distributor of the RU-486 compound.

PPSI as a world leader in Family Planning through its pharmacy members along with STDs, Condoms, etc. (see enclosed) have obtained approval from the Food and Drug Administration, USA to have mail order prescriptions sent to patient's physician if the product will be for the patient's own use.

We are a non-profit education foundation and any profit would go to the overhead and administrative costs of running this program through our national pharmacy network.

Marcel Laventurier, Vice President will be in Paris the end of September first of October and he would like to meet with you regarding establishing distribution rights for PPSI here in the United States.

Enclosed please find information and literature including our July 31 meeting with _____ and _____ of Hoechst Roussel Pharmaceuticals here in the U.S. in which we have asked to distribute this product since they do not with to be involved at this time.

Please let me hear from you and perhaps you might be coming to the U.S. when we could set up further discussions.

Sincerely,

Frederick S. Mayer
President

encls.
cc: Marcel Laventurier, R.Ph.

MIF 003744

Hoechst-Roussel Pharmaceuticals Inc.
Route 202-206 • PO Box 2500 • Somerville, NJ 08876-1258
Telex 833-449 • Cable Hoechstus, Somerville, N.J.
Telephone (201) 231-2000

Hoechst

Direct dial number: (201) 231-2110

September 27, 1989

Mr. Frederick S. Mayer
President
Pharmacists Planning Service Inc.
200 Gate Five Road
P. O. Box 1336
Sausalito, CA 94966

Dear Mr. Mayer:

I am responding to your letter of August 16, 1989 to _____ concerning RU 486. As you know, Hoechst-Roussel Pharmaceuticals Incorporated has not been involved with the development of this compound. In addition, we have no rights to this drug. I would suggest that you explore your interest in RU 486 directly with Roussel Uclaf whose address is 35 Boulevard Des Invalides, Paris 75007, France.

Sincerely,

[_____]

— ea#87

APPEARS THIS WAY
ON ORIGINAL

pharmacists planning service inc.

200 GATE FIVE ROAD P.O. BOX 1336 SAUSALITO, CA 94966 (415) 332-4066

August 16, 1989

Hoechst-Roussel
Route 202-206 North
Somerville, NJ 08876

Dear

Enclosed please find copies of correspondence regarding PPSI interest in RU 486. We have met with your representative regarding this issue and they have spoken with Mr.

We would like to pursue the distribution of RU 486 through the FDA mail order channel similar to the current distribution of foreign drugs into the USA outlined in my letter to 8/16/89.

It is our understanding that Hoescht is not interested in this distribution of RU486.

We would greatly appreciate meeting with you or your representative regarding this issue as we feel it to be of the utmost importance in lieu of the fact that drugs such as Trental (pentoxifylline) is unavailable under Medi-Cal in California due to cost constraints. (see 8/9/89 letter enclosed and 12/14/88 letter)

I'm also enclosing some of our history and public health activities in the field of sexually transmitted disease, family planning and condom promotion.

Please let me hear from you at your earliest convenience.

Sincerely,

Frederick S. Mayer
President

encls.
cc:

Mr.
J.
M. Laventurier
J. Roney, R.Ph.

MIF 003746

January 13, 1993

Food and Drug Administration
David A. Kessler, Commissioner

Room 1471
5600 Fishers Lane
Rockville, Maryland 20857

RE: RU-486 - Request for the Right to Obtain RU-486 for Treatment of an Inoperable Brain Tumor (Meningioma)

Dear Mr. Kessler and ———

This letter is written to you as a last resort in the hope that you will grant me an "Ind Number" for the issuance of RU-486 on an individual basis for treatment of an inoperable meningeal brain tumor. The fast growth of this tumor and its location preclude any further brain surgery.

APPEARS THIS WAY ON ORIGINAL

M.D., F.R.C.S., F.A.C.S., has been my neurosurgeon since its diagnosis in 1981. Dr. resected the first tumor in the left temporal lobe on 2 February 1981. Recurrence occurred in May of 1984. During craniotomy for removal, on 23 May 1984, it was found that the tumor was inoperable.

APPEARS THIS WAY ON ORIGINAL

Dr. contacted , M.D., PhD, of the neurosurgical department of the Karolinska Institute in Stockholm, Sweden. It was determined that I qualified as a candidate for the Leksell Stereotactic Gamma Knife at the Institute. This procedure was carried out on 9 September 1984. Due to the location of the tumor, Dr. was not able to "Strike" the entire tumor mass. However, it did slow down the growth and "shrink" certain portions of the tumor.

Since that time the tumor slowed in growth until 1989-1990. On 27 August of 1991, a Radiologist misread the MRI scan with Gadolinum and diagnosed me with "No recurrent brain tumor." This scan was ordered pre-op for admission to George Washington University Hospital by Dr. Neurosurgeon, for cranial debulking of the tumor in order for me to receive the Gamma Knife treatment again.

MRI SCAN WITH GADOLINUM PERFORMED ON 2 SEPTEMBER 1992, SHOWED INCREASED SIZE TO 5 X 3 X 3 CM. DUE TO A "BLACKOUT" FALL AT MY BANK ON 12/14/92, DR. ORDERED AN MRI SCAN

APPEARS THIS WAY ON ORIGINAL

9300169

MIF 003747

WITH GADOLINUM ON FRIDAY 8 JANUARY 1993. THIS SCAN PRESENTED NEW TUMOR GROWTH IN FOUR MONTHS UP TO 5.1 X 3.8 X 4.3 CM.

RU-486 has been proven to shrink meningeal female brain tumors due to tumor make-up of the progesterone hormone.

I do not have the time to get involved in a study, especially since a portion of the patients are given placebos.

Most of my success with this tumor has been predicated upon "Research Vehicles". 1984 - MRI at Einstein Medical Center, Philadelphia, Pennsylvania for a definitive diagnosis, when CT scan with Contrast did not diagnose recurring mass. 1984 - Gamma Knife was only in two countries, Stockholm, Sweden and Buenos Aires, Argentina at that time. Patients like me are those whose risks aid future medical success.

My physicians have tried relentlessly to obtain RU-486. They have made national and international calls to Roussel/ Ulcaf, ATTN: _____ Food and Drug Administration, Atlanta, Georgia and Los Angeles, California, etc. Medical records along with correspondence has been faxed to Paris, France. Contact was also made with Congressman, Steny Hoyer, (D-Md) Ron Wyden, (D-Ore) and Congresswoman Pat Schroeder, (D-Col). Dr. Steven W. Grunberg has been the least responsive.

Contact with _____, Food and Drug Administration states that both the RU-486 and Food and Drug Administration had to come to a mutual consent for the RU-486 to reach me.

On 30 July 1992, Mr. J. David Grow of Atlanta, Georgia had to appear before the House Small Business subcommittee on regulation, Chaired by Congressman Ron Wyden, (D-Ore) to obtain RU-486 for his brain tumors. Unfortunately, I do not have the time to undergo a "Protocol Study". Mr. Grow's request was granted for distribution to Nettleton S. Payne, M.D., neurosurgeon on a one-on-one basis. It has been repeatedly stated that FDA and Rosseau/Ulcaf can reach agreement for release thru communication between both parties to each other. FDA approving Ind# and Rosseau/Ulcaf then releasing RU-486.

On 6 January 1993, Health Newscaster, Ms. Rhea Blakely, Channel 7, WJLA-ABC reported on the 7:00 pm news that eight patients in America were individually receiving RU-486 for treatment of inoperable Brain Tumors. I contacted Ms. Blakely and talked with her in-depth pertaining to RU-486 for inoperable meningiomas. I believe that Channel 7 will continue their interest in the disbursement of RU-486.

Documentation of definitive success of RU-486 can be found in J. Neurosurg.-Volume 74-June 1991. (J. Neurosurg. 74:861-866, 1991) "Treatment of unresectable meningiomas with the antiprogesterone agent Mifeprestone". Page 863, Table 1,

RU-486 Continued

in a clinical summary in 14 patients with unresectable meningiomas, clearly shows seven patients with tumor sites of sphenoid bone and sinus cavernous are either regressing or stabilizing. Case Numbers 1, 4, 10, 11, 12, 13 and 14 validate my statement.

Finally, I wish to advise you of my position and reason for seeking treatment of RU-486 on this brain tumor. I recognize that entrance into this world from your mother's womb is your first day closer to death. I have no fear of death and am grateful to have lived as long as I have been able to physically function on my own. However, I fear deeply the debilitation of a stroke, paralysis and inability to function as a human being. I do not intend to bring the long term care required when I cannot speak, take care of simple daily needs and waste away with the burden to my family, friends or the Government, at home or in a nursing facility. I am already witnessing what will come later with current numbness on the left side of my face, decrease in my vision, slight loss of control of the sphincter, urinary and esophagus muscles, as well as slow decrease in equilibrum and coordination. Brain tumors that are non-malignant are slow killers. As I am currently of sound mind, I know that I will recognize the proper time to end my life. I state this not out of pity or for anyone to feel sorry for me. I have had a good life.

Sincerely,

cc: [redacted]

Ms. Rhea Blakely, WJLA-ABC-Channel 7
3007 Tilden Street, NW-Washington, D.C. 20008

M.D., F.R.C.S., F.A.C.S.
Neurological Surgeon

Main Office:

Rockville, MD 20850

URGENT: PLEASE DELIVER AT ONCE.

October 7, 1992

Rouseau/Uclaf
Attn: Dr. Silvester

fax: 011-33-1-4891-4949

RE: ***Compassionate, single patient use of RU-486 for treatment of meningioma of the brain in terminal patient***

Dear Dr. Silvester:

I am writing to you on the advice of ——— from the Food and Drug Administration to request that you consider the release of the drug RU-486 for use clinical use for a patient of ours who is suffering from a large meningioma of the brain. She is unable to participate in Dr. s Protocol in California. I am enclosing the attached brief medical history for your review, as well as her most recent MRI scan, which shows a large recurrent meningioma. As you can see, it is very urgent that we obtain RU-486 as quickly as possible, as ; life depends it.

Whatever you could do to help would be greatly appreciated. I will be following up this fax with a telephone call. Thank you so very much for your attention to this matter.

APPEARS THIS WAY
ON ORIGINAL

Yours sincerely,

M.D.

enclosures:

, M.D., F.R.C.S., F.A.C.S.
Neurological Surgeon

Main Office:

Rockville, MD 20850

RE:

To Whom It May Concern:

Ms. , is a post-menopausal woman, aged 58, who has been under my care since 1981 when she was first seen by me for excision of a meningioma of the brain. This tumor has been ongoing and has not stopped growing since 1981, despite two microsurgeries, the first in 1981 and the second in 1984, and stereotactic radiosurgical treatment for sub-total removal of the residual tumor. This tumor has recently grown so large that it effects her vision and speech, and has caused significant weakness and numbness on the left side of her face. Her health is further compromised by a serious heart condition, for which she has undergone two cardiac catheterizations.

We are currently looking into the use of RU-486, the French drug which has shown some very strong indications of stabilizing or even reducing the size of meningiomas. This is our only hope, as it is a non-invasive treatment, and could significantly reduce the tumor size.

Repeat stereotactic radiosurgery (Gamma Knife) cannot be undertaken because of tumor size. If no alternative measures are found, microsurgery will need to be attempted, which could result in a loss of speech and loss of vision.

The prognosis for Ms. is death without treatment and risk of death with microsurgical treatment because of her heart condition and the complexity of the surgery that would need to be undertaken.

APPEARS THIS WAY
ON ORIGINAL

Yours sincerely,

, M.D.

AKO:kco

MIF 003751

. M.D., F.R.C.S., F.A.C.S.
Neurological Surgery

Telephone:
Facsimile:

October 27, 1992

Mr. Steve Jenning
Rep. Ron Wyden's office

fax: 1 202 225 8950

RE: ***Obtaining RU-486 for***

Dear Mr. Jenning:

At the request of Ms. I am faxing you the documents that were sent to France. I have not received from nor sent anything to the FDA, but have spoken with who advised me that the procedure is to obtain a written guarantee that the drug manufacturer will give Ms. RU-486, and then the FDA will give us an IND number, so that we may legally obtain the drug.

I spoke with Dr. Sylvestre after she received my fax, and she said that she could not release the drug to us because she felt that would be able to be included in one of the multi-center studies currently going on around the country. cannot be involved in a protocol study for two reasons; she might get a placebo, in which case the tumor would continue to grow, and she cannot wait until an area hospital sets up such a protocol, as currently no protocols exist within a 100 mile radius. Traveling to a hospital which already has a study in progress would be out of the question, as these studies last anywhere from 3 to 18 months.

I don't know what we should do now. I have been given advice from Pat Schroeder's office to contact the media, but I'm not sure what effect that would have What do you suggest? Please call me at your earliest convenience so that we can plan how to best help and others like her to obtain this drug.

Thanks for your help.

APPEARS THIS WAY
ON ORIGINAL

Sincerely,

Assistant to M.D.

, M.D., F.R.C.S., F.A.C.S.
Neurological Surgeon

Main Office:

Rockville, MD 20850

October 7, 1992

The Honorable Steny H. Hoyer
1705 Longworth House Office Building
Washington, DC 20515

fax: 1 202 225 4300

RE:

Dear Mr. Hoyer:

I have received your name from Mr. David Groh as someone with an interest in helping patient's obtain the drug RU-486 for clinical use in reducing the size of brain tumors, such as meningiomas. I am faxing the attached document at the request of our patient, Ms. who is trying to obtain this drug for treatment of her very large meningioma. As you can see, it is very urgent that we obtain RU-486 as quickly as possible, as Ms. , life depends it.

Whatever you could do to help would be greatly appreciated. With best wishes.

APPEARS THIS WAY ON ORIGINAL

Yours sincerely,

/s/

M.D., F.R.C.S., F.A.C.S.
Neurological Surgery

Telephone:
Facsimile:

September 29, 1992

RE:

To Whom It May Concern:

The above named patient, Ms. , has been under my care since 1981 when she was first seen by me for excision of a meningioma of the brain. This tumor has been ongoing and has not stopped growing since 1981, despite two microsurgeries, the first in 1981 and the second in 1984 and stereotactic radiosurgical treatment for removal of the residual tumor.

We have looked into the possible use of RU-486, the French drug which has shown some applications for reducing the size of meningiomas. This is an experimental method and currently patients are being treated under research protocols, and long term effects and complications are not known. Repeat stereotactic radiosurgery (Gamma Knife) cannot be undertaken because of tumor size.

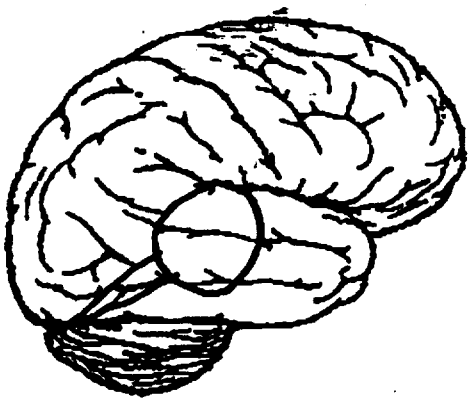
We are currently seeking alternative treatments. If no alternative measures are found, microsurgery will need to be undertaken. The prognosis for Ms. is possible death without treatment and risk of death with treatment because of her heart condition and the complexity of the surgery that would need to be undertaken.

APPEARS THIS WAY
ON ORIGINAL

Yours sincerely,

, M.D.

AKO:kco



FACSIMILE TRANSMISSION
FROM
HARTFORD HOSPITAL
DEPARTMENT OF NEUROSURGERY
Phone (203) 240-5911 - FAX (203) 240-5976

DOB

Date: 10 Oct 92.

To: _____

_____

Fax #: (202) _____

From: _____ MD

Phone: ( ) _____

Number of pages including this cover sheet: 7

Will discuss with you on the phone.

This marks of intent

MIF 003758

AJ Congress

American Jewish Congress
Stephen Wise Congress House
15 East 84th Street
New York, NY 10028-0458
212 360 1560 • Fax 212 249 3672

♀ Commission for Women's Equality ♀
Ann F. Lewis, Chair
Hanita Blumfield, Director

January 13, 1993

Commissioner David Kessler
United States Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

Dear Commissioner Kessler;

Enclosed are petitions gathered across the country by members of the Commission for Women's Equality of American Jewish Congress. In August, and again in December, I sent you a number of petitions, the signatures on them now total over 800. That our members have continued to circulate and return the petitions after many months, shows how strongly we feel about this issue. The new signatories urge you, as I do, to test RU 486 in the United States to see if it is safe for widespread use. As you know, RU 486 is not only beneficial as a non-surgical alternative to abortion but may also have benefits for curing breast cancer and other types of diseases. How can you deny women the best health care available to them?

Although President-elect Clinton has already promised to lift the ban on the importation of RU 486 soon after taking office, I am forwarding these petitions to emphasize to you and the new administration that women should have all available options when making health care decisions.

American Jewish Congress, a national social action organization with membership of over 50,000, has already passed a resolution supporting the testing and marketing of RU 486 and will continue to monitor the situation to ensure that progress is made in a timely manner.

Sincerely,

Dr. Hanita Blumfield

Enc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 22, 1993

VIA FACSIMILE
LETTER TO THE EDITOR OF THE SAN FRANCISCO CHRONICLE:

Your column by Beverly Zakarian about RU-486 ("Open Forum," 1/11/93) reflected a widespread and fundamental misunderstanding of the policy of the Food and Drug Administration.

The FDA has not obstructed import of the drug for medical research on its various potential uses. In fact, FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drugs applications (INDs).

Under the law, FDA is precluded in most cases from publicly discussing studies in progress under an IND. Your readers should know, however, that the National Institutes of Health, whose studies are public information, is using RU-486 in biochemical research and is investigating its potential for treatment of Cushing's disease and other serious conditions. Other RU-486 studies, for ailments that include several kinds of cancer, are being carried out by non-governmental entities.

All of this research uses RU-486 that has been imported legally and with FDA's approval under the IND process. The import alert on RU-486 relates only to illegal attempts to bring the drug into this country.

The basic obstacle to more widespread availability of RU-486 in the U.S. is not FDA, but the fact that the French manufacturer has declined to apply with the agency for the drug's approval.

Sincerely,

Carol R. Scheman
Deputy Commissioner for
External Affairs

9300320

[redacted] Jan 27 [redacted]

David Kessler, M.D., Commissioner
Food [redacted] Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

This letter is to bring to your attention a serious public health hazard associated with the use of RU-486 and other anti-progestational steroids as abortifacients, namely, a markedly increased risk of breast cancer. To the best of my knowledge, this issue has yet to be raised in any government hearings or in any documents submitted to the FDA concerning these drugs, despite the fact that the increased risk of breast cancer associated with abortion of first pregnancies is well established in the literature.

By 1970, the multinational WHO studies conducted by MacMahon et al.[1] had clearly established the continuous, positive association between age at first full-term pregnancy and breast cancer incidence. The same studies found that aborted first pregnancies not only failed to confer the same protection as early full-term pregnancies, but also tended to increase breast cancer risk independently. In this country, as early as 1981, Pike, Henderson, et al.[2] observed a relative breast cancer risk of 2.4 among young women who had aborted (spontaneous or induced) their first pregnancy, a finding which Henderson and coworkers reproduced exactly among Chinese women in Shanghai in 1988[3]. These findings were echoed all through the 1980's in studies of induced abortion in the US[4-6], Japan[7], Denmark[8], Italy[9] and Russia[10,11]. As long ago as 1986, the mounting evidence had convinced U.S. government scientists at NICHHD, CDC and Uniformed Services University of the Health Sciences to conclude: "Induced abortion before first term pregnancy increases the risk of breast cancer."[12] In studies with sufficient numbers of cases, multiple abortions, irrespective of their timing with relation to first birth, have also been associated with increased risk[5,6,11].

All this might be considered irrelevant if the increased breast cancer risk associated with induced abortion were attributable to any aspect of the surgical methods by which abortion is induced. Indeed, were this the case, it could be argued that medical abortifacients might provide improved long term health protection to the women who would use them. Unfortunately, all evidence points to an hormonal mechanism of risk enhancement. Epidemiologically, spontaneous abortion has

MIF 003785

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been associated with the same trend of increased breast cancer risk as induced abortion[2,4,7,8,13,14]. Endocrinologically, it is well known that early pregnancy is accompanied by a dramatic rise in endogenous estrogen levels, which promotes a burst of proliferation of breast tissue that is balanced by the [illegible] differentiating [illegible] of progesterone and other [illegible] hormones [illegible] protection against [illegible] afforded by an early full-term pregnancy is ascribed to the net differentiating effect of same, while the increased risk associated with abortion is ascribed [illegible] proliferative effect of the early pregnancy surge of estrogens, whose breast tumor promoting activity is undisputed. Moreover, these effects have been confirmed in animal experiments with chemically induced breast tumors[15].

All this might still be considered irrelevant if abortion in the US were completely unrestricted. But as you know, the US Supreme Court has recently affirmed the right of states to impose reasonable restrictions on abortion, such as parental notification, waiting periods, and the like. The legal importation of abortifacients such as RU 486 (Roussel-UCLAF) and ZK-98,299 (Schering, AG) would effectively circumvent the states' responsibility to ensure the protection of women's health, considering the ease with which prescriptions may be abused and the devastating long term health consequences attributable to abortion, i.e., the increased incidence and severity[16] of breast cancer.

What is the magnitude of the breast cancer hazard inherent in abortion? A review of the relevant literature as cited above puts the relative risk of abortion of first pregnancy at between 1.5 and 2, over and above the increased risk resulting from delaying first full-term pregnancy by any means. (For multiple abortions, relative risk estimates range as high as 4 or 5.) Conservatively, we may estimate the lifetime breast cancer risk of the average American teenager at about 10%, assuming she will eventually go on to have one or more children, starting in her 20's. However, if she becomes pregnant at 15 or 16, carrying the child to term will reduce her risk to about 7%, while aborting the pregnancy will increase her risk to about 15%! Thus having an abortion doubles her risk of breast cancer over what it would be if she has the baby--an enormous individual impact.

But the public health impact is truly staggering, considering the high (and rising) incidence of breast cancer and the high frequency of induced abortion, particularly among nulliparous girls and women (about 800,000 annually in the US). Even if we completely ignore the risk-enhancing effect of delaying first childbirth, a relative risk of 1.5 specifically attributable to induced abortion translates to 40,000 additional breast cancer cases each year. (The full effect of abortion-promoted breast cancers will likely not be felt until the turn of the century. However, annual US incidence of breast cancer is now rising past the 140,000 mark.) If we estimate most conservatively and assume that, even with highly restricted importation of RU-486, the

abortion rate in nulliparous girls and women will rise by only 10% (80,000) due to unapproved use of the steroid, we can expect at least an additional 4,000 cases per year, several years thence. If importation of abortifacient steroids should double the abortion rate, at least 40,000 excess cases would be expected to result.

As troubling as the data must be [redacted] who [redacted] responsibility of protecting the public from dangerous drugs, the most shocking aspect of the present hazard is that the issue of breast cancer risk associated with abortifacient [redacted] heretofore been raised. President Clinton may not himself be aware of the irony of his echoing the complaints of abortifacient import advocates last Friday with the words: "We must free science and medicine from the grasp of politics." Indeed, the compelling link between abortion and breast cancer is very much in the grip of "pro-choice" politics: Many researchers are clearly reluctant to reveal the risk, often minimizing their own results[3-5,7-9]. As Remennick states in her 1990 review: "An initial attitude of researchers towards abortion usually determines the way they interpret results"[1]. The "initial attitude" is often the attitude of the major medical societies, such as the American Medical Association, the Massachusetts Medical Society and the Endocrine Society, which have been vigorously pursuing a "pro-choice" agenda. Witness the July, 1992 New England Journal of Medicine review article on breast cancer, which, for all its apparently thorough discussion of risk factors, is totally devoid of any mention of abortion, even as a potential risk factor. However, the worst research comes out of the Karolinska Institute in Sweden (funded, in part, by Family Health International, an American population control organization which itself receives funding from the US State Dept.), where Lindefors-Harris, et al.[10] have attempted to dismiss the entire body of case-control evidence with the idea that in interview-based studies, the cancer patients are more likely to remember prior abortions than controls, and are also more likely to imagine abortions that never happened! They try to use their own computer registry-based study to back up that claim, a study in which they had reported a statistically significant ($p<.05$) 20% decrease in breast cancer risk among women with prior abortions[11]. However, their data actually show a predictable protective effect of parity-[redacted] abortion and a significant relative risk of 1.9 among nulliparous vs. parous women (at the time of abortion), in agreement with the widely observed risk elevation following abortion before full-term pregnancy!

Indeed, a review of the data on abortion and breast cancer reveals an unusual (for epidemiological studies) consistency across geographical, ethnic and study design lines, in the direction of increased risk. It is most ironic that one of the major arguments for the importation of antiprogestational steroids is their potential use in breast cancer therapy: In fact, years of clinical testing have produced no dramatic results in cancer therapy. Rather, the legalization of these drugs is virtually guaranteed to increase the incidence of breast cancer by the thousands of cases every year, by increasing the availability and frequency of induced abortion.

Dr. Kessler, I am familiar enough with your record as FDA Commissioner to know that you are deeply committed to the protection of the public health. This you have amply demonstrated through your steadfast refusal to permit the use of unapproved drugs, often where the hazards are much less severe or [illegible] well-defined as they are in the case of [illegible] clearly prefer to err on the side of caution, even when it means standing up to enormous political pressure. With the Clinton Administration in power, there will undoubtedly be even greater political pressure on you and your agency to err on the side of recklessness. The third great irony of this saga is the strong commitment made by Mr. Clinton and the Congress to reverse what the latter has called the "growing epidemic"[1] of breast cancer! I therefore urge you to stand firm in refusing to permit the short-circuiting of the FDA's established procedures for assuring the safety of potential new drugs.

I have invested considerable time and effort in this sabbatical year myself, to review critically the literature on breast cancer and abortion and to make my findings public in what I have found to be an unreceptive (to say the least) political climate. I shall continue to do so, for I too am committed to promoting and protecting life and health. Please be assured, therefore, that I shall make myself available to your agency to testify publicly or help in any other way I can to further these goals. Please feel free to call or write me at home: [redacted]

[redacted] Ph.D., Professor
(Biology, Chemistry, Endocrinology)

references attached

19 February 1993

Food and Drug Administration
David A. Kessler, Commissioner

Room 1471
5600 Fishers Lane
Rockville, Maryland 20857

RE: RU-486 - Request for the Right to obtain RU-486 for Treatment of Inoperable Brain Tumor (Meningioma)

Dear Mr. Kessler

This letter is written on behalf of by her family. It is her hope that you will grant an 'IND Number' for the issuance of RU-486 (Mifepristone) on a single patient use basis for treatment of an inoperable meningioma of the brain. The aggressive growth and location of the tumor preclude any further brain surgery.

M.D.- Associate Professor of Neurosurgery MUSC,has been our mother's primary neurosurgeon since 1990. Included with the compassionate use request letter is Dr. clinical summary on Mrs. . As indicated, prophylactic radiation is inappropriate because of the tumors proximaty to the brain stem. Stereotactic radiosurgery (Gamma Knife) cannot be undertaken because of tumor size. The last sugery on 2 October 1992 by M.D., University of California in San Francisco to debulk the tumor has resulted in what is hoped to be a temporary deficit in the areas of memory and equilibrium. Regrowth of this same tumor has been so great it now affects her vision and swallowing. The prognosis for our mother is death without treatment.

Faced with this dilemma our only hope is the French drug RU-486 which has shown some very strong indications of stabilizing or reducing the size of meningiomas. It is the only non-invasive treatment that could significantly reduce the tumor size.

In view of the recent publication by Dr. Grunberg on a series of meningiomas, as well as other studies on the value of this agent RU-486, it is our belief that our mother would be a good candidate for its' use. RU-486 has been proven to shrink meningeal female tumors due to tumor make-up of the progesterone hormone. The neuropathological receptor studies of our mother's tumor tissue shows intermediate (206) progesterone receptor capacity, indicating a positive outcome with treatment of RU-486.

APPEARS THIS WAY ON ORIGINAL

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RU-486 Continued

Unfortunately, our mother does not have the time to undergo a 'Protocal Study' with its' inherent danger of being part of the control group (placebo). There are currently nine patients in America who are receiving RU-486 on an individual basis for treatment of inoperable Brain Tumors. It's imperative that our mother become the tenth.

Our mother's physicians, Dr. and Dr. of , S.C., have been tireless in their efforts to otbain RU-486. Internationally they have contacted Roussel/Uclaf, ATTN: Dr.'s Ullman and Silvestre; Nationally, Food and Drug Administration, S.W.O.G., Atlanta, Georgia and University of Southern California. Clinical summaries along with correspondence has been faxed to Paris, France. Contact was also made with Vice President Albert Gore, Jr. and Congressmen Jay Rockefeller (D-WV), Ron Wyden (D-OR) and Congresswomen Pat Schroeder (D-CO). The advise given by Schroeder's office was to contact the media. That would only skirt the real issue, consent for use of RU-486 via an 'IND Number'.

Contact with ——— at the Food and Drug Administration states that both the manufacturer and Food and Drug Administration had to come to mutual consent for the RU-486 to reach our mother.

On 30 July 1992, J. David Grow of Atlanta, Georgia appeared before the House Small Business subcommittee on regulation seeking to obtain RU-486 for his brain tumors. He was subsequentially approved.

On 26 January 1993 Mrs. of received an 'IND Number' from the Food and Drug Administration to secure RU-486 from Dr. Ullman at the Roussel/Uclaf manufacturing plant in Romanville, France. Only through the relentless efforts of Mrs. and her neurosurgeon M.D. were they able to obtain the agent RU-486.

Finally, from a personal standpoint we ask you to put yourselves in our place for a moment. Our mother, the dearest person in our families lives, has suffered through five brain surgeries in the last three years. Not once, but twice she has subjected herself to craniotomies (Sagittal Sinus Cavity) that most neurosurgeons would not endeavor because of the high risk of stroke. In her last operation October 1992 she elected brain surgery even though there wad little probability of the tumor being resected in toto. She knew of no other obtainable alternative. Now with the remnants of the tumor inoperable and doubling in size every sixty (60) days, the prognosis is certain death without non-invasive treatment.

RU-486 Continued

However, that obtainable alternative does now exist with the good grace's of your office. Our bright, witty and ever energetic mother is now bedridden in a hospital nursing facility recovering from the effects of a coma induced by hydrocephalus. It almost seems as if she could regain full health but, day by day, as the tumor grows larger it becomes a greater threat. Still, she clings to the hope she'll get better. Only you and your staff can give our mother that chance she so richly deserves.

Sincerely,

and Family

APPEARS THIS WAY
ON ORIGINAL

cc: M.D.

Albert Gore, Jr., V.P.
Pennsylvania Ave., Washington, DC 20000

Rep. Ron Wyden
1705 Longworth, Washington, DC 20515

Mack Thompson, WCBD-ABC
210 W. Coleman, Charleston, SC 29464

Natalie Joost, Potomac TV-Channel 8
3007 Tilden St., Washington, DC 20008

Issue 2
Phase 3

TODAY'S BREAKTHROUGHS: TOMORROW'S CURES

RESEARCH SUMMARY

TOPIC: RU-486 AND BRAIN TUMORS
TB:TC Report #433

BACKGROUND:

A meningioma is a slow-growing tumor of the meninges, the membranes covering the brain and spinal cord. It is a relatively common intracranial tumor, accounting for 15% to 18% of all tumors of the central nervous system. Although meningiomas are benign, their growth can lead to such problems as seizures, blindness, or paralysis. Most can be removed by surgery, but some grow so close to crucial brain structures that surgery isn't possible.

In 1982 at the USC School of Medicine, Steven Grunberg, M.D., and Martin Weiss, M.D., began research on hormonal manipulation of meningiomas. In 1987, they came upon the drug mifepristone, commonly known as the French abortion pill, RU-486, as a candidate for treating meningiomas because the drug blocks the receptors for progesterone, a hormone that appears to promote growth of some of the tumors. A number of factors have suggested a hormonal dependence for meningiomas: they occur twice as frequently in females, they are often seen in conjunction with breast cancer (another tumor with progesterone receptors), and they grow rapidly during pregnancy. While a lot of controversy surrounds RU-486, Grunberg says, "We didn't set out to make a political statement for RU-486, it just appeared to fill the bill for what we were trying to do."

Based upon the results of the study mentioned in the script, Grunberg initiated in October, 1992, a larger, multi-institutional study to be based at the University of Southern California. The purpose of the 200-patient study will be to definitively evaluate the effect of a daily 200 mg dose of mifepristone (one third the dose given when the drug is used to terminate pregnancy) given for two years in preventing progression of unremovable meningiomas.

Results from the trial aren't expected for at least four years and since most meningiomas can be cured surgically, only a limited number of patients would require this type of treatment. However, long-term treatment with RU-486 may have broader implication in the treatment of other hormone-related conditions that are unrelated to abortion.

Grunberg said the drug has been studied as a treatment for breast cancer, endometriosis, and a disorder called Cushing's syndrome, which is characterized by overproduction of cortisol, the body's own cortisone.

200 Pt Study being done on RU 486 - Tumors - USC - Grunberg

FOR MORE INFORMATION, CONTACT:

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SHARON SAYLES BELTON
COUNCIL MEMBER, EIGHTH WARD

minneapolis
city of lakes

Donna Shalala
Department of Health and Human Services
200 Independence Ave. S.W.
Washington, D.C. 20201

February 11, 1993

I am writing to you to express my support for the Senate Bill S. 222 introduced by Senator Paul Wellstone. S. 222 is a Bill which would require that the FDA collect the same information on the drug RU-486 that is required to be submitted by a manufacturer with a new drug application under the Federal Food, Drug, and Cosmetic Act. RU-486, as you know, is a drug which seems to be a very effective and safe choice to surgical abortions and may have many other potential uses for treatment of diseases.

Senator Wellstone believes that a supportive Clinton Administration would encourage the marketing of RU-486 by its manufacturers. The Clinton administration has, thus far, been supportive of a manufacturer application seeking approval to market RU-486; but the manufacturer continues to show reluctance to market the product.

I want to express my support for the Clinton Administration's policy on RU486 and for Senate Bill S. 222. I believe that RU-486 will be a significant addition to the effective family planning choices available to all Americans.

Sincerely,

Sharon Sayles Belton, President
Minneapolis City Council
8th Ward
SSB/wk

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