Lawrence Lader, Abortion Rights Mobilization

Joan Malin, Planned Parenthood of New York City, Inc.

Steven Tamarin, M.D., Physicians for Reproductive Choice and Health

Virginia Reath, R.P.A., M.P.H., Access Project

Women need greater access to abortion services. The shortage of abortion providers nationwide and the marginalization of abortion *outside* the scope of women's basic health care needs have had a dramatic impact on the health and well-being of women and their families. Mifepristone has the potential to expand access to abortion by giving women another medical option. Because mifepristone can induce abortion without surgery, it can be provided in almost any health care setting, and it can be safely administered not only by obstetrician/gynecologist but also by family doctors and mid-level providers like physician's assistants and nurse practitioners. If mifepristone is approved with appropriate safeguards and without unnecessary restrictions, it will have a profound impact on women's lives by expanding *who* provides abortion services and *where*.

Joan Malin, president of Planned Parenthood of New York City, testified that based on inquires about PPNYC's training programs for RU-486 providers, medical professionals want to be able to offer the medical abortion option. This reflects national trends: A recent survey by the Kaiser Family Foundation (June 2000) found that about one third of gynecologists and family practice physicians who don't provide surgical abortions said they would be "likely" to prescribe mifepristone to their patients who

request it. This would significantly increase the availability of abortions -- especially early abortions.

In addition, restricting RU-486 administration privileges to physicians – and only physicians who perform surgical abortions would eliminate the opportunity for greater access to early abortion.

Planned Parenthood of New York City, Inc. believes that physician's assistants, nurse practitioners and other mid-level providers have the skills and clinical training needed to prescribe RU-486. Planned Parenthood has found that patient counseling is the most important skill that a clinician must have to administer medical abortion safely and effectively. Providers must be able to clearly communicate to women how to be participants in the process. Women need to know how and when the medications work, possible side effects, how to manage them, and when to seek follow-up care. These patient counseling skills and all other competencies needed to administer mifepristone effectively are skills that physician's assistants, nurse practitioners and other mid-level providers use in other aspects of their work and are well within their scope of practice.

Second, requiring that physicians who provide mifepristone be trained in surgical abortion is also a significant problem. Although providers of medical abortion must have surgical back-up arrangements, there is absolutely no reason for them to have surgical abortion experience, any more than there is reason for physicians prescribing ulcer medication to have training in gastric surgery.

In addition, requiring that the provider of mifepristone-induced abortion practice medicine more autonomously than other medical providers represents an unprecedented intrusion on medical practice in the absence of any clinical evidence that such restrictions are needed. Dr. Steve Tamarin, Board Member of Physicians for Reproductive Choice and Health, pointed out that this proposed restriction appears to require the establishment of new mechanisms for certification of providers of surgical abortion that are not justified for a procedure that is both one of the most common and one of the safest in medicine.

Lawrence Lader, president of Abortion Rights Mobilization (ARM), touched on the additional conditions for which RU-486 may be useful for treatment. In addition to the clinical trials of RU-486 that ARM oversees and that Dr. Schaff reported on earlier in the hearing, an ARM research project uses RU-486 to treat fibroid tumors, which are a major medical problem for women. The early results of these tests are highly encouraging. But it is difficult to test the use of RU-486 in treating fibroids, cancer and other conditions with the drug still awaiting approval.

"So long as mifepristone can be offered in the privacy of a doctor's office or the anonymity of a primary care clinic (where there are generally no protesters), the pool of potential providers is huge. However, if the FDA enacts the surgical-only and physician-only restrictions, this potential pool of providers would disappear," testified Joan Malin of PPNYC. "Medical abortion with mifepristone would be no more accessible than surgical abortion is now. For women living in the 42% of New York counties with no abortion provider, that would be very disappointing news."

Legal and Policy Issues: The Integrity of the Regulatory Process and the Importance of Precedent

Simon Heller, Center for Reproductive Law and Policy

Donna Lieberman, NYCLU Reproductive Rights Project

Kelli Conlin, National Abortion and Reproductive Rights Action League-NY

Nancy Millar, National Organization for Women

Placing inappropriate restrictions that are not medically called for on the delivery system for RU-486 would conflict with the *Roe v. Wade* Supreme Court decision establishing women's right to abortion, the governing language of the Food and Drug Administration and the laws of the State of New York.

According to Simon Heller, a lawyer with the Center for Reproductive Law and Policy, without compelling evidence to justify restrictions on physicians beyond thorough training and licensure, additional barriers and restrictions to abortion place improper obstacles to a woman's ability to exercise her right to privacy and a safe abortion. ~~Said~~ Mr. Heller:

> Access to abortifacients is cloaked with strong constitutional protection under the rights to privacy and equal protection of the laws. Accordingly,

the government and the FDA cannot impose restrictions on abortion access unless those restrictions further governmental interests in maternal health or potential life. Rather they threaten the health of women seeking abortions by greatly decreasing, if not entirely eliminating the increase in, the availability of abortion providers that would attend the approval of mifepristone without distribution restrictions.

Donna Lieberman, Director of the New York Civil Liberties Union's Reproductive Rights Project, pointed out that the FDA itself has said, "Congress did not intend the [FDA] to interfere with medical practice . . . [or] to regulate the practice of medicine as between the physician and the patient." (Quoted in *FTC v. Simeon Management Corp.*) A restriction that imposes special training and experiential requirements on medical professionals who seek to prescribe mifepristone, in essence, regulates the practice of medicine. Regulation of the practice of medicine is a matter for the states. Nothing in the FDA's authorizing statute empowers the agency to impose such restrictions. To the contrary, it is well established that "the FDA does not have jurisdiction to regulate the administration of a drug by a physician." (Quoted in *Simeon*) Indeed, the FDA itself recognizes that "the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert," without obtaining FDA approval. (Quoted in *Simeon*)

Furthermore, testified Ms. Lieberman, New York, like every other state, has its

own legislation that governs who can practice medicine and to what extent. In order to combat a healthcare provider shortage, New York approved certain clinical roles for Physician Assistants, Nurse Midwives, and Nurse Practitioners. These advanced healthcare practitioners have extensive medical training and wide-ranging scopes of practice that depend largely on their practice agreements with supervising or collaborating physicians. In addition, they are authorized to prescribe and dispense a broad range of medicine under New York law. She said: "The FDA does not have the authority to regulate RU-486 in a manner that would impinge on the ability of Physician Assistants, Nurse Midwives and Nurse Practitioners to serve their patients under the authority granted to them by the State."

A representative of the National Abortion and Reproductive Rights Action League - New York recapped RU-486's politically difficult road to approval in the U.S. and concluded by pointing out that the FDA is a government agency charged with neutrality, responsible for making decisions based on need, safety and efficacy, not popular opinion, emotion or organized pressure. "However, if one reviews the long, fraught journey of mifepristone through the FDA, it becomes clear that the main character of this story is not reason but politics," said a representative speaking for Kelli Conlin, president of NARAL-NY.

In the discussion it was noted the experience with RU-486 in other countries, which do not have the onerous restrictions proposed by the FDA indicates that these restrictions are not needed for the safe and effective use of RU-486.

Conclusion

The anti-abortion movement has forced doctors into bullet-proof vests, subjected patients to screaming, abusive crowds, gotten politicians involved in private health care decisions, and now threatens to distort an important decision by the FDA from one based on science to one which appears to be influenced by political pressure. It would be a historic tragedy, a threat to the fundamental principles governing the practice of medicine, to allow this to happen.

RU-486 is safe and effective, as the FDA itself said in 1996. RU-486 will bring privacy back to a procedure that deserves it most. It will increase the number of providers offering abortion services. It will improve the availability of the earliest abortions, which are safest. And it will return abortion care to a private discussion and decision in the office of a doctor or other provider. As Donna Lieberman of the NYCLU pointed out: "The fundamental right to choose is a reality only when there is access to safe and effective methods of abortion."

Submitted on September 22, 2000, by

Mark Green, Public Advocate for New York City

Jo Ivey Boufford, M.D., Dean of the Robert F. Wagner School of Public Service

Allan Rosenfield, M.D., Dean of the Mailman School of Public Health

Victor W. Sidel, M.D., President of the Public Health Association of New York City

Full Testimony
RU-486 Public Hearing
September 19, 2000

RU-486 Public Hearing:
The Impact of Possible FDA Restrictions on its Use and Distribution

September 19, 2000

List of Panelists

Hearing Panel

Mark Green
Public Advocate for New York City

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Dean, Robert F. Wagner Graduate School of Public Service at NYU

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Safety Panel

Eric Schaff, M.D.
Principle Investigator
Abortion Rights Mobilization/
University of Rochester's Mifepristone Trials

Carolyn Westhoff, M.D.
Medical Director
Columbia University's Family Planning Clinic

Laura MacIsaac, M.D.
Director of Family Planning
Albert Einstein College of Medicine

Linda Prine, M.D.
Family Practitioner, PPNYC Abortion Provider
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Access Panel

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Legal and Policy Panel

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Full Testimony
RU-486 Public Hearing
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Safety Panel

Eric Schaff, M.D.
Professor of Family Medicine, Pediatrics and Ob/Gyn
University of Rochester

Thank you for the opportunity to discuss our experience with mifepristone for medical abortion. We have been conducting trials since 1996 under the sponsorship of the Abortion Rights Mobilization, a non-profit advocacy group of NYC.

Since 1996, we have conducted 6 multi-center U.S. trials that have involved over 6,600 women. We have looked at the standard dose of mifepristone and 1/3 of the dose. Both are very effective in the range of 96-98%. We have examined the best route to use the second medication, misoprostol, by mouth and by vagina. We have concluded that vaginal use of misoprostol (97% effective) is superior to oral use (about 92%).

All of our studies have allowed women to use the second medication at home when bleeding and the actual abortion occurs. Only four women in our trials have required blood transfusions. Only one woman required an aspiration curettage to stop bleeding in the four-hour period after using misoprostol. The most common reason for aspiration curettage (about 2%) is due to heavy bleeding from 1-3 weeks later. These episodes tend to be unpredictable and have some clinician discretion associate with them (i.e., may depend on how anxious the woman is with her bleeding, how far she lives from health care, the experience of the clinician, etc.)

Over 90% of the women in our trials have found the procedure acceptable and would choose this method again if they were present. Although side effects from the medications are common, women also report that they are acceptable.

At a time when surgical abortion providers are under siege and their numbers are inadequate to provide the needed abortion services to U.S. women, medical abortion offers a safe and acceptable alternative. Medical abortion can be private. It can expand the pool of health care providers capable of helping a woman wanting to terminate her pregnancy.

Mifepristone is a new class of medication, an antiprogesterone. It has important other health indications and possibilities including the treatment for

fibroids, endometriosis, and certain progesterone-sensitive cancers such as meningiomas. It is an emergency contraceptive and a possible birth control method. It can help with labor induction with women with difficult deliveries.

Mifepristone is available in a dozen countries in Europe and China. It is time that American women have the same access and benefits from mifepristone as the women in these other countries. There should also be more funds for research with this medication for other indications.

Carolyn Westhoff, M.D.
Medical Director
Family Planning Clinic at Columbia University

I'm Carolyn Westhoff, and over the last five years I have had the opportunity to take care of patients who have chosen medical abortion. I worked first with the Population Council trials that were here in New York five years ago and more recently with in conjunction with Dr. Schaff. I also had the opportunity almost four years ago to testify to the FDA about the safety and effectiveness of this. I have even greater experience now and have found mifepristone to be more safety and effective than it was believed four years ago.

Many of us have been investigating a variety of different protocols and a variety of different approaches to doing medical abortion. Using these different protocols has been very manageable for both staff to learn how to do and for patients to understand what they're supposed to do. We heard from Dr. Schaff that this is very safe. I just want to share with you that all the patients that I see who are interested in early abortion are offered the opportunity to have surgical or medical abortion. They hear about everything. They choose the approach that they prefer. In terms of emergencies and in terms of phone calls, I see those very rarely and I see them equally from either medical or surgical patients. My most recent phone call I just got was a surgical abortion patient of ours with an episode of heavy bleeding.

The complications following abortion are rare; abortion is an extremely safe procedure overall. Problems and complications are very similar between the medical and the surgical approaches. Now my Ob/Gyn colleagues, being surgeons, often think that a surgical approach to problem solving is quicker, more certain, and of course patients would prefer to leave things in the doctor's hands. But in fact, when patients hear about both opportunities they frequently choose to undergo medical abortion and afterwards they will tell you that they are very satisfied with that experience. I was of course concerned that perhaps my patients really would be better off if I took care of everything with my own two hands. We undertook a study to investigate their satisfaction, how they were feeling physically, emotionally psychologically both before they underwent the abortion and several steps to a month following. Most women are feeling pretty

terrible right before an abortion because they have the symptoms of pregnancy; they have the stress of this difficult decision. We found that everybody got better rapidly and had much improved functioning a month later. Medical and surgical patients were equal to each other in a rapid improvement. Therefore I think it is very important that we should all accept this as a great option for women to have as soon as possible.

Laura MacIsaac, M.D.
Director of Family Planning
Albert Einstein College of Medicine

I am Laura MacIsaac; I am in a private practice at Albert Einstein College of Medicine, doing general Ob and Gyn. I am also the director of the Family Planning and Abortion service there. Prior to this move I was medical director at Planned Parenthood, the Margaret Sanger Center where I oversaw medical abortion with Methotrexate and provided and taught surgical abortion. I wanted to give my perspective as a busy clinician, doing the full range of Ob/Gyn services being particularly well educated and skilled in abortion matters.

The availability of mifepristone will change so much of the whole dialogue about fertility awareness for the general Ob/Gyn physician and her patients by encouraging women to make their pregnancy decisions early and by that virtue in itself, medical abortion with mifepristone is far safer than anything that we do now.

Part of my big push at Planned Parenthood was to institute early abortion surgically. We started the methotrexate abortions and we are waiting eagerly for mifepristone. At Albert Einstein at Montefiore, I am designing a new approach to teaching fertility for women. I believe the focus should be on making preventive decisions such as contraception and emergency contraception early and making their pregnancy decision early. If the restrictions on mifepristone become unwieldy, the entire benefit of giving out female patients the chance to make these decisions early will be removed for both early surgical and early medical abortion.

From the overall safety view, the longer any abortion waits the higher the morbidity associated with the procedure. And with almost everything that we do, the success of most of our interventions depends on our patient counseling and patient selection. So, all of the concerns people are worried about starting a medical abortion and not finishing it, is absolutely nothing new. It is what I do everyday with every patient. For example, sometimes when I start a surgical abortion I might have to put in dilators a day or two earlier. That starts her abortion and it is all the education and counseling that completes the procedure. The decision is made and we have to see it to the end. So all of the sort of

paranoia about some of the risks of mifepristone abortion are so minimal compared to what I do every day with all my other clinical problems.

The idea of a woman miscarrying at home in less than seven weeks is one of the most common things I get called for in the middle of the night. Its just sort of bread and butter Ob. Managing it safely is what we are all trained to do. Everyday we deal with these other little glitches of going through with the abortion procedure because of potential follow up issues. This is standard for everything we do, whether it is with surgical abortion or half of the other interventions that we do in regular clinical practice. I feel that the wave of paranoia about mifepristone in the scope of everyday practice is just not rational. Its implementation will make what I do, my specialty in fertility, so much easier and safer.

Linda Prine, M.D.
Family Practitioner, PPNYC Abortion Provider
Access Project

Today I would like to address the proposed FDA restriction requiring that medical abortion providers be trained in surgical abortions for the reasons of "safety". Being a family physician, and also surgical abortion provider at Planned Parenthood of New York City, I speak from experience.

In the world of family practice medicine, most of what we do is initiate treatments for patients who may need more specialized care at a later time. For example, we treat patients with heart pain by prescribing them medication. If they later need more extensive treatment like surgery, we refer them to a cardiac surgeon. Another example: we can deliver babies, but we cannot perform cesarean sections on those patients. We would refer these patients to an Ob/Gyn. These referrals to these specialists are a routine part of family practice. And it is part of our medical routine to have this type of back-up plan for everything that we do in case a different type of intervention is needed. This is part of our medical training - knowing when to refer the patient to a specialist.

I do not know that a government agency, especially the FDA, has ever dictated to the medical community that primary care doctors cannot initiate any medical treatment because it may later (in a small percentage of cases) need specialty care. If this proposed requirement, that medical abortion providers be trained in surgical abortion, were applied to other areas of medicine, the primary care doctor would not be able to treat the patient for heart pain with medication or deliver a baby.

Further, primary care doctors are actually the best ones to initiate medical treatments with patients, not the specialists. We already know our patients and their families, and we are aware of all of the counseling issues that will need to

be addressed when a patient comes in with a complicated social or emotional background. In fact, we are probably the best suited to counsel and prescribe mifepristone. The decision about whether to have a surgical or medical abortion can be a complex one, not to mention the decision about whether to have an abortion or not! If a woman chooses a medical abortion instead of a surgical one, following her through the process involves numerous phone calls and follow-up that is also best suited to primary care. The vast majority of situations that arise in patients undergoing medical abortion require talking with the patient, not surgical intervention!

In the current mifepristone trials in which 6,800 women have been safely treated, many of the providers of mifepristone are not Ob/Gyn. In fact, most of the practitioners working directly with the patients are either family practice physicians or nurse practitioners. Here in New York City, two out of the three doctors involved are family practitioners. One of these family practitioners provides surgical abortions and the other does not. This range of providers and situations has not been a safety problem. Restricting mifepristone use to providers of surgical abortion seems to be based on political judgment, not on a medical procedure that has been proven to be safe, effective and part of routine medical practice.

Access Panel

Joan Malin
Chief Executive Officer
Planned Parenthood of New York City, Inc.

Good morning. My name is Joan Malin and I am the Chief Executive Officer of Planned Parenthood of New York City. I would like to thank you for giving me the opportunity to testify today. I will be speaking from our vantage point as a provider of medical abortion, a trainer of practitioners, and an advocate for women's reproductive health and rights.

We believe, and our experience bears out, that women need greater access to abortion services. The shortage of abortion providers nationwide and the marginalization of abortion outside the scope of women's basic health care needs have had a dramatic impact on the health and well-being of women and their families.

Mifepristone has the potential to greatly diminish these problems by expanding access to abortion and by giving women another medical option. Because mifepristone can induce abortion without surgery, it can be provided in almost any health care setting, and it can be safely administered not only by Ob/Gyns but also by family doctors and mid-level providers. If mifepristone is approved with appropriate safeguards, and without unnecessary restrictions, it

will have a profound impact on women's lives by expanding who provides abortion services and where abortions are provided.

To address the provider shortage and the fact that very few teaching hospitals and medical schools offer training in abortion PPNYC established the Clinician Training Initiative (CTI) in 1993. Since then we've trained over 125 medical practitioners to provide comprehensive and caring abortion services.

Our experience as a trainer has shown us that the medical community wants to offer more options to women. Family practice doctors, Ob/Gyns, physicians' assistants, and other clinicians frequently contact us to find out when they can receive training and begin providing mifepristone to their patients.

The interest in medical abortion that we've seen in our training program is also apparent in national data. Many clinicians who are reluctant to provide surgical abortions have expressed a willingness to provide medical abortion. A recent survey by the Kaiser Family Foundation (June 2000) found that about one third of gynecologists and family practice physicians who don't provide surgical abortions said they would be "likely" to prescribe mifepristone to their patients. And while I don't have statistics on interest among other clinicians, anecdotally we've received many inquiries from mid-level providers who would like to be trained in medical abortion.

We have been providing medical abortion at our health centers since 1996, when we became a test site for methotrexate. We have provided approximately 1500 women with safe and effective medical abortions using methotrexate. Through that experience, we've learned that:

- Medical abortion is safe
- Women are pleased with the procedure, and
- Physician's assistants, nurse practitioners and other mid-levels are well suited to provide the service.

Our medical abortion clients tell us they are very satisfied with the experience and the results, and would recommend it to a friend. Women across the country have had similar responses to mifepristone: 96% of women who were part of the U.S. clinical trials said they would recommend it to others and more than 90% said they would choose it again if necessary. (Source: Archives of Family Medicine, 1998)

As you have heard throughout the hearing, women appreciate the many advantages that a non-surgical procedure offers them including being non-invasive, having a feeling of being in control and being able to undergo the procedure in the privacy of their own home.

Although we are quite satisfied with methotrexate, we know that mifepristone is a superior medication (for reasons that Virginia Reath already discussed), and it is frustrating as a provider not to be able to offer our patients the best options available.

As a provider concerned with giving our patients the safest and most effective health care treatment available we believe that there is nothing in the medical research and the clinical experience with mifepristone that warrants the FDA's proposed restrictions.

In administering methotrexate, we've found that patient counseling is the most important skill that a clinician must have to administer medical abortion safely and effectively. Providers must be able to clearly communicate to women how to be participants in the process. Women need to know how and when the medications work, possible side effects, how to manage them, and when to seek follow-up care. These patient counseling skills and all other competencies needed to administer mifepristone effectively are skills that physician's assistants, nurse practitioners and other mid-level providers use in all aspects of their work and are well within their scope of practice. It therefore makes no sense that the FDA may restrict mifepristone to being dispensed only by physicians. Given the need for strong counseling, it defies logic to exclude the group of providers whose expertise is in this area. This limitation would dramatically curtail the opportunity to expand the pool of providers

Requiring that physicians who provide mifepristone be trained in surgical abortion is also a significant problem. Although providers of medical abortion must have surgical back-up arrangements, there is absolutely no reason for them to have surgical abortion experience, any more than there is reason for physicians prescribing ulcer medication to have training in gastric surgery. Again, if this restriction is approved, any promise that mifepristone holds for expanding the number of abortion providers would evaporate.

The approval of mifepristone will have a tremendous impact on the number of abortion providers in this country, and, in turn, on women's access. So long as mifepristone can be offered in the privacy of a doctor's office or the anonymity of a primary care clinic (no protesters), the pool of potential providers is huge. However, if the FDA enacts the surgical-only and physician-only restrictions, this potential pool of providers would disappear. Medical abortion with mifepristone would be no more accessible than surgical abortion is now. For women living in the 42% of New York counties with no abortion provider, that would be very disappointing news.

Those of us who have been using methotrexate have been looking forward to the availability of mifepristone for years -- studies show mifepristone to be a "new and improved" method over methotrexate. Mifepristone is preferable because it works in pregnancies up to 9 weeks and induces miscarriage in two days rather than over one week. It is very disheartening to see the FDA propose extensive restrictions on a superior medication, thereby forcing practitioners to continue to use a medication known to be less effective and which takes longer to work.

Lawrence Lader
President
Abortion Rights Mobilization

Abortion Rights Mobilization (ARM) decided in 1989 that RU-486 could significantly change the character of the United States abortion treatment and devised strategies to win FDA approval of our research projects.

In 1991, I published a book RU-486 to educate the country about the RU-486. In 1992, ARM then brought added attention in by challenging the U.S. Customs ban. I accompanied a woman from London carrying RU-486 to JFK airport and as we'd expected, the pills were seized by Customs. Subsequently, we smuggled in Chinese abortion pills and used them to learn how to make the medication ourselves by producing 80 or so at our Westchester lab. We secured FDA approval to carry out our own clinical studies, and ultimately found a United States manufacturer to produce the pill in large numbers. We have also offered to help the Population Council, and later Danco, to make good use of our research.

Since the FDA approved our tests and the medication as safe and effective in 1996, our trials have treated over 5,700 women for medical abortion with a 97% success rate. This success rate is higher than Europe's. We have also successfully decreased the dosage from 600 mg., as used in Europe, to 200 mg. And our latest research project uses RU-486 to treat fibroid tumors in women, which is a major medical problem, and early test results are highly encouraging.

It is hard to understand why the FDA has proposed these unneeded limitations on Danco's approval process since in 1996 the FDA determined that the drug is safe and effective. Our trials certainly prove that. And these limitations will certainly not expand access to a safe abortion. The women's movement is determined to help Danco despite the negative aspects of the recent Wall Street Journal story. It mentions that the pills may possibly be made in China, which could stir new debate which is unfortunate. One thing is certain: with new appointments to the Supreme Court coming up, the next president must be a pro-

choice president to keep abortion safe and legal, and provide access to this medication.

Legal and Policy Panel

Simon Heller
Director of the Domestic Litigation Department
Center for Reproductive Law and Policy

In July of 1992, my office filed a lawsuit on behalf of Leona Benten, a California woman who attempted to bring a single dose of RU-486 into the United States at Kennedy Airport for her own personal use -- she wanted to terminate her first-trimester pregnancy by non-surgical means. The Administration of President George Bush had placed an "import alert" on all abortifacient drugs, directing the Customs Service to seize any such drugs. That import ban remains in effect to this day, and it demonstrates the stranglehold that the anti-choice movement maintains over this important option for women. Although much has happened since the summer of 1992 -- for example, RU-486 is now available in both the United Kingdom and Sweden, and is widely used in China -- the drug, known by its chemical name mifepristone, remains unavailable to American women. This is even after the French manufacturer of RU-486, Roussel-Uclaf, assigned its patent on the drug to a pro-choice U.S. non-profit organization, the Population Council, and after years of clinical trials and use by hundreds of thousands of women around the world have demonstrated its safety.

Now it appears that the Food and Drug Administration is on the brink of approving mifepristone as a prescription drug. Nevertheless, the aftereffects of the anti-choice movement's efforts to block access to this drug may yet impede the ability of women in the United States to avail themselves fully of the promise of mifepristone. The FDA is reportedly considering approving mifepristone with significant restrictions on its distribution that go well beyond those imposed on other drugs with similar records of safety and effectiveness. Such disproportionate restrictions would impede millions of women's access to this important new alternative to abortion surgery without advancing any genuine health or safety concern.

There is no legitimate basis for the FDA to seek the imposition of highly unusual and stringent distribution limitations on this very safe and efficacious product. Moreover, the FDA should be aware by now that any proposed distribution restrictions are the result of years of anti-choice political pressures by anti-abortion zealots and of the resulting concessions to those pressures made by those involved in bringing mifepristone to the U.S. market. Anti-abortion politics and zealotry, rather than science, is the root of the unusual distribution restrictions being considered throughout mifepristone's approval process. No such restrictions have been or would ever be seriously considered for any other

drug with the impressive safety and efficacy record of mifepristone. Thus, while the FDA may ordinarily give deference to a drug manufacturer's suggestions for distribution limitations, it should not do so in the case of mifepristone, where the proposed limitations stem from politics rather than science and where the restrictions would undercut rather than promote the public health benefits of the drug. Imposing distribution restrictions for political rather than health or safety reasons would undermine the FDA's reputation for careful scientific and medical decision-making.

In addition, imposition of such restrictions raises serious constitutional issues. First, unlike access to most drugs, access to abortifacients is cloaked with strong constitutional protection under the rights to privacy and equal protection of the laws. Accordingly, the government -- including the FDA -- cannot impose restrictions on abortion access unless those restrictions further governmental interests in maternal health or potential life. The restrictions under consideration do not further either of these interests. Rather, they threaten the health of women seeking abortions by greatly decreasing, if not entirely eliminating, the increase in the availability of abortion providers that would attend the approval of mifepristone without distribution restrictions. Second, the government -- including the FDA -- cannot treat abortion and abortifacients differently than comparable procedures and drugs without a strong reason for doing so. The FDA has never imposed special distribution requirements on a drug with the safety and efficacy record of mifepristone -- and there are no legitimate, let alone compelling, reasons to do so in this case. Third, the Supreme Court has long recognized that the exercise of medical judgment by a licensed physician is sufficient to ensure that an abortion is safely performed, and that any additional barriers beyond licensure of the woman's physician are therefore improper obstacles to a woman's exercise of her right to privacy. Thus, any special requirements imposed on physicians who prescribe mifepristone -- like certification in ultrasonography use or possession of hospital admitting privileges -- would impermissibly interfere with this zone of protected medical judgment.

Mifepristone has been called "the moral property of" women -- in France. It represents a major new abortion alternative for American women. Advances in abortion methods have dramatically increased the safety of the procedure in the United States since *Roe v. Wade* was decided in 1973. This progress should not be impeded or halted altogether by distribution restrictions that fail to advance public health. The restrictions under consideration are the product of years of anti-choice political pressures by anti-abortion zealots and of the resulting concessions to those pressures made by those involved in bringing mifepristone to the U.S. market.

In closing, we commend the Office of the Public Advocate for highlighting the importance of unimpeded access to mifepristone for women in the United States.

Donna Lieberman
Director
New York Civil Liberties Union Reproductive Rights Project

The fundamental right to choose is a reality only when there is access to safe and effective methods of abortion. RU-486, also known as mifepristone, is one of the most important technological advances for abortion. It promises to expand access by providing women and their doctors with a more private means of terminating pregnancies than surgical abortion. Yet, this imperative technology has been consistently undercut by anti-choice politics and the climate of fear perpetuated by anti-choice violence. Although RU-486 is described as the moral property of women, American women have been waiting ten years to gain access to it. The approval process simply is taking too long.

We know that RU-486 is safe and effective. It was approved for distribution 12 years ago in France, and is widely available in Europe. Suppliers of the drug say more than 600,000 women have used it worldwide. Four years ago the FDA adjudicated RU-486 approvable in terms of its safety and effectiveness. The FDA also has permitted clinical trials of the drug. Really, all that remains are issues regarding labeling and distribution.

Although the FDA has jurisdiction over labeling practices, it would be inappropriate for the FDA to enact restrictions on the distribution of RU-486. Restricting RU-486 distribution to those who are trained to provide surgical abortions, medical abortions and sonograms, and those who have admitting privileges to a hospital emergency room within one hour of a patient's residence, would exceed the FDA's authority.

The FDA itself has said, "Congress did not intend the [FDA] to interfere with medical practice . . . [or] to regulate the practice of medicine as between the physician and the patient."[1] A restriction that imposes special training and experiential requirements on medical professionals who seek to prescribe mifepristone, in essence, regulates the practice of medicine. Regulation of the practice of medicine is a matter for the states. Nothing in the FDA's authorizing statute empowers the agency to impose such restrictions. To the contrary, it is well established that "the FDA does not have jurisdiction to regulate the administration of a drug by a physician."[2] Indeed, the FDA itself recognizes that "the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert," without obtaining FDA approval.[3]

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[1] 37 Fed. Reg. 16,503, quoted in Federal Trade Commission v. Simeon Management Corp., 391 F. Supp. 697, 706 (N.D. Cal. 1975).
[2] Simeon, 391 F. Supp. at 706.
[3] 37 Fed. Reg. 16,503, quoted in Simeon, 391 F. Supp. at 706.

to travel to outside clinics. Women also would be able to avoid the emotional abuse dished out by anti-choice groups at abortion clinics by getting treatment in the privacy of their own doctor's office. However, if distribution of RU-486 is restricted to current abortion providers, women will have to travel to the same distant clinics and suffer the same anti-choice harassment. Moreover, if the FDA insists that misoprostol, the drug that is taken after mifepristone, be administered in the presence of a "certified provider," women will have to make yet another trip to an outside facility.

There is great potential for RU-486 to augment women's access to safe and effective reproductive healthcare. It is important that the FDA not undercut this extraordinary technological advance for abortion. RU-486 should be available for medical practitioners who are not prepared to go through the procedural and regulatory hoops to provide surgical abortion procedures. We know that RU-486 is safe and we know that it is effective. Indeed, only 5% of the women who take this pill need further treatment. It's time that politics stopped hindering American women's ability to obtain mifepristone -- a drug that will give them the means to terminate their pregnancies early, safely and privately. It's time that we improve women's access to reproductive healthcare so that the promise of reproductive choice is fulfilled in reality. It's time that we take a step forward – finally – to ensure that women can make the difficult and intimate decision of whether to continue a pregnancy to women. RU-486 has the potential to help us do that.

In New York, as in other states, in the 70s and 80s, shortage of licensed medical providers prompted the licensing of new categories of health care provider: physician assistant, nurse practitioner, nurse midwife. Generally their scope of practice depends on their training and skills and the agreements they have with physicians who supervise them and/or collaborate with them. They are not limited to specific procedures. They have varying degrees of prescriptive authority. RU-486 abortion consists of exam, counseling, and administration components. Advanced practice clinicians are authorized to perform all the components of medical abortion in this and other contexts in NY. They are active participants in the clinical trials currently going on under FDA auspices. FDA restrictions on administration of RU-486 would interfere with state regulations regarding practice of medicine. Restrictions on RU-486 distribution to MDs who are certified to provide abortion would impose a unique, medically unwarranted limitation on RU- 486. Doctors don't need special certification to do surgical abortion and or brain surgery in NY. These restrictions would interfere with state regulation of practice of medicine.

Kelli Conlin
Executive Director
NARAL-NY

My name is Cristina Page, here on behalf of Kelli Conlin and NARAL/NY. In an effort to avoid restating what many before me have explained, I will be limiting my comments to the role that politics have played in keeping RU-486, or mifepristone, from American women. It is important to note that the FDA is a government agency charged with neutrality, responsible for making decisions based on need, safety and efficacy, not popular opinion, emotion or organized pressure. However, if one reviews the long, fraught journey of mifepristone through the FDA, it becomes clear that the main character of this story is not reason but politics.

Twelve years ago, in 1988, the French minister of health approved the general use of RU-486. Then the anti-choice movement organized protests, parades and temporarily succeeded in getting Roussel to withdraw the pill from the market. In a noble decision, the French government reintroduced RU-486 to the market hailing it as the "moral property of women." It has been used safely by French women for over a decade. However, fearing similar, more intense protests and boycotts from the more organized and more extreme US anti-abortion movement: importing of RU486 to the US shores was delayed.

In 1990, the American Medical Association announced its support for the introduction of RU-486 to the United States, explaining that the drug is an equally effective noninvasive procedure which is always preferable to a surgical one. However, anti-choice forces kept pressure on the Bush administration. Choosing to follow a political recommendation instead of a medical recommendation, the Bush administration banned the drug's introduction.

The journey of RU-486 through politics has taken it to unusual places: such as an Agricultural-spending bill. Introduced by Rep. Tom Coburn, this amendment to the agricultural bill sought to prevent the FDA from using any funds to test, develop or approve drugs that can be used as abortifacients. Coburn stated, "The federal government has no right to use taxpayer dollars to develop abortion drugs." Anti-choice operatives have even tried to block the confirmation of an FDA Commissioner, because of their suspicions that she may support approval of the pill.

The anti-choice movement has been involved in trying to shape the FDA's policy; they have tried to dictate FDA protocol. In the words of Laura Echevarria, a spokeswoman for the National Right to Life committee, "We've asked the FDA to review the whole approval process."

The need for mifepristone in the United States is great. Statistically speaking, close to 50% of the nation's surgical abortion providers are close to or

at the age of retirement. With constant, increasingly violent attacks on abortion providers, the prospect of offering comprehensive reproductive health services, including abortion, to patients has become too frightening for this current generation of doctors. For them, offering abortion services means offering surgical abortion services–not a procedure that can be easily performed in a private office setting–instead most often taking place in clinics–with protestors orbiting the perimeters and where a doctors' anonymity is more difficult to preserve.

RU-486 brings privacy back to a procedure that deserves it most. It returns abortion care to a private discussion and decision in a doctor's office. The threat this drug poses to the anti-choice movement is clear: no more doctors to target. It disarms abortion opponents of their main, most successful, strategy.

The anti-abortion movement has forced doctors into bullet-proof vests, subjected patients through screaming, abusive crowds, pushed politicians into private healthcare decisions, and now threatens to scare the FDA into its first decision based not on medical proof but on fear of fallout. It would be a historic tragedy, a threat to the future of medicine, to allow this to happen.

Nancy Millar
President
New York City Chapter of the National Organization for Women

As an organization devoted to equality for women, NOW considers women's right to control all aspects of our reproduction a vital part of achieving equality. The political interests that have acted to postpone availability of mifepristone in the United States are not about drug safety; they are about limiting the reproductive choices of women. Facts show that increased reproductive options—including safe, available contraception; sex education; and safe, legal abortion—advance women's ability to participate as equals in our society through safer pregnancy and childbirth, lower maternal-mortality rates, and lower infant-mortality rates. The FDA's delay of approval of mifepristone smacks of the misogynist tactics of abortion-clinic attackers, medical schools that don't teach abortion, and religious hospitals that won't perform abortions or prescribe contraception —noxious, dangerous, and ultimately political attempts to control women's bodies through intimidation, misinformation, and unconstitutional limitations.

As a feminist organization devoted to winning equal rights for women through grassroots mobilization, NOW considers women's right to control all aspects of our reproduction a vital part of achieving equality. To that end, we have fought since the 1960s against the erosion of our most basic human right to control our bodies.

The FDA's delay of approval of mifepristone smacks of the misogynist tactics of abortion-clinic attackers, medical schools that don't teach abortion, and religious hospitals that won't perform abortions or prescribe contraception- onerous, unnecessary, dangerous, and ultimately political attempts to control women's bodies through intimidation, misinformation, and unconstitutional limitations. If it is true that the Food and Drug Administration consistently considers patients' safety above all other factors, then why were potentially dangerous drugs such as Viagra and Fen-Phen approved so quickly and without similar obstacles? And why are silicone breast implants still widely available? The political interests that have acted to postpone availability of mifepristone in the United States are not about drug safety; they are about limiting the reproductive choices of women.

Research shows that increased reproductive options-including safe, available contraception; sex education; and safe, legal abortion-advance women's ability to participate as equals in society through safer pregnancy and childbirth, lower maternal-mortality rates, lower infant-mortality rates, and increased control of planning when and if to have children. The approval and availability of mifepristone as a safe and affordable method of early abortion will offer women more reproductive options and, thus, healthier and longer lives. Mifepristone's value lies in its ability to complement surgical abortions, which are increasingly difficult to obtain for women around the U.S. But tacking on medically unnecessary restrictions that make mifepristone just as scarce and inaccessible as surgical abortions renders its potential meaningless.

The proposed restrictions violate the rights and privacy of patients and doctors, and they establish a standard for abortion drugs that is unequal to and more burdensome than standards for other drugs. The Food and Drug Administration's Advisory Committee for Reproductive Health and Drugs recommended approval of mifepristone in 1996, and thousands of women in Europe and China have successfully and safely used the drug for more than a decade. The women of New York urge FDA Commissioner Jane Henney and President Bill Clinton to approve mifepristone, without restrictions, for use in the United States now.

Submission of Steven Tamarin, M.D. of Physicians for Reproductive Choice and Health

The American Academy of Family Physicians believes that documentation of training and experience is of utmo... only for residents preparing for their first application for hospital privileges, but also for practicing physicians who will b... subjected to increasingly rigorous recredentialing procedures.

The AAFP recommends that family physicians document all significant training and experience so that it is recorded and can be reported in an organized fashion. Such documentation should include at a minimum all procedural skills, intensive/critical care experiences, treatment of major illnesses, and other significant training and experiences. (1989) (1995)

Electrocardiogram Interpretation Privileges

The AAFP believes that qualified family physicians should be allowed to interpret electrocardiograms in the hospital and that local tests to assure competence may be appropriate as long as they apply equally to all physicians. (1982) (1998)

Emergency Care Services Privileges

Family physicians, through training and experience, are qualified to provide emergency care services. The American Academy of Family Physicians believes that privileges to practice in the emergency department should be based on the individual physician's documented training and/or experience, demonstrated abilities, and current competence and not solely on the physician's specialty. (1995)

Family Physicians

Family medicine encompasses continuous, comprehensive, quality care emphasizing patient advocacy. Family physicians should have access to their patients in all areas of a healthcare institution, including areas of high technological care, through appropriate privileges. Patients should have access to family physicians in all these areas. (1984) (1996)

Family Practice Departments and Privileges

The AAFP recommends the establishment of family practice departments in all hospitals departmentalized by specialty. The department of family practice should have all the rights, duties, and responsibilities comparable to other specialty departments of the medical staff. It should have the right to recommend directly to the appropriate committee those privileges which fall within the scope of family practice. The assent or approval of any other department should not be required.

Privileges for family physicians very often overlap those in other clinical departments, and there seems to be some confusion as to which department is responsible for recommending privileges. For example, the family physician may request "surgical" privileges

Submission of New York State Assemblywoman Deborah J. Glick

THE ASSEMBLY
STATE OF NEW YORK
ALBANY

DEBORAH J. GLICK
Assemblymember 66th District
New York County

CHAIR
Ethics and Guidance Committee

COMMITTEES
Children and Families
Governmental Employees
Social Services
Environmental Conservation
Ways & Means

TESTIMONY ON THE POSSIBLE FDA RESTRICTIONS ON THE USE AND DISTRIBUTION OF RU - 486

The approval of RU-486 is already long overdue. The pill has been tested in both international and national trials and in spite of the results indicating it is as safe as many drugs already approved for use, the FDA continues to withhold its approval and is considering restrictions that will limit its access.

RU-486 is most commonly known for its use as a non-surgical means for early abortion, however, there are other uses for which it should also be licensed. While abortion may be legal, in over 45% of the counties in New York State women still don't have local access. This is due in large part to doctors and other service providers hounded out of performing the service because their lives and practices have been threatened. When the most responsible of providers are chased away, the likelihood exists that those left providing the service may do so in smaller and less appropriate settings.

The FDA proposal to require all physicians dispensing and administering RU-486 to register and currently be licensed to perform surgical abortions and have admitting privileges in hospitals no more than an hour from their offices, deters them from offering the pill because they will again be exposing themselves to the possibility of anti-abortion violence. The FDA's proposal is both restrictive and counterproductive. The availability of RU-486 should provide greater access and availability to women who want to terminate an unwanted pregnancy, not the same level of difficulty and discouragement they currently encounter.

There is no scientific or medical basis to delay the approval of RU-486 any longer and no reason other than ultra-conservative politics to restrict women's access to it. It is clearly the promise of ensuring the availability of early abortion, in relative confidence, without the fear of violence or harassment that is delaying approval at this time. RU-486 is considered to be one of the most significant developments in the pro-choice movement. It is a simple, immediate and private alternative for a woman seeking to terminate her pregnancy at an early stage.

All women should have access to the most current and the best medical treatments available. The early-abortion pill, RU-486 represents just such treatment. No other medication has had this degree of restriction and licensing requirements imposed on it. These requirements represent an undue burden for health care providers. They create unacceptable barriers to safe medical treatment for women seeking to exercise their constitutional right to abortion. Clearly, the restrictions are totally unacceptable. RU-486 is being held hostage to politics and the restrictions on dispensing it must be lifted to expand rather than continue to limit choices for women.

❑ DISTRICT OFFICE: 353 Broadway, Suite 2120, New York, New York 10003-4703, (212) 674-5153, FAX (212) 674-5530
❑ ALBANY OFFICE: Room 454, Legislative Office Building, Albany, New York 12248, (518) 455-4841, FAX (518) 455-4649

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 4, 2000

Mr. Mark Green
Public Advocate for the City of New York
1 Centre Street
New York, New York 10007

Dear Mr. Green:

Thank you for your letter of September 22, the copy of the public hearing report, and your support for the approval of mifepristone. As I am sure you are aware, FDA approved this non-surgical alternative on September 28. I am enclosing a copy of a press release announcing the approval. For more detailed information on the approval, please review our website, which may be found online at:
http://www.fda.gov/cder/drug/infopage/mifepristone/

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

Enclosure

trac# 00 5966

cc:
HF-1 (2 copies)
HF-2
HF-8
HF-10
HFA-224

RD: -40:9/29/2000
cleared/revised: :HF-40:10/02/00
cleared/revised HF-40:10/03/00
Revised HF-1:10/4/00
F/T: -40:10/4/00

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P00-19
September 28, 2000
FOR IMMEDIATE RELEASE

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6250
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA APPROVES MIFEPRISTONE FOR THE TERMINATION OF EARLY PREGNANCY

The Food and Drug Administration today approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.

Under the approved treatment regimen, a woman first takes 600 milligrams of mifepristone (three 200 milligram pills) by mouth. Two days later, she takes 400 micrograms (two 200-microgram pills) of misoprostol, a prostaglandin. Women will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated.

Because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side

-More-

- Current long-term therapy with corticosteroids
- History of allergy to mifepristone, misoprostol or other prostaglandins
- Bleeding disorders or current anticoagulant (blood-thinning) therapy.

Under the terms of the approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding -- or they must have made plans in advance to provide such care through others.

To gather additional data about the use of mifepristone, the Population Council (sponsor of the product) has made a commitment to conduct postmarketing studies. These include a study comparing patient outcomes among physicians who refer their patients needing surgical intervention, compared to those who perform surgical procedures themselves; an audit of prescribers that will examine whether patients and their physicians are signing the patient agreement and placing it in the patient's

medical record, as required; and a system for surveillance, reporting and tracking rare ongoing pregnancies after treatment with mifepristone in the U.S.

Mifepristone, which was developed by a French pharmaceutical firm, was first approved for use in France in 1988. Since then, more than 620,000 European women have taken mifepristone in combination with a prostaglandin to terminate pregnancy. The drug has also been approved in the United Kingdom, Sweden, and other countries.

Mifepristone will be distributed in the U.S. by Danco Laboratories, LLC, New York, N.Y.

More detailed information about this product is available on FDA's website at http://www.fda.gov/cder/drug/infopage/mifepristone/

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Mifepristone – Public Affairs provided *NBC's Today Show* with background information on the approval of mifepristone. The story is expected to focus on the science behind the approval and how women can obtain the drug. The segment is expected to air next week.

DRUGS

PRODUCT APPROVALS

Mifeprex Approved – On September 28, the Agency approved Mifeprex (mifepristone) for terminating early pregnancy (49 days or less since last menstrual period). Because it is important to closely follow the treatment regimen, a medication guide will be given to each woman receiving the medication. The medication guide will explain how to take

DRUGS

Write-in Campaign – Since May, the Agency has received 9,801 letters, cards, and e-mail messages from the public concerning the pending approval of mifepristone.

Mifepristone Write-in Campaign – Through July 19, the Agency has received 2,114 letters, cards, and e-mail messages supporting the approval of mifepristone. During the same period, the Agency received 56 messages opposing mifepristone.

- The *Wall Street Journal* submitted three requests for information concerning mifepristone. These are 1) copies of all correspondence, approval records, and labeling from 1996 to present; 2) copies of all correspondence from the Population Council; and 3) copies of all correspondence on mifepristone and Danco Labs, Neogen Pharmaceuticals, Neogen holdings, and Neogen investors.

Write-in Campaign – As of May 1, the Agency received 388 cards/letters in support of and 31 against the approval of mifepristone.

APPEARS THIS WAY
ON ORIGINAL

Write-in Campaign – On March 9, the Agency received 244 cards in support of making mifepristone available to women in the U.S. (This total represents the initial day-1 mailing on this issue.)

Approvable Letter Issues for Mifepristone – On February 18, the Agency issued an approvable letter to the Population Council for mifepristone. Mifepristone, when used in

combination with misoprostol, is being evaluated for terminating early pregnancy. Under PDUFA, the Agency has a 6-month goal for acting on information submitted in response to an original action. The Agency first acted on this application by issuing an approvable letter on September 18, 1996. OPA issued a Talk Paper in conjunction with the release of the letter to further describe this action.

September 27, 1996

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

WRITE-IN CAMPAIGNS

[redacted]

2. RU-486 - The campaign in support of the approval of RU-486, coordinated by Working Assets Citizen Letter, has now generated 29,800 letters to Dr. Kessler. Another write-in campaign, spearheaded by the Feminist Majority Foundation resulted in 4,800 letters to the Commissioner in support of the drug; this campaign has now ended.

[redacted]

September 20, 1996

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

WRITE-IN CAMPAIGNS

1. RU-486 - The campaign in support of the approval of RU-486 coordinated by Working Assets Citizen Letter has now generated 26,400 letters to Dr. Kessler. Another write-in campaign spearheaded by the Feminist Majority Foundation has resulted in 4,800 letters to the Commissioner in support of the drug.

DRUG ISSUES

5. RU-486 Approvable Letter - On September 18, the Agency issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. Additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made. On July 19, the Reproductive Health Drugs Advisory Committee voted 6-0 with two abstentions that the benefits outweigh the risks for use of the regimen for the proposed indication in the U.S. The mifepristone NDA was filed on March 18, 1996.

August 30, 1996

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

7. RU-486 Write-In Campaign - In the last two weeks, we have received about 4,000 identical letters urging the Agency to approve mifepristone for medical use in the U.S. A sample letter is attached.

CitizenLetter

An urgent message from a concerned citizen

August 24, 1996

Commissioner David Kessler
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner David Kessler,

I am writing to urge you to approve mifepristone for medical use in the United States.

Commonly known as RU-486, mifepristone is a safe and effective method for ending early pregnancies without surgery. Women in Europe have been using this drug with great success for nearly a decade. But anti-choice forces have used intimidation and scare tactics to keep mifepristone out out of this country.

Why have U.S. women been denied access to RU-486? Because, it can be administered in the privacy of a doctor's office, making it more difficult for anti-abortion zealots to harass and terrorize women. After years of scientific research, a special advisory committee for the Food and Drug Administration has finally recommended its approval.

Once mifepristone is approved, it will allow women to exercise an important constitutional right and offer them a safe, private alternative to surgical abortions. I urge you to keep politics out of medicine and to make mifepristone available in the U.S. without delay.

Please tell me what you intend to do on this vital issue.

Sincerely,

July 26, 1996

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

2. RU-486 (mifepristone) - The Reproductive Health Drugs Advisory Committee met on July 19 to discuss the NDA for mifepristone for the interruption of early pregnancy. Presentations were made by the Population Council and the Reproductive and Urologic Drug Products Division, as well as by an extensive list of interested parties in the open session. The committee voted 6-2 that the results from open label studies in France established the efficacy of the proposed regimen (600 mg oral mifepristone within 49 days after the beginning of the last menstrual period, followed by 400 mcg oral misoprostol 48 hours later). The committee voted 7-0 with one abstention that the regimen was safe for use in the U.S. for the proposed indication. The committee voted 6-0 with two abstentions that the benefits outweigh the risks for use of the regimen for the proposed indication in the U.S. The committee also addressed labeling issues and the proposed drug distribution system and recommended post-marketing studies.

July 19, 1996

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

MIF 003950

6. Advisory Committee Meeting to Review RU-486 - The Reproductive Health Drugs Advisory Committee is meeting today to discuss the NDA for mifepristone (RU-486) for the interruption of early pregnancy. A number of anti-abortion groups wrote Commissioner Kessler a letter on July 10, asking for the cancellation of the advisory committee meeting. The letter alleges that as many as five of the advisory committee members may have a direct or apparent conflict of interest because of a financial interest in organizations that provide abortions or because of other biases. FDA responded to the letter on July 16, assuring the groups that the Agency consulted with the HHS Office of the Special Counsel for Ethics and the U.S. Office of Government Ethics, which found no violations of any ethics law or regulations (thereby obviating the need to consider cancellation of the meeting). Recent consumer letters to FDA supporting approval of RU-486 ——— outnumber those against approval.

July 12, 1996

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

9. Upcoming Advisory Committee Meetings -

The Reproductive Health Drugs Advisory Committee will meet again on July 19 in Gaithersburg to discuss NDA data submitted by the Population Council for **mifepristone (RU-486)** for the interruption of early pregnancy. Demonstrations are possible.

April 5, 1996

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

March 24, 1995

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

5. RU-486 Application Submitted - The Population Council, U.S. patent holders of RU-486, last month submitted an NDA based on trials in more than 2,000 American women. RU-486 would be the first drug specifically approved by the Agency for non-surgical abortion. Side effects may include heavy bleeding and nausea. The Population Council has given exclusive legal rights for manufacturing and distribution of the drug to

March 3, 1995

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

3. Citizen Petition on RU-486 - On February 28, Americans United for Life, members of Congress (including Thomas J. Bliley, Jr.), and others submitted a citizen petition to FDA specifically requesting that the Commissioner refuse to approve any NDA for RU-486 for use as a pharmaceutical abortifacient. The petitioners are concerned, in part, that RU-486 could be approved in the U.S. based largely on foreign data, with only limited safety data generated from studies conducted in the U.S.
(Contact:

May 20, 1994

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

[redacted]

DRUG ISSUES

2. RU-486 - On Monday, Secretary Shalala announced that Roussel Uclaf is donating, without remuneration, its U.S. patent rights for RU-486 to The Population Council, a not-for-profit corporation. The Secretary emphasized that the donation does not mean that RU-486 has been approved for use in the U.S. The Population Council must conduct clinical trials, identify a manufacturer and submit an NDA to FDA. She indicated that FDA will do all it can to quickly evaluate RU-486 once an NDA is submitted and that FDA's decision will be based solely on the scientific and medical evidence as to the safety and efficacy of the drug. (Contact: [redacted]

[redacted]

March 18, 1994

TO: Dr. Kessler/Dr. Henney/

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

In Thursday's New York Times, a letter was published in the OP-ED section from Lawrence Lader, President of Abortion Rights Mobilization (ARM), describing ARM's arrangements with a commercial laboratory to begin producing 3,000 grams of RU-486 for testing in animals. Mr. Lader's letter calls on Congress to begin holding hearings immediately on the possibility of removing Hoechst's patent on RU-486 based on "the public interest." (Contact:

February 18, 1994

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

DRUG ISSUES

1. RU-486 - According to today's New York Times, the Marie Stopes Health Clinic in London has reached an agreement with the British Government's Department of Health allowing the clinic to offer RU-486 to nonresidents. Until now, British health authorities have forbidden the drug to be dispensed to nonresidents.
(Contact:

November 19, 1993

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

[redacted]

5. Clinical Testing of RU-486 for Breast Cancer Approved - According to today's New York Times, FDA has approved clinical testing of RU-486 to treat women with advanced breast cancer. The tests will be conducted by the Breast Center and Cancer Institute at Long Beach Memorial Medical Center and will involve as subjects 40 women whose cancer has spread beyond the breast. The subjects, now being sought for the trial, must have responded in the past to some form of hormonal cancer treatment to be eligible to participate in the trial. Similar trials have been underway in Canada and France.

[redacted] (Contact: [redacted]

[redacted]

September 10, 1993

TO: Dr. Kessler/

SUBJECT: Office of Executive Secretariat Weekly Information Update

- RU-486 - On Thursday, a number of papers reported on an IOM committee's report recommending that FDA evaluate RU-486 based on European data without additional testing in this country. The committee recommended that RU-486 and other antiprogestins be extensively studied as possible treatment for many health problems besides abortion.

4

May 21, 1993

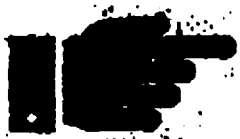
TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

MIF 003964

8. RU-486 Petitions - This week, the Office of Executive Secretariat received a large box of petitions "to keep RU-486 out of the U.S." The petitions were prepared by the Right to Life League of Southern California and are addressed to Edouard Sakis of Roussel-Uclaf, Wolfgang Hilger of Hoechst, and Frank Young of FDA. A sample is attached at Tab A. (Contact: [redacted]

(7)



Send this form to the Right to Life League of Southern California,
50 N. Hill Ave., #306, Pasadena, CA 91106.

PETITION TO KEEP RU-486 OUT OF THE U.S.

To: Edouard Sakis, Chair
Roussel Uclaf
Paris
FRANCE

To: Wolfgang Hilger
Hoechst, A.G.
Frankfurt
W. GERMANY

To: Hon. Frank Young
Food & Drug Adm.
Rockville, MD 20852

Whereas Roussel Uclaf holds the patent on RU-486, the new human pesticide, chemical coathanger, death pill, which will kill millions/billions of babies and maim thousands of women;

Whereas Any firm will be subjected to economic reprisal if it tries to bring RU-486 into the U.S.;

Whereas The vast majority of Americans are opposed to the slaughter of children; whether by dismemberment, chemical, or other means;

Therefore I add my name to the list of American humanitarians who love children, who will fight ardently to keep this death pill out of our country, and who desire to see a return of the scientific community to research for the preservation, not destruction, of life.

MIF 003966

(2)

Send this form to the Right to Life League of Southern Cal., 50 N. Hill Ave., #306, Pasadena, CA 91106.

To: Edouard Saikh, Chair
Roussel Uclaf
Paris
FRANCE

To: Wolfgang Hilger
Hoechst, A.G.
Frankfurt
W. GERMANY

To: Hon. Frank Young
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Rockville, MD 20852

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Address zip Date

The scientific community is advertising this abortion pill, RU-486, with potential side effects of severe nausea, vomiti and uterine bleeding as a "safe and effective treatment". The most devastating side effect is to terminate the life of a pre-born child, and it also puts the mother's life at risk.

PETITION TO KEEP RU-486 OUT OF THE U.S.

To: Edouard Saikh, Chair
Roussel Uclaf
Paris
FRANCE

To: Wolfgang Hilger
Hoechst, A.G.
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W. GERMANY

To: Hon. Frank Young
Food & Drug Adm.
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Therefore I add my name to the list of American humanitarians who love children, who will fight ardently to keep this death pill out of our country, and who desire to see a return of the scientific community to research for the preservation, not destruction, of life.

Copy

February 26, 1993

TO: Dr. Kessler/ [redacted]

SUBJECT: Office of Executive Secretariat Weekly Information Update

[redacted]

5. RU-486 - On February 24, the agency met with representatives from Roussel-Uclaf, the manufacturer of RU-486. The agency has said that it would welcome an NDA for RU-486 to allow it to determine if the drug represents a safe and effective alternative to surgical abortion. The February 24 discussions concerned clinical and manufacturing data on the drug, focusing on the types of data FDA would need in considering an NDA for RU-486. The manufacturer pointed out that an early step toward approval would be a large clinical trial in which U.S. physicians would be trained in the use of RU-486 and data could be collected on how the drug could be safely and effectively administered in typical medical settings in this country. While asserting that RU-486 should be made available in the U.S., the firm emphasized the importance of finding a way to achieve that goal without the involvement of Roussel-Uclaf. FDA and Roussel-Uclaf agreed to continue to work on this matter until remaining issues can be resolved. The company also said that it remains strongly committed to continuing to make the drug available for research on other potential uses. (Contact:

February 12. 1993

TO: Dr. Kessler

SUBJECT: Office of Executive Secretariat Weekly Information Update

6. RU-486 - On February 5, Secretary Shalala published in the Federal Register President Clinton's January 22 memorandum which directs FDA to review its import alert on RU-486 (mifepristone) and to assess initiatives to promote testing of RU-486. (Contact: [redacted])

November 20, 1992

TO: Dr. Kessler/ [redacted]

SUBJECT: Executive Secretariat Information Update

4. RU 486 Write-In Campaign - Since Monday, our office (Executive Secretariat) has received over 3,800 form letters urging the agency to life its import ban on RU-486. A sample of the form letter is attached at Tab B. (Contact: [redacted]

CitizenLetter

CitizenLetter is a service of Working Assets Long Distance.

November 10, 1992

Commissioner David Kessler,
Food and Drug Administration
5600 Fishers Lane
Rockville, MD
20857

Dear Commissioner Kessler,

An agency of your stature should not ban drugs for political reasons. Yet that is what you have done with RU 486.

RU 486 is a proven, no-surgical method of terminating pregnancy that has been safely used by over 100,000 European women. It also shows promise as a "morning after" pill for preventing pregnancy, and as a treatment for breast cancer and other diseases affecting women.

RU 486 is not sold in the United States because the manufacturer has been unwilling to face the political controversy it generates. But the drug COULD be imported for personal use if your agency had not placed it on the "import alert" list. This requires U.S. Customs officials to stop the drug from entering the country, even for use under medical supervision.

Normally, drugs are placed on the import alert list because they are dangerous. This is not the case when RU 486 is used under a doctor's supervision. Clearly, your ban was imposed for political, not medical, reasons.

Please don't play politics with women's freedom and women's lives. I urge you to lift the import ban on RU 486 now.

Sincerely,

MIF 003973

FILE COPY

September 11, 1992

TO: Dr. Kessler [redacted]

SUBJECT: Executive Secretariat Information Update

[redacted]

DRUGS ISSUES

2. Swedes Approve RU-486 - CDER has received word from the World Health Organization that RU-486 has been approved in Sweden as an abortifacient. The Swedes have recommended its use with the prostaglandin Gemeprost suppository, which is not approved in the U.S. The French also approved Gemeprost suppository to be used with RU-486. (Contact: [redacted]

[redacted]

July 31, 1992

TO: Dr. Kessler

SUBJECT: Executive Secretariat Information Update

3. RU-486 Hearing - Representative Wyden's House Small Business Subcommittee on Regulation, Business Opportunities and Energy conducted a hearing on RU-486 last week at which the actress Cybill Shepherd, among others, urged Congress to allow importation of the drug. FDA did not testify. [redacted], Atlanta, a brain meningioma victim, recounted his and his physician's futile attempts to acquire RU-486 from Roussel Uclaf to treat his condition under a single-patient (compassionate) IND. He testified (incorrectly) that FDA's import "ban" on RU-486 jeopardizes his chances to survive and that red tape has thwarted his efforts. However, he also testified that the company was not willing to release the drug to him.

[redacted]

(Contact: [redacted]

[redacted]

File

July 17, 1992

TO: Dr. Kessler/ [redacted]

SUBJECT: Executive Secretariat Information Update

6. RU-486 - In the case of the RU-486 pills carried into the country from England by a 7 1/2 week pregnant woman and seized by customs officials in New York on July 1 in keeping with FDA's import alert, a class action suit was filed on July 7 on behalf of all women who want to import the drug for personal use. A U.S. District Court judge ruled in her favor and found FDA's policy illegal. Justice Department lawyers obtained an order from the appeals court staying the District Court ruling. The case is expected to be decided by Justice Clarence Thomas, possibly this afternoon. (Contact:

July 2, 1992

TO: Dr. Kessler

SUBJECT: Executive Secretariat Information Update

7. RU-486 - A woman attempted to bring RU-486 into the country yesterday for her personal use as an abortifacient. The drug was confiscated, amidst much publicity, under the import alert for RU-486. (Contact: [redacted]

FILE COPY

March 13, 1992

TO: Dr. Kesslen

SUBJECT: Executive Secretariat Information Update

2.

4.

MIF 003981

6. Mifepristone – FDA provided *NBC's Today Show* with background information for a story on the approval of mifepristone. The story is expected to focus on the science behind the approval and how women can obtain the drug. The segment is expected to air next week.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2000

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

NEW ITEMS

1. Mifeprex (Mifepristone) Approved – On September 28, the Agency approved Mifeprex (mifepristone) for terminating early pregnancy (49 days or less since last menstrual period). Because it is important to closely follow the treatment regimen, a medication guide will be given to each woman receiving the medication. The medication guide will explain how to take the drug, who should avoid it, and its side effects. Under the terms of approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or they must have made plans in advance to provide such care through others. To gather additional data about the use of mifepristone, the Population Council (sponsor of the product) has committed to conducting postmarketing studies. Mifepristone was first approved in France in 1988 and is also approved in the United Kingdom, Sweden, and other countries. The press release, the medication guide, and more information on this approval is available on FDA's web site.

6. Write-in Campaign – Since May, the Agency has received roughly 11,200 letters, cards, and e-mail messages from the public concerning the pending approval of mifepristone.

/S/

FDA Executive Secretariat

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 18, 2000

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

UPDATES

3. Mifepristone – Today, FDA issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol. The drug regimen is being evaluated for the termination of early pregnancy. The Population Council's new drug application was filed in March 1996, and in July of that year, an FDA advisory committee found the data supportive of approval. The Agency issues approvable letters to manufacturers or sponsors when questions need to be resolved before final marketing approval can be granted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 20, 1996

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

NEW ITEMS

1. Approvable Letter for Mifepristone (RU-486) - On September 18, 1996, FDA issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol (an oral prostaglandin), for the termination of early pregnancy. The Agency has determined that the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision. However, additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made. Adverse events in the European and U.S. clinical trials involving more than 4,480 women included contractions of the uterus, nausea, vomiting, diarrhea, pelvic pain and spasms, and headache. A very small percentage of patients required hospitalization, surgical treatment, and/or blood transfusions.

   Over the past few weeks, FDA has received more than 31,000 letters in support of the approval of RU-486.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 8, 1996

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

3. RU-486 Application Submitted - The Population Council, U.S. patent holders of RU-486, last month submitted a new drug application to FDA based on trials in more than 2,000 American women. RU-486 would be the first drug specifically approved by the Agency for non-surgical abortion. Side effects may include heavy bleeding and nausea. The Population Council has given exclusive legal rights for manufacturing and distribution of the drug to

/S/

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 12, 1996

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

11. Reproductive Health Drugs - The Advisory Committee for Reproductive Health Drugs will meet on July 19, 1996, to discuss the new drug application for mifepristone (RU-486) for the interruption of early pregnancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 28, 1996

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

ADVISORY COMMITTEES

6. Reproductive Drugs - On July 19, 1996, the Advisory Committee for Reproductive Drugs will consider data submitted by the Population Council as part of a new drug application for mifepristone (also known as RU-486 and the "French abortion pill") for interruption of early pregnancy. As part of its review process, FDA routinely seeks outside input and will ask the panel for a recommendation on the safety and effectiveness of the drug.

/S/

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 4, 1994

Note to: [redacted]

This note is to provide you with background on selected FDA issues and activities.

UPCOMING HEARINGS

8. RU-486; - The Subcommittee on Regulation, Business Opportunities, and Technology of the House Committee on Small Business (Wyden) has scheduled an oversight hearing on May 16, 1994, regarding obstacles in getting RU-486 approved in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 16, 1992

Note to: [redacted]

This note is to provide you with background on selected FDA issues and activities.

4. RU-486 in Sweden - The World Health Organization has informed FDA that RU-486 has been approved in Sweden as an abortifacient. Swedish health officials have recommended its use with the prostaglandin Gemeprost suppository, which is not approved in the U.S.

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

Attachments

WEEKLY REPORT -- (October 6 to October 23, 2000)

FDA Approves Mifepristone (Known as RU-486 in Europe). On September 28, the Agency approved Mifeprex (mifepristone) for terminating early pregnancy (49 days or less since the last menstrual period). Because a patient must closely follow the treatment regimen, each woman will receive a medication guide along with the medication. The guide will explain how to take the drug, who should avoid it, and what side effects to expect. Under the terms of approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or they must have made plans to provide such care through others. To gather more data about the use of mifepristone, the Population Council (sponsor of the product) has committed to conducting postmarketing studies. France was first to approve mifepristone in 1988, and the United Kingdom, Sweden, and other countries also market it. The press release, the medication guide, and more information on this approval are available on FDA's web site.

RU-486. The *Wall Street Journal* has asked FDA for information concerning mifepristone (RU-486), all correspondence, approval records, and labeling from 1996 to present, all correspondence from the Population Council, and all correspondence on mifepristone and Danco Labs, Neogen Pharmaceuticals, Neogen holdings, and Neogen investors.

WEEKLY REPORT -- (February 25 to March 12, 2000)

AGENCY/OFFICE: FDA

FDA Issues Second "Approvable" Letter for Mifepristone: On February 18, the Food and Drug Administration issued an approvable letter to the Population Council for mifepristone (known in Europe as RU-486), when used in combination with misoprostol. The drug regimen is being evaluated for the termination of early pregnancy. The Population Council's new drug application was filed on March 18, 1996. On July 19, 1996, an FDA Advisory committee found the data supportive of approval of the drug. The agency first acted on this application by issuing an approvable letter on September 18, 1996. The Population Council has filed a response to the outstanding issues. (Under the Prescription Drug User Fee Act, the Agency has a six-month goal for acting on information submitted in response to an original action.) FDA issues approvable letters to manufacturers when remaining questions need to be resolved before final marketing approval can be granted.

WEEKLY REPORT -- (September 23 - October 11, 1996)

AGENCY/OFFICE: FDA

RU-486 Approvable. On September 18, FDA issued an "approvable" letter to the Population Council for RU-486 (mifepristone), when used in combination with the prostaglandin, misoprostol, for the termination of early pregnancy. The combination has been determined to be safe and effective when used under close medical supervision, but additional information on other issues, including manufacturing practices and labeling must be submitted before a final approval decision can be made. An FDA advisory panel voted 6-0, with 2 abstentions, on July 19, 1996, that the benefits of the RU-486/misoprostol regimen outweigh the risks.