



# FROM SECRET TO SHELF:

HOW COLLABORATION IS BRINGING  
EMERGENCY CONTRACEPTION TO WOMEN

BY BARBARA PILLSBURY, FRANCINE COEYTAUX, AND ANDREA JOHNSTON



PACIFIC INSTITUTE FOR WOMEN'S HEALTH  
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## Summary

Due to market risks and perceived liability, pharmaceutical companies are no longer actively investing as they once did in the development of new contraceptive methods. New approaches are thus needed to bring a greater range of contraceptive methods onto the market. There is need for new partnerships and collaboration, including public and private sectors, and new modes of funding.

The case of “emergency contraception” -- most commonly known as the “morning-after pill” -- illustrates this approach. It is a story of how people worked together, of new partnerships, of greater collaboration among different actors to move forward strategically, and of diverse actions to address multiple fronts at the same time. Philanthropic foundations have been major forces in this story.

Emergency contraception has been called “America’s best-kept secret.” This report chronicles what it took to move it from secret to shelf. The fact that an emergency contraception product is available today in many pharmacies is indeed a very major accomplishment. But the job is not yet done. The shelf it needs to be found on is not just the pharmacists’ shelf, behind the counter -- but the shelf in the medicine cabinet in millions of homes everywhere -- like aspirin, “just in case.”

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## Preface

During the Kosovo crisis of 1999, the Vatican announced that women who were raped should not be given emergency contraception. The uproar was deafening in response to this callous disregard for the needs and human rights of women victimized in war or ethnic conflict. The Vatican was too late, the secret was already out, and women were not going to give up this important option.

*From Secret to Shelf* is the story of how old science and new communications, activists and advocates, foundations and organizations came together to get that secret out in a short period of time. For the David and Lucile Packard Foundation it was an opportunity that came our way, thanks to many professionals in the reproductive health field whom we already knew — including our colleagues at the Pacific Institute for Women's Health — and also others whom we have happily come to know in this process. While our professional colleagues were familiar with post-coital contraception, now known as emergency contraception (EC), and its potential to prevent an unintended pregnancy, the public was not. Because of this major effort, a generation of American women is learning about this option and vigorous efforts to get this information to the rest of the world's women will continue.

The Packard Foundation has put over \$6 million into emergency contraception. We see EC as a way to give women control over their own lives, by allowing them to manage their own fertility. More than 3 million unintended pregnancies occur in the United States each year, 1.4 million of which end in abortion. It is estimated that emergency contraception could prevent 800,000 of these abortions.

An urgent need for emergency contraception also exists in the developing countries, where there are high percentages of unplanned pregnancies and where tens of millions of women resort to unsafe abortions, a major cause of maternal mortality. Emergency contraception can prevent much pain and injury. Our first foray into this technology was a modest grant to the Family Planning Association of Tanzania for EC using both pills and intrauterine devices (IUDs). We have had a special interest in helping women, including teens, to know that the pills that they or their sisters or neighbors have on hand, or an IUD inserted at a clinic, can be used to inhibit a pregnancy when they might have thought it was too late. We look forward to the day when using IUDs for this purpose is more widely known. For the time being, we hope to have every woman know that the oral contraceptives already in her community can be used for this purpose.

We are fortunate to have had the opportunity to participate in this massive, multi-donor effort for EC. We want to thank Barbara Pillsbury, Francine Coeytaux, and Andrea Johnston of the Pacific Institute for Women's Health for producing this special publication to tell the story. This story can be seen as a model for giving women worldwide an even greater range of reproductive choices. This model of collaboration might apply equally well in other areas such as the environment, education, and children's health.

**Martha M. Campbell, Ph.D.**   **Sarah C. Clark, Ph.D.**

SENIOR PROGRAM OFFICER   DIRECTOR, POPULATION PROGRAM

THE DAVID AND LUCILE PACKARD FOUNDATION



## THE STORY



## I. The Challenges of Contraceptive Development

Contraceptive development. Once it was the exciting new frontier, holding promise for a dramatic new product that would easily, safely and effectively prevent unwanted pregnancy. Pharmaceutical companies invested in research and, during the decades, brought forward new products. Today, due to market risks and perceived liability, pharmaceutical companies no longer invest so actively as before in the development of new contraceptive methods.<sup>1</sup> Amidst achievements have been many disappointments, leaving many reproductive choice proponents today wondering “Where next?”

Today one exciting success story is “emergency contraception.” It is an important story that demonstrates the many pieces of the puzzle that need to fall into place in order to successfully bring a new product to market -- one that women worldwide should have had 25 years ago.

### What is Emergency Contraception?

*Emergency contraception is a method to prevent pregnancy after unprotected intercourse. The most common form consists of birth control pills taken after unprotected sex -- often called the “morning-after pill.” Emergency contraceptive pills are effective if taken within 72 hours (three days) after unprotected sex. They prevent pregnancy by preventing ovulation, fertilization or implantation. Emergency contraceptive pills (“ECPs”) should not be confused with RU 486, the French abortion pill. ECPs, in fact, will not be effective if a pregnancy is already established. Two products, PREVEN™ and Plan B, are now being marketed in the U.S.*

*Emergency contraception can also be provided by insertion of a copper-bearing IUD. This can be done up to 5 days after unprotected intercourse, is more effective than the use of pills, and may be a good decision for women who would like to use the IUD as an ongoing method of birth control.*

## II. The History: From Morning-After Pill to Emergency Contraception

### THE 1960s: THE BIRTH OF AN IDEA

It was 1964. “The Pill” became commercially available in the United States and, some say, changed the course of history.

Not only did the birth control pill become available as a reliable means to prevent pregnancy. A few gynecologists and other research-oriented physicians began exploring the possibility of preventing pregnancy by using birth control pills **after** sexual intercourse. They described this in the scientific literature, referring to it as “post-coital contraception.”<sup>2</sup> Soon this came to be known as the “morning-after pill.”

The “morning-after pill” was actually not a single pill but several birth control pills taken together, and its effectiveness was not just the morning after but for about three days following unprotected sex. Unlike other forms of contraception, it had the unique advantage of avoiding unwanted pregnancy **after** sex.

### THE ‘70s AND ‘80s: SPOTTY AVAILABILITY, MANY OBSTACLES TO EXPANSION

On college campuses across the country, student health centers began to offer the morning-after pill to female students who’d had a night of passion without using contraception. Or for whom a condom had failed. Or who had been raped. Likewise in a few Planned Parenthood and individual feminist clinics, providers recognized the value of being able to offer the morning-after pill to women who did not want to become pregnant. The common approach was to cut up packets of birth control pills, put the number of pills needed for “the morning after” in an envelop with instructions on their use, and give them to women coming to the clinic.

In 1974 doctors in Canada confirmed the effectiveness of the method with studies documenting that if a woman took two tablets of a birth control pill, Ovral, within 72 hours of having sex, and two more pills 12 hours later, her chances of becoming pregnant would be reduced.<sup>3</sup> In Europe doctors were also cutting up and providing pill packets to women in need. In addition, pharmaceutical firms

there began to put on the market products dedicated for emergency contraception use.

Continuing into the 1980s, in the U.S. a small number of progressive doctors attempted to make the method more widely available. These pioneers encountered tremendous obstacles. Among these were legal, liability, and effectiveness issues. The birth control pill had been legally approved by the U.S. Food and Drug Administration (FDA), but the pharmaceutical companies producing the pills had either declined or neglected to apply to the FDA for approval of post-coital use of the pill, and consequently this was not included in the package inserts. Thus use of the pill after sex constituted off-label use. For this reason many doctors and other health care providers felt uneasy about the method; even if safe, it didn’t feel scientific and legitimate. Many were concerned about its effectiveness and were apprehensive that women would not use it properly and would rely on this rather than use a regular birth control method of greater established effectiveness.

Furthermore, in contrast to most new pharmaceutical products that benefit from large-scale promotion by the companies that make the product, for the morning-after pill there was no promotion. Not only was there no single product with companies to promote it; because the method was not FDA approved, it could not be readily promoted by anyone else either.

Finally, there was not much demand for the method, because few women knew about it.

Not surprisingly, the morning-after method languished. The birth control pill itself came under attack as side effects of the high-dose pills made many women fearful and scientists sought a perfected lower-dose pill. Priorities of the pharmaceutical companies vis-à-vis “the pill” were to put improved low-dose pills on the market -- which they did. Their attention was not on after-sex emergency use of the pill.

Only in the early ‘90s did things begin to happen in the U.S. that transformed the morning-after pill from spotty availability of cut-up packets to FDA-approved emergency contraception.

### THE 1990s: MAKING THE CASE

In 1992, two important articles were published in the journal *Family Planning Perspectives*. In the first, co-authors James Trussell and Felicia Stewart laid out the theoretical and scientific data on emergency contraception.<sup>4</sup> In the second, the authors coined the term “emergency contraceptive pills” and argued that making them widely available in the U.S. could greatly reduce the numbers of unintended pregnancies and abortions.<sup>5</sup> Not only that. On a personal level it could spare many women from misery.

### The “anthropology” of emergency contraception: Traditional remedies to bring on a late period.

*In 1998 the Wallace Global Fund funded Population Services International (PSI) to do a feasibility study for social marketing of emergency contraception in Nigeria. PSI found that “...consumers and providers already have considerable knowledge... Many women use post-coital methods, without concerns about abortion...”*

*In fact, post-coital methods to bring on a late menstrual period are not a new thing. In Mexico, for example, many women use teas of roots and herbs to BAJAR LA REGLA (“bring down the period”). Women do so around the world, in most places far more frequently than they use such indigenous methods to prevent pregnancy before intercourse. Malay Chinese women, for instance, traditionally do all sorts of things after sex to avoid becoming pregnant: douche, jump up and down, and use herbs to TIAO JING (“regulate the menses”). If the period does not come, they use stronger herbs to “clear” the menses (TONG JING) -- an important distinction.<sup>6</sup> This suggests that an effective approach in traditional communities might be to present emergency contraceptive pills as a modern and more effective product for what is already a well-established traditional practice.*

## III.

## Advocates Demand: Why Isn't This Available?

According to the authors, three things needed to be done: (1) educate women about emergency contraception, (2) educate clinicians about it, and (3) remove barriers to obtaining the pills within 72 hours after unprotected intercourse. The authors pointed out that having a commercial brand-name product would help on all three fronts: the company would be out there promoting it, instructions would be available, and this would make it easier to use.

Dr. Felicia Stewart, while serving as Medical Director of the Planned Parenthood affiliate in Sacramento, had taken it upon herself to provide the method to women in her clinic and had been doing so for many years.<sup>7</sup> Women knowing about this method? She was determined that they should. She describes the challenge of popularizing emergency contraception as "...a snowball kind of thing, the kind that starts with what has to be a good idea, that must be timely and strategically good. Given this, others will join. They'll sign on, doing their own thing, things that never occurred to you."

Many signed on, and with innovations never envisioned in 1992.

What made emergency contraception take off? While the scientific literature was clear, the method still remained a near secret. The spark that ignited the smoldering idea was women activists saying "We can't believe this method was out there and we didn't know about it." Why should this method exist, be available and used in Europe, yet remain almost a secret in America?

#### Refugees and Emergency Contraception

*In 1994 the Compton Foundation funded a study to examine the condition of victims of violence among refugees in the former Yugoslavia. The study (by Lael Stegal and Sharon Camp) had not set out to focus on emergency contraception, but concluded there was tremendous need for it. Before long most refugee agencies, despite the overwhelming presence of Catholic organizations among them, also concluded that emergency contraception for rape victims was an extremely important part of refugee assistance; UNICEF and many others bought in to make it available.*

Leading the charge was a group of activists who had created, in 1988, the Reproductive Health Technologies Project (RHTP). RHTP brought together leaders from many constituencies for dialogue, debate, and consensus-building on issues of reproductive health and technology, especially highly-charged issues where science, politics and the interests of women often clash. Included in the group were leading activists from women's organizations such as the National Women's Health Network, the National Latina Health Organization, and the National Black Women's Health Project. It also brought senior representatives of organizations such as the Population Council, Planned Parenthood Federation of America, and the American Public Health Association together with local community advocates and service providers with hands-on experience in meeting the needs of low-income women and women of color.

## IV.

## Valentine's Day 1996: A Hotline Is Born

One of the three things that Trussell, Stewart, and colleagues had identified in 1992 that "had to be done" was educating women about the method. "If we could just let the public know...if the public knew there is this possibility, they would begin demanding it," they predicted. This led to a book, web site, and hotline.

The book, *Emergency Contraception: The Nation's Best-Kept Secret*, included a national directory of providers in the United States who were willing and able to prescribe emergency contraception.<sup>8</sup> "As its publication date approached, we thought it would be much better if it were connected to web site and a hotline," says Trussell. "That was October 1994, when there were not yet any reproductive health web sites at all. We thought eventually it would be useful, although not at that time, because most women didn't yet have access to the Internet. We thought a hotline would be much more effective."

#### The Emergency Contraception Website

*Updated monthly, the website provides up-to-date information on emergency contraception, including dosages for all the different pills (see back cover). As of early 1999, the website had received 350,000 hits. The website includes a directory of EC providers, frequently-asked questions (and their answers), EC in the News, and a list of important publications.*



(Go to [www.not-2-late.com](http://www.not-2-late.com))

In early 1995, James Trussell and a research associate, Jacqueline Koenig, with support from the John Merck Fund and the Kaiser Family Foundation, developed a protocol for a national Emergency Contraception Hotline. On Valentine's Day, 1996, in collaboration with the Reproductive Health Technologies Project, they launched the hotline.



## V.

### A National Media Campaign is Launched: Billboards! Buses! Radio! TV!



The Valentine's Day launching attracted significant publicity from the press and the Hotline was soon averaging 1,000 calls per week. By calling the 800 number, women could obtain information on emergency contraception (in English or in Spanish) and the phone numbers of the three nearest providers. "This was a terrific idea," says Dr. Joseph Speidel of the Hewlett Foundation. "It's critical there be a place to call for information, especially at 2 am."

The Princeton University and RHTP collaborators soon realized that, for the hotline to succeed, it would need sustained publicity and a major public education campaign. "When a simple mention of the hotline on MTV prompted 4,200 calls in two days," exclaims Marie Bass, director of the Reproductive Health Technologies Project, "we took this as a clear sign that we needed to mount a major, ongoing media campaign."

This they did. The campaign had two goals: to advertise the hotline and to increase public awareness of emergency contraception. DDB, a premier commercial advertising firm, was hired to produce public service announcements for television, radio and the print media. By fall of 1997, women and men in four cities -- Chicago, Los Angeles, San Diego and Seattle -- were seeing ads about emergency contraception on billboards, bus stop shelters, and on the sides of buses. Miami and Philadelphia were added soon after. Spots on television and radio referred people to the hotline.

Work with the media included educating writers for women's and teen magazines. This was time-consuming but paid off. It quickly became clear that reporters and writers were significant allies. Most were women, but most had never heard about emergency contraception -- and many were angry that it had existed for so long without their knowing about it. A large number of articles about emergency contraception appeared in such popular magazines as *Cosmopolitan*, *Elle*, *Glamour*, *Seventeen*, *Self*, *New Woman*, *Essence*, *Playboy* and *Playgirl*.<sup>9</sup> Kaiser Family Foundation joined the media effort, working with producers of popular television shows. "A nice long story in *Glamour* or *Mademoiselle* is much more important in reaching young women than an article in the *New York Times*," observes Felicia Stewart. "And even more important is television. The mention and use of emergency contraception on episodes of two popular prime-time TV shows -- *ER* and *Felicity* -- may have educated more people than anything else."

## VI.

### Educating and Reassuring The Providers

Getting emergency contraception on television was a very significant milestone. The television ad for emergency contraception in the fall 1997 was one of the first ads ever to appear on U.S. television for any form of contraception. "You hear routinely that TV stations don't want to show ads for contraception because of public backlash," comments James Trussell. "Initially some TV stations didn't want to run the ads, but later they said 'Me too, me too.' We all learned that the sky did not fall in."

A campaign of this size and this commercial quality would not have been possible without major support from foundations. The media campaign, even while relying on unpaid advertising, cost \$1 million. The David and Lucile Packard Foundation, the John Merck Fund, the Irving Harris Foundation, and the Kaiser Family Foundation, among others, all pitched in. "The most innovative aspect of the campaign was RHTP's use of commercial marketing strategies to advance its public interest goal. This was a new way for the reproductive health community to reach its target audience," observes Ruth Hennig of the John Merck Fund.

#### Media campaign in India

*Following initial steps to introduce emergency contraception in India, the Population Council designed a series of television and radio public service announcements, articles for the print media, and a documentary video in 1997. The campaign was critical to building on the momentum generated by the other introductory efforts in India and increased popular understanding, support, and participation in the public dialogue on emergency contraception.*

Despite a growing demand for emergency contraception, many providers remained uninformed about the method or uneasy about prescribing it. Most doctors, including gynecologists, did not inform women about emergency contraception. As recently as 1997 a survey commissioned by the Kaiser Family Foundation showed that, even among clinicians who knew about emergency contraception, only 10% routinely counseled women about its use.<sup>10</sup> This was a serious bottleneck. Doctors simply were not counseling women in advance and many did not know how to answer questions when asked. "Even if women did know to ask about it, they were likely to run into a provider who was clueless," lamented Dr. Stewart.

#### Informing providers and the public in Mexico

*As the lead organization in Mexico for the international Consortium for Emergency Contraception, the Population Council has proceeded on multiple fronts, much as activists were doing in the U.S. This includes training and informational packets for doctors and pharmacists, development of brochures for doctors, pharmacists and clients, and setting up and running an emergency contraception hotline. All activities are based on use of existing birth control pills, which are available over-the-counter in Mexican pharmacies. A dedicated product should soon be on the market as well. The latest element is a media campaign in 1999 to inform women, particularly young women in the Mexico City area, about the use and availability of emergency contraception. The media messages will direct their audiences to further information, primarily the Mexican emergency contraception hotline, funded by The Summit Foundation.*

**ENTER A LARGE HMO:  
THE SAN DIEGO DEMONSTRATION PROJECT**  
In early 1995, the Pacific Institute for Women's Health, based in Los Angeles, and Kaiser Permanente of Southern California, a large health maintenance organization, took on the challenge of educating providers and developing a system for making emergency contraception more available. Together they conducted the first large-scale demonstration project of emergency contraception in the U.S.

## VII.

## FDA Says Yes! Declares Emergency Contraception Safe and Effective

Kaiser Permanente of Southern California would repackage oral contraceptive pills for use as emergency contraception and make the method available to interested women throughout its San Diego service area. PATH (Program for Appropriate Technology in Health) would develop training materials for the providers and educational materials for the clients. Pacific Institute researchers would evaluate the results, testing the acceptability of the method to both the providers and the clients. The project would take three years and cost over a million dollars. "This was an ideal partnership," says Diana Petitti, MD, Director of Research and Evaluation at Southern California Kaiser Permanente Medical Group. "We were able to provide the context for introducing emergency contraception and our partners provided expertise that was not available in our organization. The partnership enhanced acceptance of the project results outside of Kaiser Permanente and gave legitimacy to the project within the organization."

Again, for a project of this magnitude support of several foundations was essential. The David and Lucile Packard Foundation and the John Merck Fund provided seed grants to launch the effort, and the Wallace Global Fund and an anonymous donor joined in to fund the whole project. Kaiser Permanente provided substantial in-kind investment.

The demonstration project rolled out smoothly. Even before final analysis was completed, the success of the project within a relatively conservative but well-established medical care organization provided a good model and encouraged others to move ahead. "The San Diego project made emergency contraception consumer-friendly," comments Jacqueline Koenig, Senior Program Officer at the Kaiser Family Foundation. "Knowing about the project gave other providers confidence to do likewise."

#### ACOG GIVES SEAL OF APPROVAL WITH PRACTICE GUIDELINES

A crucial element in educating and motivating providers was the willingness of the American College of Obstetricians and Gynecologists (ACOG) to write and publish a "practice pattern" on emergency contraception.

This was an extraordinary decision by ACOG." PATH also took the materials it had developed for the San Diego project and, in collaboration with the Kaiser Family Foundation, added information from the ACOG practice guidelines to produce a comprehensive information packet for health care providers. These packets, *Emergency Contraception: Resources for Providers*, were endorsed by 12 major medical organizations -- including the American Medical Association (AMA) -- and distributed to over 50,000 providers nationwide, giving tremendous credibility to emergency contraception.

(Go to [www.path.org/acog/](http://www.path.org/acog/))

#### Introducing "EC" in Tanzania: schools and medical centers

*In 1995, the Packard Foundation gave the first grant ever from any foundation for making emergency contraception available in a developing country. This went to the International Planned Parenthood Federation (IPPF) for an 18-month pilot project in Tanzania carried out by UMATI, Tanzania's IPPF affiliate. Recognizing the high number of school girls who become pregnant and resort to unsafe abortions -- rather than drop out of school and go through an unwanted pregnancy -- the objective was to provide emergency contraception and information about it to as many young girls as possible through secondary schools and medical centers. The approach emphasized use of IUDs as well as pills for emergency contraception.*



The final obstacle to the promotion and provision of the method by doctors was the lack of specific approval for emergency contraception from the Food and Drug Administration. In a historic move in February 1997, the FDA issued a Federal Register notice declaring six brands of oral contraceptives to be safe and effective for emergency contraception and publishing the dosage.<sup>12</sup> This was one of the very few times that the FDA has taken such a step without a request from a pharmaceutical company. And it never would have happened without the leadership of David Kessler and his colleagues within the FDA. Their commitment to women's health and their willingness to tackle a potentially controversial issue was key.

Behind the FDA decision was crucial strategic legal work by another partner in the overall effort, the Center for Reproductive Law and Policy, supported by the Packard Foundation.

"We determined, in 1994, that FDA's *condoning* of pharmaceutical companies not identifying the method was a major obstacle," explained Janet Benshoof, founder and President of the Center. (Fearing legal or political fallout or both, manufacturers of birth control pills had declined to provide instructions on how to use their products for emergency contraception.) The Center thus filed a Citizens' Petition to the FDA in November 1994. First to sign on as petitioners were the American Medical Women's Association, the American Public Health Association, and Planned Parenthood of New York City. By early 1995, 22 groups had signed on to the petition. Its first point: FDA should declare post-coital contraception to be safe and effective. Its second point: FDA has an obligation to require the pharmaceutical companies to correctly label, in their package inserts, that this is an acceptable use of the pills and define the dosage.

The FDA took the petition seriously, held hearings and, in February 1997, published the historic notice in the Federal Register that declared post-coital emergency contraception safe and effective. It also published the dosage and regime to be used.<sup>13</sup> "Technically this was the FDA doing its own labeling," explains Benshoof. "So we completely won in a back-handed way. With this FDA action, it would be malpractice for doctors *not* to have this option available."

"Once the FDA notice appeared in the Federal Register, it was a clear go-ahead," says Trussell. "Coupled with the ACOG guidelines, this changed the medical climate 180 degrees.... made an enormous difference." "It was also important, Stewart explains, "because Planned Parenthood clinics use FDA approval as a way of deciding what should be in their protocols. If FDA says yes, it helps them. This regulatory issue is extremely important for all the public clinics, making clear what is the standard of medical care."

On the worldwide scene, important research had been done and legitimacy conferred upon the method by the World Health Organization (WHO), the lead body in research on new methods of emergency contraception. International Planned Parenthood Federation and the U.S. Agency for International Development also gave it their imprimatur as an important method for expanding choice for women and preventing unwanted pregnancies and abortion.<sup>14</sup>



## VIII.

## Quest For A “Dedicated Product”

Many things were happening in parallel.

While women activists in the U.S. were expressing outrage and dismay that this method existed, unbeknownst and unavailable to most American women, in Europe the situation was otherwise. In 1994 the Reproductive Health Technologies Project, with funding from the Rockefeller Foundation, sent Sharon Camp, its founding chair, on a study tour to Europe to learn lessons for making the method available for American women. Dr. Camp found that two European pharmaceutical companies were marketing dedicated products specifically for use as emergency or post-coital contraception -- and that these were widely available in the United Kingdom, Holland, Germany, Switzerland, Finland, Sweden, Hungary and other countries in Eastern Europe.<sup>15</sup> In England, for instance, a commercial product with the trade name *PC 4* (four pills packaged and sold specifically for post-coital use) had been on the market since 1984 and was being provided through the National Health Service. Elsewhere in Europe were dedicated products with other brand names: *Neoprimovlar*, *Tetragynon*, and *Postinor*.

In the U.S., in contrast, there was no product packaged and marketed specifically for emergency contraception. Some activists and health professionals believed it would be a great advantage to have a commercially-marketed “dedicated product,” accompanied by the kind of marketing that would come with commercialization. Not only would it help build consumer demand; it would also make doctors more inclined to provide it. And it would make it easier for women to get and use emergency contraception.

Although the need for a dedicated product was clear, it was equally clear that the major U.S. pharmaceutical companies were not going to meet the need. Based on what they perceived as negative experiences with other contraceptives (the IUD and Norplant, for example), they were unwilling to accept what they viewed as substantial risk of liability. They feared that anti-choice groups in the U.S. would seek to equate emergency contraception with abortion and possibly threaten to boycott their entire line of products as these groups had done with RU 486, the French abortion pill.

They also worried that the use of emergency contraception might decrease revenues from sales of birth control pills.

The San Diego Project helped assuage some of these fears. For this demonstration project, Kaiser Permanente’s California Regional Pharmacy Operations Group had repackaged oral contraceptive pills under its FDA-approved repackaging authority. This essentially created a dedicated product for emergency contraception. By making this product available throughout this large HMO, and by documenting the acceptability of the method among both women and providers, the Pacific Institute for Women’s Health and Kaiser Permanente proved two points: first, that there was a demand for emergency contraception and, second, that emergency contraception could be introduced without political fallout. “The key political learning was the need to consult widely and to be responsive to our providers’ recommendations about the content of the informational materials concerning emergency contraception,” emphasizes Dr. Petitti.

## The Consortium for Emergency Contraception: Working Worldwide

*At the same time as activists were pushing ahead on many fronts in the U.S. and in Europe, they were also looking beyond U.S. shores, eager to make emergency contraception -- especially a dedicated product -- available in developing countries as well. They hit upon the idea of bringing lead agencies involved with emergency contraception together in a consortium in which they could pool their ideas and energy -- and which could seek funding collectively from donors, rather than have all the individual organizations separately approaching the donors for support. This was in itself an innovative approach. In October 1995, five founding organizations came together to form the Consortium for Emergency Contraception.<sup>16</sup> They adopted as objectives:*

- *To create a partnership among public organizations and private industry that harnesses the human and financial resources of both sectors in order to make emergency contraception available to large numbers of women worldwide at the lowest possible cost; and*
- *To demonstrate a dynamic model of international cooperation among major public sector organizations that minimizes duplication of efforts, maximizes the use of scarce donor resources, and promotes rapid adoption of proven strategies for the expansion of information and services.*

*Under the leadership of Dr. Sharon Camp, formerly Senior Vice President of Population Action International, the Consortium raised funds which were distributed among the member organizations to implement a set of coordinated activities in agreed-upon countries. The Rockefeller Foundation provided an initial grant of \$100,000. The Packard Foundation provided generous early support (one million dollars), along with the Wallace Global Fund, the Compton Foundation, and ten other foundations.*

*The strategy was to focus initially on four countries: Kenya, Indonesia, Sri Lanka, and Mexico. In the first three of these countries, the strategy was to promote use of a dedicated product. Chosen for this purpose was *POSTINOR*, pills produced and packaged by the leading Hungarian pharmaceutical firm, Gedeon Richter, which collaborated with the Consortium through a contractual agreement with the Concept Foundation, a member of the Consortium.*

*Through this unique public-private partnership, the Consortium has introduced, expanded, and upgraded the provision of emergency contraception around the world. This included developing state-of-the-art client education materials, service delivery guidelines, and training materials; training a broad range of service providers; and working with the manufacturer to improve packaging and labeling of the pills.*

*This was a very innovative and successful approach. An evaluation in 1998 concluded:*

*“The Consortium enabled a concentration of influence that exceeded that of the sum of its individual members. It is unlikely the individual members of the Consortium could have attempted and achieved so much if they had acted in isolation. Bringing together major and respected family planning players, each with its particular strengths, as a unified team facilitated enormously winning the gold medal for EC.”<sup>17</sup>*

*As Susan Rich, program officer at the Wallace Global Fund, noted: “One of our problems in this field is lack of a united voice. This is something the Consortium could achieve because it was created on the premise of cooperation.” The Consortium successfully: shared information, knowledge and expertise; spoke in a unified and accurate voice; and brought together resources (including staff, field offices, technical expertise, and funding). This strategy of collaboration and these key elements have been at the root of the entire effort to make emergency contraception easily available to all women.*

## New Pharmaceutical Companies Enter The Scene

Still, the big pharmaceutical companies were not willing to get involved. The next chapter in this remarkable story of determination and innovation was the decision that new companies had to step in to do the job of bringing to market the long-sought dedicated product for emergency contraception.

**PREVEN!** Having declared emergency contraception safe and effective, the FDA conferred with Roderick Mackenzie, a former president of Ortho Pharmaceutical Company, and asked him to consider marketing the first product for emergency contraceptive. “While the task ahead was daunting, the need for emergency contraception was so compelling in this country, with over 3 million unintended pregnancies every year,” says Mackenzie. “I could not refuse.” In 1995 Mackenzie had founded Gynetics Inc., dedicated to developing and marketing women’s health care pharmaceutical products and medical devices. At the outset, Gynetics was funded by Mackenzie himself before eventually raising the \$20 million it took to bring to market the PREVEN™ Emergency Contraceptive Kit. PREVEN™ was FDA-approved in September 1998 and hit the market in October.

Thus finally, about three decades after the morning-after pill first came into sporadic use, America’s first commercially-marketed emergency contraception product at long last became available in many pharmacies across America in fall 1998. It required a prescription, but it was there. “It’s wonderful that a manufacturer was willing to take the risk and put a product on the market...,” says Allan Rosenfield, Dean of Columbia University’s School of Public Health.

PREVEN™ is currently available across the U.S. in nine of the top ten chain drug stores, usually costing between \$21 and \$25. Each kit contains detailed patient instructions, a pregnancy test, and four pills (combined estrogen and progestin). Women take the first two pills as soon as possible after unprotected sex, followed by the second two pills 12 hours later. The pregnancy test is included as an integral part of the kit to ensure that women using the pills are not already pregnant from an earlier sexual encounter. [Go to [www.preven.com](http://www.preven.com)]



**PLAN B!** In early 1997, a second company -- Women’s Capital Corporation -- was created specifically for the purpose of bringing emergency contraception to market. In July 1999, WCC, based in Seattle, received FDA approval for another emergency contraception dedicated product (this one containing only progestin, levonorgestrel). It comes in a discreet 3x3x1/4 inch package with the trade name Plan B™. According to Sharon Camp, who founded Women’s Capital Corporation: “This new product, tested in 15 countries by the World Health Organization, should help bring emergency contraception into the mainstream of reproductive and sexual health. *Plan B* is easier to administer and use than the older regimens. And without estrogen, there should be less concern about telephone prescriptions, advance provision, and over-the-counter sales -- all things we know can reduce major barriers to access.”

[Go to [www.go2planB.com](http://www.go2planB.com)]

Dr. Camp adds: “We are probably the world’s smallest pharmaceutical company. It’s likely that in time we will be acquired by a much larger company, but my hope is that, before then, we can set some things in concrete, namely commitment to take the product over the counter, and affordable pricing.” Says Dr. Rosenfield: “It would be great to get some major pharmaceutical company involved, but this is a daunting challenge, given their reticence in this area to date. It is absolutely essential that advocates for this method continue efforts to move this forward.”

## Making Access Easier: Eliminating The Doctor’s Visit

In fact, this drug development would not have been possible without creative financing by activist foundation partners. Several U.S. foundations and Planned Parenthood affiliates actually invested in Women’s Capital Corporation. These included Robert Wallace of the Wallace Global Fund, the Compton Foundation, the Wallace Alexander Gerbode Foundation, and the International Foundation for Family Health. The Packard Foundation took a very innovative approach: it awarded the Women’s Capital Corporation a \$2-million “recoverable grant.” Once WCC’s after-tax earnings reach a certain threshold, indicating viability of the company, this grant is to be repaid to non-profit organizations working with Women’s Capital Corporation to promote the product. This is in essence an interest-free loan, designed to come back to the charitable field provided WCC doesn’t fail -- a recycling of the Packard Foundation monies through a for-profit activity and back again into not-for-profit socially-driven activities.



Imagine: A woman has unprotected sex or, worse, coerced sex. The realization and fear that she may become pregnant. What to do? Emergency contraception? Have to call a doctor. What doctor? What day is it? Saturday morning. Sunday morning. How to see a doctor? Monday only? But I’m working. Call in sick, manage to get a doctor’s appointment. Going there. Waiting. Waiting. Worrying. That was Friday night, this is Monday morning. 72 hours? Will it still work? Need to pay the doctor. How much? Doctor arrives. Some questions. A prescription. Going to the pharmacy. More waiting. Finally, the relief.

Even with a dedicated product at the drugstore, obstacles to getting the pills remain enormous. Many women who want to use emergency contraception simply are not able to get to a doctor in time. Given FDA’s declaration of safety, and the absence of contraindications to one-time or even occasional use of emergency contraception, many activists argue that no medical reasons remain to require a woman to see a doctor to obtain these pills.

### ALLOWING PHARMACISTS TO PRESCRIBE

One of the most recent and important developments in this story occurred in the state of Washington: provision of emergency contraception by pharmacists *without* requiring a doctor’s visit.

PATH, based in Seattle, learned that on the books in Washington State is a *pharmacy drug therapy statute* that enables pharmacists to provide services that elsewhere typically require a doctor’s visit -- for example, giving childhood immunizations or insulin for diabetes. This mechanism, PATH realized, could allow pharmacists to provide emergency contraceptive pills directly to women without requiring they first visit and get a prescription from a doctor.

PATH did research on what Washington’s collaborative drug protocols would allow and arranged focus groups with pharmacists to find out what their concerns might be. They had many -- about misuse by women, and how much time it would take for counseling by themselves -- but some saw it as a good way to attract clients and enhance their business.

PATH reviewed the relevant legislation for all states and did a small survey of providers in four other states where it appeared that collaborative protocols might be possible. The response was favorable. PATH thus concluded the time was right for a demonstration project and brought partners together: the Washington State Board of Pharmacy, the Washington Pharmacists Association, the University of Washington and, for a public media component, DDB, the Seattle-based advertising agency. The project linked up to the national Emergency Contraception Hotline, adding contact information for participating pharmacists to the hotline.

#### *"In our own back yard": the Northwest Coalition*

*In 1996, while helping prepare information on emergency contraception for nationwide and international distribution, staff at PATH decided to see if there was "something we can do in our own back yard." PATH arranged a meeting with Planned Parenthood of Western Washington and other public health agencies -- which led to creation of the Northwest Emergency Contraception Coalition. Funding from the John Merck Fund and the Horizons Foundation supported several of the Coalition's activities and was instrumental in helping it evolve. Unrestricted funds given by an individual donor for any EC-related work PATH would choose gave PATH flexibility that was crucial for establishing and sustaining the Northwest Coalition.*

*At a coalition meeting in late 1997 a local pharmacist pointed out "We have this prescriptive pharmacy protocol in place here in Washington," and asked, "Why don't we use that?" PATH staff took the idea to the Packard Foundation, saying "We suddenly have this opportunity for Washington state, and it might be something that could be done later in many other states. Can you help us get this started?" The Packard Foundation responded almost immediately with seed funding for an exploratory study. This was the genesis of the "Washington State Emergency Contraception Demonstration Project."*

This became the Washington State Emergency Contraception Demonstration Project. Through the project, pharmacists provided emergency contraceptive pills directly by entering into a collaborative drug therapy agreement with either a doctor or an advanced registered nurse practitioner, under whose authority the pharmacist can prescribe emergency contraception to any woman -- even women who were not "patients" of the collaborating doctor. Women could find a participating pharmacist by calling the national Emergency Contraception Hotline (1-888-NOT-2-LATE). A media campaign informed the public about this new convenience.

"The Packard Foundation was very responsive in funding this," says Elisa Wells of PATH. "We wanted to start this quickly -- though there were fears about picketers. It was extremely refreshing to come up with a really good idea, put together the partners, and then have a donor say very quickly, 'Yes!'" From the Packard Foundation perspective, according to program officer Martha Campbell, this was a dream project. "This kind of a lever on change was totally consistent with the foundation's philosophy -- giving women a whole new level of liberty from constraining systems of birth control access, and in a consumer-friendly mode. We decided to recommend to our trustees that a half million dollars be put in quickly, so the project could get a fast start. In good part because of PATH's careful background work for this proposal, it was approved very easily and they were off and running."

"The response from women has been amazing," adds Wells. "They are so relieved to be able to get the pills so quickly and conveniently. We estimate the project has prevented more than 600 unintended pregnancies in just the first year. The impact of this initial foundation investment will continue to grow as more states move to replicate the approach."

By all counts, the project was a great success. It demonstrated that pharmacists' provision of emergency contraceptive pills is immensely appreciated by women and also satisfactory to the participating pharmacists and their collaborating doctors and nurses.

Thousands of women in Washington state have successfully used emergency contraception within the critical 72-hour time frame by receiving the pills directly from a pharmacist. Response from Washington pharmacies, many of whom were fearful at first, has snowballed and become far greater than anticipated. Some 140 pharmacies have received training on emergency contraception and are listed on the emergency contraception hotline; four major pharmacy chains have joined in. PATH is now doing an add-on project to respond to requests from additional pharmacists and pharmacy chains in Washington who want the training. Some pharmacy chains have even paid for it. PATH hopes that pharmacists and the chains will themselves take on training of others.

Replication? There has been a great deal of interest from other states. About 20 states also have various laws on the books that would allow similar collaboration. With follow-on funding from the Packard Foundation, PATH is now training pharmacists and others from other states. Internationally, through the Consortium on Emergency Contraception, the Washington state model has also inspired and informed work with pharmacists in Kenya and Mexico City. It also contributed to the recent landmark decision of Britain's Royal Pharmaceutical Society to press for over-the-counter (non-prescription) sale of emergency contraception pills in that country.

#### **ADVANCE PRESCRIPTION AND PRESCRIBING OVER THE PHONE**

Planned Parenthood Federation, along with several foundations and with 132 local affiliates across the U.S., has also been working to eliminate the obstacle of the doctor's visit. With strong backing of its medical director and board, it took three important steps to liberalize provision of emergency contraception. First was to encourage advertising. Second was to allow advance prescription. Third was telephone prescribing. In 1998, it announced two nationwide programs: "EC-To-Go" and "Dial EC."<sup>18</sup>

*Advance Prescription.* In late 1997, the 24 family planning clinics that make up the Family Planning Council in Philadelphia began offering advance supplies of emergency contraceptive pills to all family planning clients -- a packet to have at hand "just in case." Since then, clinics in many other states are also experimenting with advance provision.<sup>19</sup> A very important step forward is Planned Parenthood's nationwide "EC-To-Go" campaign. This offers clients packets of emergency contraception pills to take home and have ready at hand should emergency need arise -- at the same time as Planned Parenthood also counsels the same women to use a regular birth control method as their primary means of contraception.

#### *Testing "advance provision" in a developing country: Pilot project in India*

*In 1996, the Population Council, with funding from the Packard Foundation, conducted a demonstration project in Maharashtra, India, to determine whether advance provision of emergency contraception can succeed in developing countries. This project challenged the widespread concern among family planning professionals that women in developing countries would be confused by this method. The Population Council developed training materials for providers and informational materials for clients and conducted staff training to educate about EC. Preliminary results were encouraging. The effort is ongoing in Maharashtra and has subsequently been replicated elsewhere in India and in Ghana.*

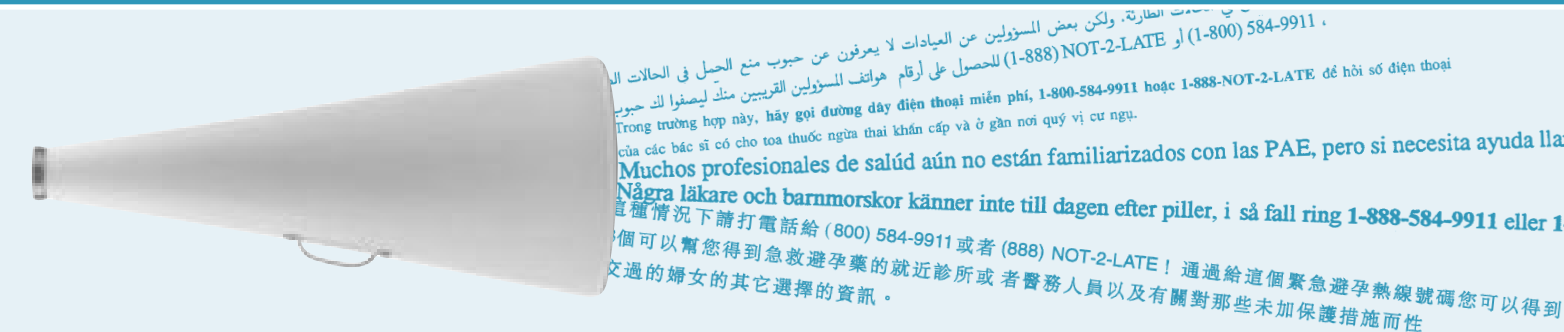


## XI.

Getting The Word Out –  
And In Many Languages

*Prescribing Over the Phone.* Ability to prescribe over the phone is limited by state pharmacy laws. The San Diego Project was first to explore a strategy that came close to prescribing emergency contraception over the phone. Callers were connected to a nurse who screened the client over the phone and provided the pills under protocol without conducting a physical examination. Planned Parenthood’s “Dial EC” project likewise allows its providers to discuss emergency contraception over the phone and, when they judge it appropriate, to call in a prescription to a local pharmacist (including for women who were not previously their clients).

“Over-the-phone prescribing first began as a strategy to overcome distances,” explains Dr. Michael Burnhill, medical director for Planned Parenthood, “something requested by affiliates who wanted to be able to prescribe over the phone to clients that might be quite far away -- for example, in Montana in a snowstorm. But when the national medical committee looked at the idea, we thought ‘Why not locally too?’ In Georgia, the Planned Parenthood affiliate picked up the idea and ran with it,” says Dr. Burnhill. “It can now prescribe over the phone to any woman, across the whole state. This is something that can be done without changing any laws and even without the pharmacist authority of Washington state.” Especially for women working a 9-to-5 job, this was a very important step forward.

**WHAT DO WOMEN AND PROVIDERS KNOW?**

Another critical piece of the puzzle has been surveys to determine the level of knowledge about emergency contraception, both among women in the general public and within the medical community. National surveys sponsored by the Kaiser Family Foundation have been important in tracking knowledge and providing a basis for knowing how to launch educational campaigns. “If you know that fewer than 30% of family practice doctors are familiar with the method, then you know a lot more still needs to be done,” emphasizes Dr. Felicia Stewart. Even after FDA approval and the advances already achieved, many women and providers alike were still quite ignorant about the method. A survey in 1997 found that about 66% of women of reproductive age had “heard of” emergency contraception or morning-after pills, but that their effective knowledge was far more limited. Only half of these women understood that the pills could be used after sex to prevent pregnancy. Most surprising was that 72% of women surveyed who had heard of emergency contraception thought either that it wasn’t available in the U.S. or just didn’t know.<sup>20</sup>

It was clear that information needed to be made more available to women and to providers -- and that it needed to be available in many forms.

**COMMUNICATING TO WOMEN  
IN THEIR OWN LANGUAGE**

What about all the non-English-speaking women? Getting information to them about emergency contraception was an additional concern. Perhaps a one-page information sheet in many different languages would be the answer. Perhaps a concise and easily understood “patient education” brochure in the woman’s own language.

At the request of the Packard Foundation, Robert Hatcher, MD, the founding author of *Contraceptive Technology*, produced a one-page instruction sheet on how to use existing birth control pills for emergency contraception. This includes dosages, telling women how many of each brand of pills to use. This was translated into 25 languages. The most important user information was placed into two even smaller and handier formats, a wallet-sized card and a bookmark, also in the same 25 languages. All three formats contain the 1-888-NOT-2-LATE hotline number. The foreign-language bookmarks and cards were also adapted for use internationally with specific pill information for 40 different countries.

Aiming for the widest use possible, in both the U.S. and worldwide, these materials were intentionally not copyrighted, but rather are to be freely used and adapted. They can be downloaded from the web and have been and disseminated widely to 50 leading international family planning and reproductive health organizations and to 500 selected U.S. colleges with large international student bodies, with encouragement to use them in creative ways.<sup>21</sup>

PATH has also produced a booklet of information sheets to make emergency contraception accessible to the immigrant population in its Seattle area. Titled “*Emergency Contraception: Client Materials for Diverse Audiences*,” and funded by the Kaiser Family Foundation, this presents the basic facts on emergency contraception, repeated on separate pages in each of 13 languages, and directs service providers to reproduce and give their clients the relevant pages. These are also available also on PATH’s website.<sup>22</sup>

*IPPF/Western Hemisphere translates information package into Spanish for all Latin America and Caribbean*

*Throughout Latin America and the Caribbean, many organizations were asking for materials on emergency contraception. In 1996 the Packard Foundation made a grant to the International Planned Parenthood Federation/Western Hemisphere Region, a network of 46 family planning associations in Latin America and the Caribbean, to modify as needed and translate into Spanish the informational packet developed by the Consortium for Emergency Contraception. This was distributed throughout the region, providing a prototype training curriculum, questions and answers for decision-makers and media spokespersons, sample client brochures, and a step-by-step framework for introducing emergency contraception. USAID financed reprinting of the Spanish packets as well as production of packets in Portuguese.*

**MAKING INFORMATION EASY FOR PROVIDERS**

Surveys also revealed that many doctors and pharmacists as recently as 1998 still had never heard of emergency contraception or believed it illegal or not available in the U.S. “Don’t have it... don’t know anything about it,” responded one New York City pharmacist. “Never heard of the morning after pill,” said another. “There’s no morning after pill available in this country,” stated another. “Go to a hospital for that; the pharmacy does not carry it.” “Emergency contraception is not available in the U.S. It’s in trials only at clinics. “...doctors haven’t approved it yet.”<sup>23</sup> Other doctors and pharmacists, as many in the general public still do, confused it with RU 486. “It’s the French abortion pill.”

*Planned Parenthood Campaign.* With such continued widespread ignorance and misconceptions, Planned Parenthood in 1998 launched an Emergency Contraception Public Education Campaign. Its goal: to develop widespread visibility of the method among women and also to educate and motivate reproductive health care providers -- and their office staff -- to share information about emergency contraception as a routine part of health care. The strategy is to “ripple out” the message from the national office to communities across the country through the national network of 132 Planned Parenthood affiliates. Easy-to-use and hard-to-misplace pocket guides -- in attention-grabbing bright gold, red and blue -- give providers accurate, client-oriented information about emergency contraception in both English and Spanish.

*Managing Contraception.* Dr. Robert Hatcher and his team revised the authoritative *Contraceptive Technology* to include a section on emergency contraception.<sup>24</sup> An additional innovation is *A Pocket Guide to Managing Contraception*, designed to make information readily available (“You will not want to leave home without it!”) to doctors and medical students. “Precious little time is devoted in medical schools to the immensely important subjects of family planning and contraception. Less than four hours in four years of medical school are devoted to these subjects,” observes the Hatcher team, whose goal in producing the small guide is that it should find its way into the pockets and then minds of all medical students and interns. This book describes in detail how to use existing pills, by brand, and also IUDs, for emergency contraception.<sup>25</sup>

*Training the Trainers.* Aiming for a multiplier effect, the Association of Reproductive Health Professionals (ARHP) designed a curriculum for training trainers of service providers. Funded by the Packard Foundation, ARHP has now trained over 80 health care professionals to present the accredited curriculum to service providers. The curriculum includes clinical issues, the legal environment, responding to the media, and all EC options, including off-label use of birth control pills, the new EC dedicated products, and the IUD. All training materials are available on-line, including slides, references, a resource list, and a lecture request form.

Over 300 professionals from 14 countries have downloaded the materials since March 1999.

*“Spread the Word.”* In California, another partner in the effort, Educational Training and Resource Associates (ETRA), has produced a comprehensive set of provider and client materials with the slogan “SPREAD THE WORD.” Its package includes technical information, a video, and clinic posters for providers; for clients it includes a video, brochures, and wallet cards. Aiming to make education about emergency contraception routine and widespread, the package of materials has been produced both in English and Spanish and is being distributed nationally and especially in California through key networks.<sup>26</sup> The Packard Foundation has funded the preparation and distribution of these materials.

*JAMWA.* Also in 1998, a special supplement of the *Journal of the American Medical Women’s Association (JAMWA)* synthesized the experience to date with emergency contraception.<sup>27</sup> Funded by the Kaiser Family Foundation, the Packard Foundation, and The Open Society Institute, this provided a valuable overview of what has been achieved but also indicated gaps and work remaining.



THE WAY FORWARD





## XII.

## Lessons Learned

By all counts, the story to date is one of unique success. At the beginning of the 1990s, the morning-after pill still remained largely a secret, available only to a small number of women who happened to have access to a small number of progressive doctors. By the end of the '90s, all stakeholders were behind the method: the FDA had declared emergency contraception safe and effective, leading medical authorities had sanctioned and promoted its use, two dedicated products were on the market, and there had been few negative consequences -- no medical catastrophes, no attacks on providers.

*The overarching reason for the success to date is that activists began with what was intrinsically a very good idea and then were able to collaborate on multiple fronts to overcome blockages and carry the idea to fruition. To bring the method to market required activists to set the snowball rolling and keep it rolling forward. It took a combination of women's advocates, providers, entrepreneurs, legal and regulatory fighters and the foundation world, working together from all different angles and willing to take risks.*

The story of emergency contraception reveals many important lessons that could guide other efforts to improve contraceptive access and reproductive health and choice. Five essential ingredients made for the success of this effort. They are:

1. Recognition of a good idea,
2. Identification of blockages -- and passion and determination to overcome them,
3. A collaborative mode of attack -- collaboration rather than competition being the driving operational norm,
4. Working simultaneously on many diverse fronts, and
5. Sufficient financial support for the cause.

### 1. RECOGNITION OF A GOOD IDEA

The idea -- mainstreaming the morning-after pill -- was intrinsically a very good idea. It was timely, scientifically sound, and strategically good. What made it so appealing to work on was "a rather ideal combination of things," in the assessment of Dr. Felicia Stewart.

- "First, it involved technology and science that were already well-established. We already had a feasible option in hand.
- Second, this was quite different from other contraceptive options in that there weren't any other options for *post*-intercourse -- in contrast to *before* intercourse for which there were many options.
- Finally, we knew this was something that could have a potentially big impact. We knew that about half of all unintended pregnancies occur to couples using nothing at the time; therefore they account for a disproportionate share of unintended pregnancies. The other half are those with method failure, or not all-the-time use. So we knew the potential impact could be significant.

This was how it made good sense, including politically."

### 2. IDENTIFICATION OF BLOCKAGES -- AND PASSION AND DETERMINATION TO OVERCOME THEM

The use of birth control pills to prevent pregnancy after intercourse had been set forth in the scientific literature as early as the 1960s, but a quarter-century later the method still remained "the nation's best-kept secret." It took activists -- women, and men who felt strongly that they had a right to the method -- to move emergency contraception into the mainstream. Activists saw that what was keeping the method from women were the complex fears and issues of the medical profession and pharmaceutical companies. They viewed this as an infringement of women's right to reproductive freedom and knew they had to figure out what were the barriers and what was needed to overcome them. Blockages were identified as:

- the public not knowing and thus not requesting,
- providers either not knowing or hesitant to prescribe,
- medical and legal issues, and
- the lack of a dedicated product.

### 3. A COLLABORATIVE MODE OF ATTACK -- COLLABORATION RATHER THAN COMPETITION BEING THE DRIVING OPERATIONAL NORM

A diversity of organizations and increasingly widening circles sought to collaborate and speak with a unified voice. Advocates, academics, providers and funding organizations all came together to attack and overturn barriers.

Activists came together to create *mechanisms* to facilitate collaboration. First on the domestic front was the Reproductive Health Technologies Project. Focusing at the international level was the *Consortium for Emergency Contraception*. Bringing key organizations together created synergy and accelerated the effort in a significant way that provides important lessons for other efforts to expand contraceptive availability. Consortium successes lay in (a) its sharing function, (b) bringing together resources of the individual organizations (staff resources, field offices, and technical expertise), and (c) approaching funding sources with a unified voice. Its leaders reflect: "The Consortium was about people getting together for a common cause, a partnership that worked and allowed us to advance this important method of contraception in a way that would not have occurred if people had not been working together. In fact it was a whole series of unique partnerships, including among foundation donors coming together and being willing to fund us as a consortium. We generated cooperation among the donors by cooperating ourselves."

The American Society for Emergency Contraception, inspired by the Consortium and formally created in 1998, represents another example of groups coming together to share information and collaborate on strategies.

Groups learned to work in innovative and path-breaking new ways, and with new partners. These included new public-private partnership and collaboration with the media, with legal bodies, with pharmaceutical companies, and with the medical establishment. These partnerships made possible approaches and outcomes that would not have been possible otherwise.

#### INNOVATIVE NEW PARTNERSHIPS.

1. *The Reproductive Health Technologies Project (RHTP) and Princeton University establishing and maintaining a hotline and website.*
2. *RHTP's hiring a commercial advertizing agency, DDB, to design and conduct a media campaign -- the first time a not-for-profit activist organization had hired a PR firm to market a contraceptive product.*
3. *DDB's partnering with the media -- recognizing that producers of popular television shows, reporters and writers for women's and teen magazines could be significant allies -- and using DDB's clout to put emergency contraception on prime-time television and in high-visibility print media.*
4. *The Pacific Institute for Women's Health collaborating with a large HMO, Kaiser Permanente of Southern California, to provide emergency contraception in an HMO setting and evaluate the response of women, providers, and administrators.*
5. *The Consortium for Emergency Contraception's collaboration with WHO and a foreign pharmaceutical firm, Gedeon Richter in Hungary, to make emergency contraception available in developing countries.*
6. *The Center for Reproductive Law and Policy petitioning the FDA to review emergency contraception (something usually done only by pharmaceutical companies) and an FDA commissioner and committee being willing to take on the issue and declare a historic judgment where pharmaceutical firms had balked.*
7. *PATH's collaboration with pharmacists, pharmacists' associations, and pharmacy chains to make emergency contraception available directly from pharmacies, without a woman first needing to talk to a doctor.*
8. *New pharmaceutical companies exploring new strategies for financing in order to put a dedicated product on the market.*

#### 4. WORKING SIMULTANEOUSLY ON MANY DIVERSE FRONTS

Essential to the success was the diversity of actions taken on multiple fronts to address the blockages -- and the willingness and ability of foundations to support such diverse measures. Actions ranged from acceptability studies and training of providers to the hotline and media campaigns to legal action with the FDA to work with pharmacist chains -- and were pursued on both domestic and international fronts.

Pushing forward simultaneously on both the domestic U.S. and international fronts had important synergistic effects. The San Diego HMO Demonstration Project, for example, gave important legitimacy to efforts of the U.S.-based Consortium to move ahead in developing countries. Developments in other countries also helped efforts in the U.S. For example, many working on emergency contraception in the U.S. worried that advance provision of emergency contraception would cause risk-taking and reliance on it rather than on regular, more reliable methods of contraception. Research in Scotland, however, showed that this did not happen and helped quell those worries.<sup>28</sup> Also significant were WHO's clinical trials to test the efficacy of various products, including levonorgestrel.

Critical to the ability of activists to work on many fronts at the same time was the willingness of foundations to fund a multitude of organizations and approaches. "It was unusual and made a huge difference, for example, that the Packard Foundation was willing to get involved from all angles, not just biomedical, but from lab work to media to public interest campaigns, to service delivery," emphasizes Charlotte Ellertson of the Population Council. "And not only was it willing to support a broad range of approaches; it has also supported *competing* strategies, such developing new options while also refining existing methods."

#### 5. SUFFICIENT FINANCIAL SUPPORT FOR THE CAUSE

Private philanthropic foundations played an essential role in bringing emergency contraception to the mainstream. Numerous foundations joined forces to provide support in diverse, innovative, and need-responsive ways. Foundations recognized the importance and potential of the method and worked tirelessly to garner support for the many actions activists were undertaking. As a result, it is widely recognized that "Without foundation support, EC wouldn't be happening."

The case of emergency contraception illustrates the strength of foundations: that they can facilitate change and innovation faster than individuals, faster than the government sector and, in the case of contraception, faster than today's commercial sector is willing to do. Clearly foundations can make a significant impact in controversial areas. In fact foundation support is not only important, but may be essential for introducing potentially controversial products, including contraceptive methods.

Four specific aspects of foundation support have been important:

- *Substantial amounts of funding, and sustained over a period of time.* Many of the activists say that a great deal was achieved with modest funding. Relative to the sums that pharmaceutical companies invest in developing and bringing to market a new product, the investment for emergency contraception, since 1992 when activists began to move the idea forward, has been modest indeed. From the perspective of non-profit organizations, however, the sums received were substantial.
- *The crucial role of seed money and general support.* Seed money and general support allow for important flexibility which is essential for innovation. Several major advances, including FDA's pronouncement and PATH's pharmacy project, were achieved because of seed money or a general support grant to implementing organizations known to be competent and creative.
- *The value of quick funding.* The ability of some donors to give support without long delay was instrumental in allowing innovation to take place. A good example were the grants the John Merck Fund made to Princeton University to design the hotline and to RHTP to launch it. Likewise, the funding of the San Diego Demonstration Project, granted on the basis of a phone call and a letter, enabled the Pacific Institute for Women's Health to seize a unique opportunity to partner with a large HMO.
- *Collaboration among donors.* The Foundations collaborated among themselves, providing a critical mass of financial support that made it happen. They encouraged each other, supplemented each others' funds, leveraged additional funds, and complemented each other. Often one foundation could do what another couldn't do. For example, the Packard Foundation supported many introductory efforts in individual developing countries. This was something the Wallace Global Fund was less apt to do because it funds *globally*, not country-specific work. The Wallace Global Fund, however, was able to support the Consortium coordinator and the evaluation of the Consortium, as these were global components.

*The importance of seed money and general support is illustrated by the experience of the Center for Reproductive Law and Policy (CRLP). As explained by CRLP's president, Janet Benshoof: "In 1992 the Packard Foundation gave CRLP a general support grant. In doing so, it gave us the freedom to be creative and innovative in the entire field of contraceptive access. For example, it allowed us to advise others on legal questions -- such as doctors who wanted to prescribe contraceptives by fax, or when New York City Planned Parenthood wanted to do bus ads for emergency contraception and asked 'Is this legal?' None of our early contraceptive work would have been possible without general support grants, like the one from the Packard Foundation." CRLP's successful work with the FDA was not in its initial funding proposal but was part of the innovation made possible by the general support grant.*

## OVERCOMING FEAR OF OPPOSITION

We believe that all five ingredients above -- a good idea, overcoming blockages, a collaborative approach, working on all fronts simultaneously, and sufficient support -- constitute a successful formula for introducing a new method. We also learned that our own fears -- fears of opposition and backlash -- may have held back advances unnecessarily. Many of the activists were nervous or afraid of what the anti-choice movement would do and some admit having let fear influence their willingness to move forward. Says one activist: "It was discouraging to go to the meetings when there was so much talk about fears of opposition. We should have been talking more about what's working and about how to replicate good outcomes!"

In fact, negative reaction has been minimal. "We've done it and the sky did not fall in." The hotline got hardly any complaint calls or charges of killing babies, no one trying to block the lines. The pharmacy project got a few letters, but no picketing. Wal-Mart decided not to carry PREVEN™, but other chains and pharmacies do. Pharmacists for Life protested, but other anti-choice organizations have issued statements saying they don't take a stand on emergency contraception. There was no opposition to the billboards, nor to the public service announcements. The lesson here:

*Be bold. Give women the information and let them decide.*

## XIII.

### The Way Forward

Despite tremendous gains, the job is not yet done. Important legal issues have been overcome and a dedicated product for emergency contraception is on the shelf in many pharmacies. These are huge steps forward. But emergency contraception is not on the shelf in the medicine cabinet and the thousands, or even millions, of women who would want to use it if they knew about it -- still do not know about it. Access issues are still tremendous. Many service providers remain ignorant or misinformed. The doctor's prescription remains a major obstacle. It is still expensive. Clearly much work remains.

*We are only just beginning to make emergency contraception available, to put it in the mainstream. We're not there yet.*

Several activists working to mainstream emergency contraception express concern over decreasing foundation interest and hope for support to sustain the momentum that has been achieved. "I'm worried about foundations fading away from the EC scene," said one. "We're not yet at a place where EC is a household word." Said another: "Even though a product is now on market, we must stay with it. It's why you continue to see McDonald's hamburger ads. McDonald's didn't run them just once."

The possibility remains that, without needed follow through, emergency contraception might easily fizzle out. To realize the gains to date still requires sustained effort.

What is still needed?

### 1. PROVIDE MORE RAPID ACCESS.

Need remains to get rid of delaying barriers -- the delay between the time a woman thinks 'Oh my god!' and when she has pills for emergency contraception in her hand. Given the time-critical nature of the problem -- and of this method as solution -- rapid access is crucial. The assumption that women can fit in a doctor's appointment ignores the fact that most women are working.

What to do?

- **Make emergency contraception available over-the-counter, without prescription.** This is key -- essential -- in the opinion of many. In Britain, the clear leader internationally in emergency contraception, the Royal Pharmaceutical Society is pressing for this. Many proponents in the U. S. are also adamant that over-the-counter availability is essential. In the words of one, "There's no reason not too! You can't even kill yourself with emergency contraception as you can with many other drugs -- even aspirin. It should be as available as aspirin. Many women can't find their boyfriend within 72 hours, let alone a doctor to prescribe."

As set forth in the special issue on emergency contraception of the *Journal of the American Medical Women's Association*: "The harm entailed by keeping this safe, simple, and effective option out of the hands of women almost certainly exceeds any harm that could result from making ECPs [emergency contraception pills] widely available. It is time that the special paternalistic scrutiny accorded to contraceptive methods used by women be relaxed."<sup>26</sup>

- **Advance provision.** Access to emergency contraception would be greatly increased if every sexually-active woman were provided with emergency contraception when she visits a clinic or doctor's office for gynecological care, contraceptives, or treatment for a sexually-transmitted disease. She would then have emergency contraception in her medicine cabinet, readily accessible should she need it.
- **In the meantime, pursue other options for increasing access.** This is where the Washington pharmacy model is so promising, but follow up is needed to introduce pharmacist provision in other states. Prescription over the phone as in Georgia and now Planned Parenthood's *Dial EC* campaign should also be expanded.

### 2. EDUCATE DOCTORS, PHARMACISTS AND OTHER PROVIDERS ABOUT EMERGENCY CONTRACEPTION AND PUT SUPPORTIVE SYSTEMS IN PLACE.

What's not in place? Providers haven't been trained, don't have enough information, and don't have adequate ways of billing. What's needed? Training and systems. Most family planning service providers have not truly integrated emergency contraception into their delivery of other family planning methods. In addition, with the expansion of Catholic and other religious health care systems, provision of needed reproductive health services is increasingly threatened. Emergency contraception should be included in all basic medical training as well as continuing education.

### 3. MAKE EMERGENCY CONTRACEPTION MORE AFFORDABLE.

This means getting more affordable products on the market. It also includes getting insurance coverage for contraception, including emergency contraception. In the meantime, providers need to figure out how to bill.



#### 4. REACH MINORITY AND DISADVANTAGED POPULATIONS.

How to reach the most disadvantaged, the ones with the greatest need who are typically last to have access? Efforts are turning to finding out how best to communicate this option to low-income women -- "niche populations that commercial firms would never go after." RHTP is reaching out to under-served women in Los Angeles and Philadelphia. PATH is initiating a project to "reach ethnically and linguistically diverse groups with emergency contraception." An African-American Pharmaceutical Association with a branch in Washington state aims to improve the counseling skills of pharmacists serving diverse audiences.

#### 5. REACH TEENS.

How to get the news out to adolescents who become sexually active? This is an area where there is no magic bullet but where many things matter. Parents, teachers, MTV, magazines, sexuality education, religious leaders, peers -- all matter. Teens are a favorite target of commercial firms but this is an area where the companies say they "will not stand up and be shot."

#### 6. ENSURE EMERGENCY CONTRACEPTION FOR VICTIMS OF RAPE.

All hospitals and emergency room facilities must have protocols for the provision of emergency contraception to rape victims -- and must provide it.

#### 7. SUSTAIN AND DEEPEN WOMEN'S AWARENESS.

Despite fairly widespread *superficial* awareness of emergency contraception (or the morning-after pill) among women, many lack the knowledge that would lead to their using it in a situation of need. Work must continue at all levels to inform the public -- women and men -- about this important new method.

#### 8. GET SECOND-GENERATION PRODUCTS ONTO THE MARKET.

We now know there are better methods or products for emergency contraception than what are currently available. Progestin-only products (such as Plan B) cause few side effects and may be more effective. Gynetics and Women's Capital Corporation are both working to bring a superior second-generation progestin-only product to market and third-generation products are also in the works.

#### 9. INTERNATIONALLY MUCH WORK REMAINS TO INTRODUCE AND EXPAND AVAILABILITY AND USE OF EMERGENCY CONTRACEPTION IN DEVELOPING COUNTRIES.

Introduction has barely begun in many developing countries. Donors such as UNFPA, USAID and its cooperating agencies need to include emergency contraception as part of the contraceptive "cafeteria" and emergency contraceptive pills should be on the lists of all major suppliers of contraceptive commodities, including USAID, UNFPA, UNICEF and WHO.



*From secret to shelf?*

*It is our hope that by the year 2010, these little pills that can give a woman a second chance will no longer be a secret and that throughout the world emergency contraception will be on the shelf in every woman's home -- "just in case."*

## Notes

<sup>1</sup> *Contraceptive Research and Development: Looking to the Future*, Polly F. Harrison and Allan Rosenfield, eds., Institute of Medicine, Committee on Contraceptive Research and Development, 1996; and J. Joseph Speidel, "Barriers to Contraceptive Development in the United States," Testimony to the 102nd Congress, 1992.

<sup>2</sup> For example, F.J. Saunders in *Endocrinology* 77, 1965; Malcolm Potts and Alexandre Psychoyos in *Comptes Rendu des Seances* 264, 1967.

<sup>3</sup> This is called the Yuzpe regimen, an increased dose of combined oral contraceptives -- estrogen and progestin. It is named after the Canadian gynecologist who published defining data on the method (A.A. Yuzpe et al., "Post-Coital Contraception -- A Pilot Study," *Journal of Reproductive Medicine* 13:53-58, 1974). See also Charlotte Ellertson, "History and Efficacy of Emergency Contraception: Beyond Coca-Cola," *Family Planning Perspectives* 28:44-48, 1996.

<sup>4</sup> Trussell, James and Felicia Stewart, "The Effectiveness of Postcoital Hormonal Contraception," *Family Planning Perspectives* 24:6 (Nov/Dec):262-264, 1992.

<sup>5</sup> Trussell, James, Felicia Stewart, Felicia Guest and Robert Hatcher, "Emergency Contraception Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives* 24:6 (Nov/Dec):269-273, 1992.

<sup>6</sup> Chor-Swang Ng, "Indigenous Fertility Regulating Methods Among Two Chinese Communities in Malaysia." In Lucile Newman, *Women's Medicine: A Cross-Cultural Study of Indigenous Fertility Regulation*, pp. 25-41. New Brunswick, NJ: Rutgers University Press, 1995.

<sup>7</sup> As early as 1979 Stewart and colleagues had featured "Morning-After Birth Control" as a separate chapter (apparently the first time to receive such attention) in *My Body My Health: The Concerned Woman's Guide to Gynecology and Health* (Felicia Stewart, Felicia Guest, Gary Stewart, and Robert Hatcher, New York: John Wiley & Sons).

<sup>8</sup> Hatcher R.A., J. Trussell, F. Stewart, S. Howells, C.R. Russell, and D. Kowal, *Emergency Contraception: The Nation's Best-Kept Secret*. Decatur, Ga: Bridging the Gap Communications, 1995.

<sup>9</sup> James Trussell, et al. "Promoting Emergency Contraception in the United States." In *Journal of the American Medical Women's Association*. Special issue: *Emergency Contraception*. 1998, pp. 247-250.

<sup>10</sup> The Henry J. Kaiser Family Foundation, *Is the Secret Getting Out? 1997 National Surveys of Americans and Health Care Providers on Emergency Contraception*. Menlo Park, Calif, December 1997.

<sup>11</sup> "Emergency Oral Contraception," *ACOG Practice Patterns* Number 3, December 1996. Only once before had ACOG published a "practice pattern" (for vaginal delivery after caesarean-section). Ronald Chez, emeritus past president of ACOG, wrote the practice pattern for emergency contraception. "He was truly visionary about this," says Elisa Wells of PATH.

<sup>12</sup> FDA subsequently extended approval to 11 brands (and two dedicated products).

<sup>13</sup> Food and Drug Administration. "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception." *Federal Register* 56:203-210, 1997.

<sup>14</sup> World Health Organization, *Emergency Contraception: A Guide for Service Delivery*. Geneva, WHO/FRH/FPP/98.19, 1998; International Planned Parenthood Federation, "Statement on Emergency Contraception," *IPPF Medical Bulletin* 28:1-4, 1994; and U.S. Agency for International Development, *USAID Fact Sheet on Emergency Contraception*, Washington D.C., 1997.

<sup>15</sup> The German pharmaceutical company, Schering AG, had PC 4 and two other products on the market based on the standard Yuzpe regimen of combined oral pills. The leading Hungarian pharmaceutical company, Gedeon Richter Ltd., was marketing a progestin (levonorgestrel)-only product, *Postinor*, in packages of four or ten tablets.

<sup>16</sup> The five organizations were: the World Health Organization (WHO, Special Programme of Research, Development and Research Training in Human Reproduction), Pathfinder International, Concept Foundation, Program for Appropriate Technology in Health (PATH), and Pacific Institute for Women's Health. They were joined later by the International Planned Parenthood Federation (IPPF), the Population Council, and Population Services International (PSI).

<sup>17</sup> Walter Mertens, "Evaluation Report on the Emergency Contraception Consortium." Boston: Management Sciences for Health, 1999 (revised). The workings of the Consortium are well-documented. Illuminating strengths and problems are also two reports to the Packard Foundation plus minutes of all Consortium meetings.

<sup>18</sup> Collaborative funding for Planned Parenthood's work on emergency contraception is provided by the Open Society Institute, the Packard Foundation, the Educational Foundation of America, and an anonymous donor.

<sup>19</sup> Castle et al, *Introducing Emergency Contraceptive Pill Services at Family Planning Clinics in Philadelphia: The Organizational and Social Context*. Pacific Institute for Women's Health, 1999.

<sup>20</sup> Henry J. Kaiser Family Foundation. *Is the Secret Getting Out? 1997 National Surveys of Americans and Health Care Providers on Emergency Contraception*. Menlo Park, Calif, December 1997. See the foundation's website ([www.kff.org](http://www.kff.org)) and *Journal of the American Medical Women's Association*. Special issue: *Emergency Contraception*, vol. 53, no. 5, supplement 2, pp. 242-246, 1998.

<sup>21</sup> See Choices website at: [www.emory.edu/WHSC/MED/FAMPLAN/choices.html](http://www.emory.edu/WHSC/MED/FAMPLAN/choices.html) -- and [www.managingcontraception.com](http://www.managingcontraception.com). The one-page instructions for emergency contraception led to one-page descriptions of all major forms of birth control, which can be also downloaded from the web. All underwent scientific review and are not copyrighted, in order to be adaptable for different countries and languages.

<sup>22</sup> See PATH at: [www.path.org](http://www.path.org).

<sup>23</sup> Planned Parenthood of New York City, Inc., *Emergency Contraception: Do Pharmacists Know About This Important Method to Prevent Pregnancy?* February, 1999.

<sup>24</sup> Robert A. Hatcher, James Trussell, Felicia Stewart, Willard Cates, Jr., Gary K. Stewart, Felicia Guest, and Deborah Kowal, *Contraceptive Technology*, 17th Revised Edition. NY, NY: Ardent Media, 1998.

<sup>25</sup> Robert A. Hatcher, Miriam Ziemann, Alston Watt, Anita Nelson, Philip Darney, and Erika Pluhar, *A Pocket Guide to Managing Contraception*. Dawsonville, Georgia: Bridging the Gap Communications, 1999.

<sup>26</sup> Based in Santa Cruz, California, ETR's materials can be accessed at: [www.etr-associates.org/ETR](http://www.etr-associates.org/ETR).

<sup>27</sup> *Journal of the American Medical Women's Association*, Supplement 2, 1998 (Vol. 53, No. 5).

<sup>28</sup> See Anna Glasier and David Baird, "The Effects of Self-Administering Emergency Contraception," *New England Journal of Medicine*, 339:1-4 (July 2), 1998.

<sup>29</sup> Ellertson, Charlotte, James Trussell, Felicia Stewart, and Beverly Winikoff, "Should Emergency Contraception be Available Without Prescription?" *Journal of the American Medical Women's Association*, special issue: *Emergency Contraception*. Vol. 53, No. 5, pp. 226-229, 232. 1998.

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## Thirteen brands of Emergency Contraceptive pills in the United States

<b>BRAND</b>	<b>MANUFACTURER</b>	<b>PILLS PER DOSE</b>
Ovral	Wyeth-Ayerst	2 white pills
Alesse	Wyeth-Ayerst	5 pink pills
Levlite	Berlex	5 pink pills
Nordette	Wyeth-Ayerst	4 light-orange pills
Levlen	Berlex	4 light-orange pills
Levora	Watson	4 white pills
Lo/Ovral	Wyeth-Ayerst	4 white pills
Triphasil	Wyeth-Ayerst	4 yellow pills
Tri-Levlen	Berlex	4 yellow pills
Trivora	Watson	4 pink pills
Ovrette	Wyeth-Ayerst	20 yellow pills

### **DEDICATED PRODUCTS**

Preven	Gynetics	2 blue pills
Plan B	Women's Capital Corporation	white pill