

The Emergency Contraception Newsletter
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ABOUT THIS NEWSLETTER:

This newsletter is prepared and distributed as a voluntary activity on behalf of the American Society for Emergency Contraception and the International Consortium for Emergency Contraception. It is distributed electronically twice each year to anyone wishing to receive it. To contribute a news item, please send it to AmSocEC@aol.com or to Tara Shochet (tshochet@umich.edu). We reserve the right to check and edit items as appropriate. To add or remove your name from the newsletter circulation list, please write to AmSocEC@aol.com. More information about ASEC and the Consortium is located at the end of this newsletter.

COUNTRY UPDATES

List of countries with OTC or pharmacist status

Princeton University's Office of Population Research is pleased to provide a list of countries where EC is available direct from a pharmacist or over the counter:

Available direct from a pharmacist: Albania, Australia, Belgium, Benin, Cameroon, Congo, Denmark, Estonia, Finland, France, French Polynesia, Gabon, Ghana, Guinea, Guinea-Bissau, India, Israel, Ivory Coast, Latvia, Lithuania, Madagascar, Mali, Mauritania, Mauritius, New Zealand, Nigeria, Portugal, Senegal, South Africa, Sri Lanka, Switzerland, Togo, Tunisia, Uganda, United Kingdom, + parts of United States and Canada

Available over the counter: Norway, Sweden

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Update from the Alaska Emergency Contraception Project

Good news from the North! A bill (SB 138) to eliminate the Pharmacy Regulations that allow for Collaborative Drug Therapy Agreements expired with the final gavel of the

2004 legislative session. Pharmacists and other medical professionals came out en masse to testify against this bill during the only hearing it received. The AK EC Project did a massive mailing to Family Physicians, OB/GYNs, Nurse Practitioners, Certified Nurse Midwives and Physicians Assistants in Alaska encouraging advanced prescriptions. The response has been very favorable. Several practitioners have contacted us for everything from sample protocols to signage for their offices. We have also just begun a month-long radio campaign on the Alaska Public Radio Network (APRN). APRN is made up of 26 radio stations; many stations serve as the only media outlet for several remote villages. Lastly, AK EC Project volunteers helped decorate a Porta-Potty at the Alaska Run for Women. Our chosen theme was “Wipe-out Unintended Pregnancy”.

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Canada moves closer to allowing EC without a doctor’s prescription

Health Minister Pierre Pettigrew announced on May 18, 2004, that Health Canada was moving forward with allowing access to levonorgestrel without a doctor's prescription. Health Canada has proposed to amend the Food and Drug Regulations by removing levonorgestrel from Schedule F, Schedule F drugs being those which can only be made available by prescription. Once a drug has been removed from Schedule F, the provincial and territorial pharmacy regulatory authorities decide on the conditions for its sale in consultation with the National Drug Scheduling Advisory Committee (NDSAC) of the National Association of Pharmacy Regulatory Authorities (NAPRA). NDSAC has recommended that provinces and territories adopt Schedule II status (behind-the-counter) for levonorgestrel 0.75mg, which would require professional intervention from the pharmacist at the point of sale.

The proposed amendment has been published in the issue of the Canada Gazette, Part I, of May 22, 2004 and will then be the subject of a consultation period of 75 days. Such consultations are a standard requirement for proposed regulatory amendments. Plan B is expected to be marketed BTC in Canada approximately 6 months after the publication in the Canada Gazette, Part I. In English Canada (Common Law), there will be no limit of age for access to EC in pharmacies. It is up to the provider to verify if the teenage woman understands all required instructions. In French Canada (Civil Code), the lower limit of age for access to EC in pharmacies is 14 years. Under this age, parental consent is necessary (actually, in the province of Quebec, when EC is prescribed by a physician to a teenage woman under 14 years, this parental notification is rarely made). As for the province of Quebec, such a modification in the access of EC will have no effect on its delivery status. Pharmacists will still receive a governmental fee for delivering Plan B and the drug will still be reimbursed by the provincial drug insurance plan.

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CANADA

Promoting NorLevo in Western African countries

The first dedicated levonorgestrel-only ECP, NorLevo[®] was first made available in Senegal in the private sector in February 2002, under BTC status, with the initial objective of providing access to the product to women who face unwanted pregnancy following unprotected intercourse. Active promotion had to be undertaken among every target directly concerned by the treatment in order to emphasize their role in the provision of the treatment:

- Among pharmacists, to ensure accessibility of the product and direct information to women;
- Midwives, nurses, as one of the major source of information and health services to women;
- Doctors, gynecologists in order to implement EC into the range of occasional contraceptive options;
- And obviously among women, who need to know about the indication of the treatment and the way for her to get access to the treatments ASAP when needed.

The 9th VIM (International Medical Vision Conference, held in Dakar early April 2004) was the appropriate opportunity to provide accurate medical information to healthcare providers who were attending the event, with the support of educational product leaflets and posters. HRA Pharma conducted three conferences detailing the core medical information one should know about the treatment, and announcing the “Single Intake” mode of administration that was being progressively implemented in the market. Emphasis was put on specificities observed during the day-to-day experience of EC providers, in forms of practical cases, FAQ and recommendation of answers, etc. This event was of great success for NorLevo[®]. Most of all, enthusiasm and interest were shown by many of the gynecologists and midwives, willing to actively share their daily experience on EC with us.

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NorLevo to be available without a prescription in Dutch pharmacies

In November 2003, the contraception foundation in the Netherlands started a project to allow women to download a prescription for levonorgestrel-only ECP for free. With that prescription they could go to any pharmacist and obtain NorLevo[®]. Between the start of the project and mid-April 2004, over 1,700 prescriptions were downloaded. Starting in the summer of 2004, NorLevo[®] will likely be available at pharmacies with no prior prescription needed! Following a 2-month evaluation procedure, the Dutch Evaluation Committee approved the switch from Rx to non-prescription status. If this decision is validated by the Medical Agency, women in the Netherlands will have wider access to the treatment, with the new delivery status allowing the treatment not only to be more accessible at pharmacies, but also opening the channel of the Dutch drugstores for emergency contraception. The change was approved with very few conditions such as a slight modification of the Summary of Product Characteristics with regards to the vomiting. The second condition was for Laboratoire HRA Pharma to edit a more patient-friendly version of the leaflet. The implementation of both of these changes shall take place by the end of 2004.

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Success story - launch of NorLevo in Baltics

NorLevo[®] was launched in two Baltic countries – Estonia and Latvia – in spring 2003 and was therefore the first levonorgestrel-only dedicated emergency contraceptive pill to be under OTC status. In order to secure successful entrance into market, Nycomed communicated to end consumers & specialists with simple message – “New emergency contraceptive!” The launch campaign mainly consisted of:

- Use of media channels: TV (sponsoring Youth TV Reality show), print media, Indoor and Internet;
- Use of Youth organizations (to distribute information and special gimmicks, e.g. condoms packed in NorLevo[®] branded pack, to teenagers and youngsters);
- Promotions for end consumers, buy NorLevo[®], get condom free of charge;
- Sales people visits to gynaecologists and pharmacists.

The availability of hormonal emergency contraception has been increased by the OTC status. It also allowed the company to market the NorLevo[®] treatment directly to the patients with a special focus to young women, thus leading to a global increase of the general knowledge on reproductive health and more specifically, the contraception of every woman.

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Implementing a global strategy to increase access to EC – the Belgian experience

NorLevo[®] has been available in Belgium since September 2000. Following scientific experts' advice, the Belgian Health Authorities decided to remove the requirement for a medical prescription to obtain NorLevo[®] in June 2001, thus facilitating access to and provision of emergency contraception. Since May 2004, women under 21 years old have even had free access to the treatment. These measures were supported by a targeted and widespread information campaign:

- In schools, via pharmacists and family planning
- Via youth magazines
- Via Internet websites such as www.72.be (a friendly site which shows the hectic life of the spermatozoid and provides accurate information about the “morning-after pill”) and www.norlevo.be were quickly made available as a key support.

Advance provision (at home) of NorLevo[®] could optimise its use, efficiency and access. How? Since April 2004, an active strategy was implemented to recommend prescribing LNG-only ECP conjointly with a regular oral contraceptive, to provide information on the preventive aspect and occasional side effects of the product, and to answer to any woman's concerns. Available data on risky sexual behaviour studies illustrate a convergence to assert that good knowledge of EC reinforces regular contraception use and above all doesn't encourage its abuse: co-prescription of an oral contraceptive and emergency contraception presents a good opportunity.

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Update on the Emergency Contraception Hotline in South Africa

The Emergency Contraception Hotline in South Africa (a 24-hour toll free hotline operating in the Western Cape Province) was launched on 24 October 2003. Six hotline staff (five lay counselors and one registered nurse) was specifically trained for this information and referral service. Two gynaecologists with a special interest in family planning backed up the staff for any inquiries. Up to date 261 health care professionals (42 medical doctors, 12 specialists, 31 pharmacists and 176 nursing staff) have been

trained in 11 workshops and one satellite training transmission. A linear increase in calls to the hotline was logged from its commencement on 24 October 2003. Of the 1151 calls during the first 36 weeks, 409 were during the evening and 742 during daytime. More than 65% of the callers are female and just over 20% are male callers. Most of the calls (nearly 55%) are for information on EC. The mean age of the callers is 23.8 with a standard deviation of 6.13. The most calls received have been from people 30 years and younger (87%) but the ages range from 12 years to 56 years of age. The project is currently launching additional advocacy campaigns and research is conducted on a continual basis. The complimentary website (www.not-2-late.co.za) had 1063 visits during the same time. The project also received 10532 units of progesterone-only-emergency contraception free of charge from HRA Pharma, through Medi-Challenge for free distribution.

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ECP sales and use boosted in Jamaica in award-winning “ACE” campaign

Futures Group created a social marketing program that promoted abstinence, condom use and emergency contraceptive pills (ECPs) as sequential options (in order of preference) for sexually active Jamaican youth under the Commercial Marketing Strategies (CMS) project. Futures Group has defined this triple message campaign as the “ACE” (abstinence, condoms, and emergency contraception) approach to describe an appropriate prevention strategy for youth. Despite extremely limited funds and a short duration, the social marketing campaign nearly doubled ECP sales over the previous year (for a non-subsidized commercial ECP product), increased knowledge of ECPs as a method to avoid pregnancy from 28% to nearly 50% among girls and from 17% to 32% among boys aged 15-to-19, and increased use of ECPs after unprotected sex from baseline 2% to nearly 8% among girls 15-to-19. At the same time condom sales increased. The campaign was awarded the Population Institute’s Global Media Award for “Best Commercial Advertising Campaign” in 2003.

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PSI launches dedicated EC product in Paraguay, Zimbabwe

With support from the Erik E. and Edith H. Bergstrom Foundation, PSI/Paraguay launched Vikela from HRA Pharma, over-branded as *Pronta*, in February of this year. PSI is using mass media and interpersonal communications address low levels of EC awareness as well as women's misconceptions of EC. Since its launch, PSI/Paraguay has made *Pronta* available in 75% of pharmacies and trained more than 3,500 medical providers.

PSI/Zimbabwe launched Gedeon Richter's *Postinor II*, Zimbabwe's only dedicated EC product, in spring 2004. Prior to the product launch, PSI offered extensive training on EC to its 800-member national family planning provider network, *Profam*, as well as nurses in college health clinics. Product information has been integrated HIV programs through PSI's *New Start* Voluntary HIV Counseling and Testing Centers that reach more than 10,000 clients per month.

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Scale up of EC services by the Government of Bangladesh (GOB)

The Directorate of Family Planning of Bangladesh, in collaboration with the Frontiers in Reproductive Health (FRONTIERS) Program of the Population Council, Pathfinder International and JSI, conducted an operations research study in 1999-2003 to document the feasibility of introducing emergency contraceptive pills (ECP) as back-up support for temporary family planning methods in a country where about 33 percent of pregnancies are unplanned per year. Prior to the study, they found that unprotected intercourse was common (18% of couples in last 9 months), and only about one percent of community health workers were aware of the availability and potential use of ECP. Most couples (85%) were using some method of contraception, albeit ineffectively, when unprotected intercourse occurred. The results of the research indicate that after training and the provision of IEC support, more than 90 percent of community health workers could learn and correctly retain information on the indications and instructions for ECP use. Of the 2446 women in the study areas, 65% reported use of ECP after the introduction campaign, and use was much higher (74%) when women are given a supply prophylactically than when required to request ECP after each episode of unprotected sex (47%). The probability of ECP use was significantly higher if women received a

brochure on ECP along with the product. After using ECP, 96% of women adopted a regular family planning method; of those not previously using a method, 68% began using a method after the single use of ECP. Most women are willing to pay 10 Taka (US\$ 0.17) for Postinor 2 through community health workers. Postinor 2 is available in the commercial sector in Dhaka for 35 Taka (\$0.60). During 2003-2004, the National Family Planning Program has been scaling up the provision of Postinor 2 in the Dhaka Division covering a population of 52 million, and selling it at the price of 8 Taka (US\$0.13). Monitoring of scale up continues, and the Government of Bangladesh, in collaboration with UNFPA, which has donated the product, is planning on national scale up during 2005. Reports and summaries of this research are in the process of production, and should be on the Population Council web site by September 2004. Funding for this activity was provided through a cooperative agreement between the Population Council and USAID, HRN-A-00-98-00012-00.

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PROSALUD to sell one-millionth box

PROSALUD INTER-AMERICANA is pleased to announce that its network partner PROSALUD (Venezuela) will distribute its 1 millionth cycle of Postinor-2 sometime during the month of August. Launched in March 2000, it has reached this milestone in 53 months. It believes that the second million will be obtained within 24-30 months. These results indicate that overall usage increases with increasing use of Postinor 2.

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Registration of Postinor-1 underway

PROSALUD INTER-AMERICANA is pleased to announce that its network partners PROSALUD (Venezuela) and PROSALUD (Peru) have started the registration process for Postinor-1, a one-pill presentation of Postinor-2. With the WHO finding that the single taking of both tablets of Postinor 2 offered the same benefits as taking the two pills 12 hours apart, the manufacturer of Postinor decided to offer a single dose. The registration is expected to take 90-120 days. Postinor 1 will improve compliance, as human error will be virtually impossible with regards to administration. PROSALUD plans to gradually discontinue the availability of Postinor 2 in favor of the newer presentation.

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EC programs in Argentina, Ecuador set to begin

PROSALUD INTER-AMERICANA is pleased to announce that its network partner PROSALUD (Argentina) will commence activities in August. Funded in part by donations from Bergstrom Foundation, Population Services International, and PROSALUD INTER-AMERICANA, the program will replicate the PSIA model that has been successful in both Venezuela and Peru. Postinor 2 has been registered in Argentina since September 2003 and will be commercialized by a well-established importer/distributor of pharmaceutical products.

PROSALUD INTER-AMERICANA is also pleased to announce that its network partner COPPRENDE will commence activities in Ecuador in August. Funded in part by donations from Bergstrom Foundation, Population Services International, Compton Foundation, Conservation, Food and Health, and PROSALUD INTER-AMERICANA, the program will replicate the PSIA model that has been successful in both Venezuela and Peru. The registration of Postinor 2 will be completed in July and will be commercialized by a well-established importer/distributor of pharmaceutical products.

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Registration of Postinor-2 underway in Bolivia

PROSALUD INTER-AMERICANA is pleased to announce that its network partner APPRENDE (Bolivia) has started the registration process for Postinor-2. The registration is expected to take 120 days. Upon registration, APPRENDE will implement the same PSIA model that has been successful in both Venezuela and Peru.

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IPAS Vietnam holds contraceptive training

Ipas Vietnam conducted two three-day update contraceptive training courses in May 2004 for health providers from provincial, district, and commune levels. These trainings covered technical information about contraceptive methods and counseling skills and EC was a large topic in these courses. Updated information on EC was also given through presentation and case study exercises conducting at two separate workshops in Vietnam hospitals in May of 2004.

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EC to be included into Policy Project's FamPlan Spectrum Model

The POLICY Project facilitates the creation of policies that promote and sustain access to high quality family planning/reproductive health (FP/RH), HIV/AIDS, and maternal health programs in developing countries. The four key components of the project's work are: strengthening political and popular support for FP/RH programs and service; improving finance and planning for these programs; ensuring that accurate information informs decision making, and building in-country capacity to participate in the policy process. POLICY's had developed a series of computer models to help GOs/NGOs decide on resource allocation. The models are part of a software system called **SPECTRUM**, which is integral to these activities. The models comprising SPECTRUM are used to project the need for reproductive health services and the consequences of not addressing reproductive health needs. Most models are available in English, French, and Spanish. The FamPlan Model projects family planning requirements needed to reach national goals for addressing unmet need or achieving desired fertility. It can be used to set realistic goals and to plan for the service expansion required to meet program objectives. The program uses assumptions about the proximate determinants of fertility and the characteristics of the family planning program including method mix, source mix, and discontinuation rates to calculate the cost and the number of users and acceptors of different methods by source. Work has now started by the Policy Project to include EC in the method mix.

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NEW MATERIALS AND CAMPAIGNS

Back Up Your Birth Control mobilizes EC activists in support of Plan B OTC

Under the banner of the third annual Back Up Your Birth Control Campaign, coordinated by the Reproductive Health Technologies Project (RHTP) and NARAL Pro-Choice New York, over 35,000 activists participated in efforts to urge the FDA to approve Plan B for non-prescription status with no restrictions. Using rallies, teach-ins, postcard petitions, and most notably, e-action alerts, more than 130 national, state, and local organizations made it known to the White House, the FDA, and the Department of Health and Human Services that politics has no place at the FDA. Fact sheets, talking points, and sample letters are available on the campaign website backupyourbirthcontrol.org. To further raise the profile of this issue, RHTP and Public Interest Media Group used earned media to generate significant news coverage of the FDA's review and ruling on the application, amounting to over 150 million impressions between December 2003 and June 2004. By and large, the stories were extremely positive, focusing on the public health and medical support for and OTC switch and characterizing the FDA's delay and eventual non-approval as a reflection of political interference. In addition, at least 70 unique newspapers wrote editorials in support of EC over-the-counter, many of them opining on the subject more than once.

Notable Articles*:

"Contraceptive Clears Hurdle to Wider Access," *NY Times*, 12/17/03
"A Public Health Victory," *NY Times* Editorial, 12/18/03
"Debate Intensifies Over 'Morning-After' Pill," *Washington Post*, 2/13/04
"Science or Politics at the FDA?" *NY Times* Editorial, 2/24/04
"Making Contraception Easy Shouldn't Be So Difficult," Syndicated Column by Ellen Goodman, 2/27/04
"FDA, Politics, and Plan B," *New England Journal of Medicine* Editorial, 4/8/04
"Plan B Won't Be Sold Over-the-Counter," *Washington Post*, 5/7/04
"Staff Scientists Reject FDA's Plan B Reasoning," *Washington Post*, 6/18/04
*Copies are available from RHTP.

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California's EC Pharmacy Program shows continued success

California's EC Pharmacy Program continues to grow with over 2500 pharmacists now trained and approximately 900 pharmacies providing EC services statewide. Effective January 2004, two bills (SB490 & SB545) further streamlined EC pharmacy services. As a result, pharmacists are now able to use a statewide protocol authorized by the State Board of Pharmacy and Board of Medicine available at <http://www.pharmacy.ca.gov/> and only need to complete a minimum of 1 hour of continuing education in EC. In June, Pharmacy Access Partnership launched a new online EC training program for pharmacists and health care professionals nationally, providing 1 hour of CE or CME credit (visit www.pharmacyaccess.learnsomething.com). The Partnership will be evaluating consumers' experiences in accessing EC in CA pharmacies (direct access versus prescription) this summer. The Partnership continues to support and stimulate pharmacy access in other states through www.go2ec.org. In May, the Partnership brought together pharmacy and advocacy leaders from 19 states and provinces to share lessons learned, best practices, and strategies to expand access to EC. Pharmacy Access Partnership was deeply saddened to lose its founder and director, Dr. Jane Boggess, who passed away unexpectedly in January 2004. Partnership staff is, however, excited to welcome Belle Taylor McGhee as the new director starting mid-July.

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PATH updates from around the globe

Mainstreaming EC: PATH's new publication, *Resources for Emergency Contraceptive Pill Programming: A Toolkit*, is now available in both English and Spanish. The purpose of this toolkit is to help policy makers, program planners, donors, and family planning providers integrate emergency contraceptive pills (ECPs) into family planning and reproductive health programs in developing countries. This toolkit has been introduced in national workshops in Indonesia and Kenya and will be introduced in upcoming meetings in Bolivia, Paraguay, Nicaragua, and Ethiopia through collaborations with CISTAC, PROMESA, the Latin American Consortium for Emergency Contraception, and ECafrique. The toolkit is available online at http://www.path.org/resources/ec_reseccprog-toolkit.htm in English and

http://www.path.org/resources/ec_resecpprog-toolkit-sp.htm in Spanish. To order a copy of the CD-ROM, please send a message to publications@path.org.

In a related effort to mainstream EC, PATH is working to have EC included in key reproductive health planning tools whenever contraceptive methods are discussed. Discussions to date have focused on the inclusion of additional questions about emergency contraception in the core DHS reproductive health questionnaire, which is being updated; incorporation of an EC fact sheet in the USAID-funded Deliver Project's contraceptive fact sheets; and the possibility of a link to PATH's toolkit in the resources accessed through the MSH Health Manager's Toolkit.

PATH's Youth-Friendly Pharmacy Program: As mentioned in a previous newsletter, a renewal grant from the William and Flora Hewlett Foundation is making it possible for PATH to scale up its RxGen Project in Cambodia, Kenya and Nicaragua, and to expand the approach to Vietnam. Working with local partners, including pharmacies in the private commercial sector, the public health sector, universities, and NGOs, the project aims to strengthen the capacity of pharmacy personnel to provide EC and other reproductive health services in a youth-friendly manner, and to build linkages between pharmacies and local health providers. With funding from another Hewlett Foundation grant, PATH is adding to the pharmacy training program a new component on the management of unintended pregnancy. This component will explore the information and services that can be provided at the pharmacy level for clients who have missed the window of opportunity for EC use.

In the United States: PATH is working with colleagues in the Washington State Department of Health (DOH) and Department of Social and Health Services (DSHS) to increase access to EC through multiple state programs and systems. This collaboration in Washington State has shown that incorporating ECP information and services into a range of health and social programs is an effective and sustainable way to reach a wide audience, particularly low-income and underserved populations. With funding from several foundations, PATH and DOH and DSHS colleagues hosted a workshop in Seattle for program managers and planners from five states: California, Illinois, Massachusetts, New Mexico, and New York. These states were selected for participation in the workshop because in each of them there is strong interest, both within and outside of state agencies, in increasing women's access to ECPs. The workshop provided the opportunity to share successful strategies, learn how agencies can mutually reinforce each other's programs, and develop state-specific strategies for EC awareness raising and information and service provision.

Eastern Europe and Former Soviet Union: PATH has received foundation funding to establish an electronic EC Network in Eastern Europe and the Former Soviet Union. PATH will translate into Russian and distribute by email to network members the International Consortium for Emergency Contraception newsletters and some materials on EC.

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Expansion of EC project for displaced populations

The Reproductive Health Response in Conflict Consortium (RHRC Consortium) is pleased to announce that its project to expand access of emergency contraception (EC) to communities affected by armed conflict has been generously funded by the Compton Foundation. The project will focus on districts in northern Uganda with large numbers of refugees and internally displaced people. This project builds on the existing EC work of the RHRC Consortium, which includes the production of a distance learning module *Emergency Contraception for Conflict-Affected Settings* (available from info@rhrc.org).

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EC Funding Strategy Meeting held in June

On June 22nd, more than 75 people gathered in New York City for an all-day Emergency Contraception Funding Strategy Meeting, co-sponsored by the Compton Foundation, John Merck Fund, Open Society Institute, and American Society for Emergency Contraception. Participants heard in detail from senior management at Barr Laboratories on its regulatory and marketing plans in light of the May 6, 2004 action of the Food and Drug Administration denying as “non-approvable” the petition to permit Plan B to be sold over-the-counter. After that, there was a full discussion about the FDA decision and its implications for future work and funding support. The meeting agenda was based on the three overarching priorities identified in *From Secret To Shelf: How Collaboration is Bringing Emergency Contraception to Women*: (1) educating women about emergency contraception, (2) educating clinicians, pharmacists, policymakers, and other stakeholders, and (3) removing barriers to obtaining the pills within 72 hours after unprotected sex. A summary of the meeting discussion will be available shortly.

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PPFA has updated online EC fact sheets

The Katharine Dexter McCormick Library at Planned Parenthood Federation of America has recently updated its four key fact sheets on emergency contraception. They can be accessed on www.plannedparenthood.org. The titles are:

- Emergency Contraception
- A Brief History of Emergency Contraception
- Obstructing Access to Emergency Contraception in Hospital Emergency Rooms
- The Difference Between Emergency Contraception and Medical Abortion

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AGI initiates new project: “Advancing access to EC in the United States: Assessing state mechanisms for regulating EC”

The Alan Guttmacher Institute has initiated a new project, with the support of the Compton Foundation, designed to provide advocates and policymakers with information about the options states have to make access less burdensome if the FDA maintains the prescription requirement—or about restrictions states could impose if the FDA were to approve for Plan B over-the-counter sale. Over the course of a year, the Institute will examine state laws and regulations to understand states’ latitude to regulate over-the-counter products and prescription drugs. Summaries of the results will be made available in future issues of *The Guttmacher Report on Public Policy* and will be disseminated widely to coalition partners, advocates, the media and policymakers at the state and federal levels. The Institute will also include state legislative developments related to EC in monthly updates posted on the *State Center* on AGI’s website (www.guttmacher.org/statecenter/index.html) and will expand its *State Policies in Brief* series on EC to include new legislative and regulatory avenues taken by states to increase or impede access.

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NYCLU trainings increase awareness of “EC-in-the-ER” law in New York State

Since New York first began requiring hospital emergency rooms to provide EC on-site to survivors of sexual assault last year, the New York Civil Liberties Union’s Reproductive Rights Project has been working to educate emergency personnel about the new law in the context of trainings on an adolescent’s right to obtain confidential rape crisis medical services without parental involvement. Anna Schissel, Staff Attorney for the Reproductive Rights Project, has collaborated with organizations that provide training for rape crisis counselors, forensic evidence collection specialists, and other hospital and law enforcement personnel who work with sexual assault survivors. Through partnerships with the New York City Alliance Against Sexual Assault, various hospital rape crisis counselor training programs, and in particular a collaboration with the New York State Coalition Against Sexual Assault (NYSCASA), Ms. Schissel has trained over 1,000 hospital staff and law enforcement officials across the state. The trainings, which rely on a Powerpoint presentation and emphasize the right of minors to receive confidential rape crisis treatment, including EC, have confronted the ignorance and errant hospital policies surrounding the provision of health care to minors. In each training, Ms. Schissel calls attention to a hospital’s duty to offer and provide EC to all survivors, noting that teenaged survivors also may obtain EC and that the teen’s parents may not be notified unless the teen so desires.

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Expanding knowledge and access to EC in Honduras

Ashonplafa, the International Family Planned Parenthood Federation (IPPF) affiliate in Honduras, Marie Stopes International (MSI) in Honduras and the Population Council, Regional office for Latin American and the Caribbean (based in Mexico City), recently completed a four-year project with the goal of increasing Hondurans’ awareness and access to emergency contraception. After conducting baseline KAP surveys among family planning clinic attendees, we developed informational materials including printed brochures, posters and radios spots aimed at specific populations (adolescents, adults and factory workers). We also developed an educational video for youth and participated in several interviews/debates on radio and TV. Other activities included workshops on EC for health professionals, mass media members, pharmacy vendors, factory workers, and women’s groups throughout the country. Ashonplafa took the lead in creating a specially packaged EC kits containing a 4-pill + 4-pill Yuzpe regimen (using a popular Honduran

oral contraceptive called Perla) for availability in clinics and NGOs servicing rape victims, youth and other special groups. Follow-up KAP surveys were completed in November 2003, and in February 2004, we organized an end-of-project stakeholder meeting to share project results.

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COPPRENDE (Ecuador) to offer symposium

PROSALUD INTER-AMERICANA is pleased to announce that its network partner in Ecuador COPPRENDE has been invited to present a symposium on Emergency Contraception as part of the annual congress being held by the Ecuadorian Federation of the Gynecology and Obstetrics Societies (FESOG). Participants will be well known specialists from the region: Dra. Soledad Diaz (Chile), Dr. Alfredo Guzman (Peru), and Dra. Maria Elena Ortiz (Chile). COPPRENDE will use this opportunity to distribute its training course on CD-rom, product samples, and new studies to all practitioners in attendance. The symposium will be held during the week of November 8th.

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California Family Health Council EC projects continue to get results

With surveys showing an 89% increase in the advance provision of Emergency Contraception (EC) among providers receiving technical assistance and an EC Provider kit, the California Family Health Council EC Initiative continues to demonstrate strong results in increasing awareness, access, and availability of EC. Now in its fourth year, this Title X funded EC awareness campaign works to give providers the tools to integrate EC into existing health care systems as well as to educate and promote greater access to EC in the community. The community awareness segment of this EC campaign has been tailored to appeal to both men and women, reaching diverse communities with a new and innovative campaign each year. The EC education and promotion media developed by

this project include interior bus posters, community billboards, postcards, wallet cards and EC client education brochures. This EC community campaign has won two consecutive Latino Marketing Awards and Communicator Awards of Distinction for 2002 and 2003.

Other CFHC EC Projects:

- In collaboration with the CFHC EPA division, the EC Initiative developed an EC client education brochure titled, “You can still prevent pregnancy–after sex.” Originally available in English and Spanish, the brochures were adapted into Chinese, Korean, and Vietnamese with cultural specificity. Written at about 4th grade reading level, these materials were designed to meet the needs of clients with low literacy. This EC brochure series was given the 2004 Institute for Healthcare Advancement’s Health Literacy Award.

- The CFHC Research division has completed a community-based EC clinical trial, which recruited nearly 10,000 women from 18 different clinics. Half of the participants received free EC pills and the other half received information on how to get EC pills. Study participants were surveyed six months afterward to determine the outcome of EC use. The results showed that those women who received the pills were more likely to take them, but there was no reduction in the use of routine birth control. These results will be presented at the 2004 Annual American Public Health Association meeting in Washington DC.

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Society for Adolescent Medicine provides position statement on EC

The Society for Adolescent Medicine has recently written a position statement on EC. The statement includes support for both advanced prescription and OTC availability for adolescents. The statement was published in the July 2004 issue of the Journal of Adolescent Health (Volume 35, pages 66-70).

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FIAPAC conference to include several EC presentation

This September, the International Federation of Professional Abortion and Contraception Associates (FIAPAC) will hold their 6th conference: “United to improve women’s health.” The meeting, which will be held in Vienna, will include several presentations on EC. More information can be found at <http://www.fiapac.org>.

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EC for rape victims on National Sexual Violence Conference agenda, paper to be presented at APHA

Emergency contraception for rape victims was on the agenda for the first time at the CDC’s 3rd National Sexual Violence Prevention Conference in Los Angeles in May 2004. A workshop entitled *Preventing Pregnancy Following Sexual Assault: A Multidisciplinary Approach* outlined strategies for pro-choice and anti-sexual violence organizations to work together to improve access to EC for rape victims receiving treatment at hospital emergency departments. Staff of the Education Fund of Family Planning Advocates of NYS, the Duvall Project of the ACLU of Pennsylvania and the National Sexual Violence Resource Center collaborated to present the workshop and to staff an exhibit table offering information about EC. Education Fund staffers have also received acceptance from the American Public Health Association to present a paper on “Pregnancy Prevention for Rape Survivors: Forming Advocacy Partnerships Between Reproductive Health and Anti-sexual Violence Groups to Improve Care” at APHA’s annual meeting in Washington, D.C., in November 2004.

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Workshop held on EC for sexual assault victims

In May, Duvall Director Carol Petraitis, Lois Uttley of Family Planning Advocates of NYS, and Caroline Campagna of the National Sexual Violence Resource Center held a workshop on EC for sexual assault victims at the third annual National Sexual Violence Prevention Conference in Los Angeles, CA. Over a thousand advocates, researchers, and medical professionals attended the conference. At the coalition booth, we distributed copies of the Duvall/ACLU manual, *EC in the ER*, and the coalition's toolkit, *Preventing Pregnancy from Sexual Assault: Four Action Strategies*, along with a host of other materials.

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PRCH very active in support of EC OTC

Physicians for Reproductive Choice and Health (PRCH) has been very active in support of making emergency contraception available over-the-counter.

- PRCH dedicated the February issue of our newsletter Choice Notes to emergency contraception and the importance of having a dedicated product available over-the-counter to women of all ages.
- PRCH held an advocacy day this spring with 16 physicians from around the country in support of the Emergency Contraception Education Act. We met with 18 elected officials and secured three additional sponsors to the bill.
- Physicians unable to attend the spring advocacy day enthusiastically responded to an e-mail alert asking them to contact their legislators, urging support of the bill.
- PRCH's Kenneth J. Ryan MD Memorial Program dedicated its ACOG Annual Clinical Meeting to the issue with a panel of four national experts on emergency contraception; Drs. Harry Jonas, Philip Corfman, David Grimes and Carolyn Westhoff.
- PRCH co-hosted a press conference with ACOG on the critical need for EC to be available OTC and calling on the FDA to make a decision based on medical and scientific evidence.
- When the decision not to approve the product was rendered, PRCH immediately sent a press release out to approximately 150 media outlets.

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IPPF/WHR concluding project to increase knowledge about, access to, and appropriate use of EC in five countries

With the support of the Bergstrom Foundation and other donors, IPPF/WHR is in the final stretch of a 30-month project to increase knowledge about, access to and appropriate use of ECPs in five countries in Latin America and the Caribbean by: 1) strengthening institutional capacity to integrate EC into service delivery; 2) increasing awareness and access among clients, stakeholders, and women's groups; and 3) increasing knowledge about effective EC promotional strategies among SRH and related organizations in country and across the region. **BEMFAM in Brazil** has trained a range of providers in their own institutions and through agreements with municipalities in the public sector while incorporating EC into its programs and materials addressing contraceptive provision strategies and vulnerable populations. **APROFA in Chile** persists in training public and private sector providers and giving more visibility to EC as they counter legal opposition and advocate for the inclusion of EC in pharmacies and government services. **PROFAMILIA in Colombia** will be entering its 10th year of successful defense, social marketing and commercial distribution of a dedicated EC product, but recently has garnered airtime for radio programs and space for nationally broadcast television shows on EC while strengthening the capacity of their nationwide network of youth peer promoters. **PROFAMILIA in the Dominican Republic** has actively sensitized and trained thousands of service providers and updated institutional protocols, manuals and educational materials with the latest on EC, including a hip-hop CD created by youth educators. In addition, PROFAMILIA has partnered with a local laboratory to promote a dedicated EC product through a unique "sales" and education force. **PLAFAM in Venezuela** has developed EC kits to distribute to clients and tailored information for outreach to university students, professional medical societies and others in the community, including survivors of gender-based violence, HIV-positive women and commercial sex workers. *The overall project results will be disseminated during a region-wide meeting of all IPPF/WHR affiliates this fall in Mexico.*

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Advocates for Youth EC initiative

Since 2000, Advocates for Youth has worked at the national, state, and local levels to raise awareness and improve access to emergency contraception (EC) for adolescents. Advocates' communications and media strategy includes public service announcements, radio tours, and briefings with producers and writers of teen-focused television shows to encourage placement of story lines related to teens and EC. In addition, Advocates' Clearinghouse on Adolescents and Emergency Contraception provides publications, strategic technical assistance, training, resources and networking opportunities to state teen pregnancy prevention coalitions, sexuality educators, youth serving professionals, and adolescent health providers. Advocates actively involves young people in its efforts to promote EC. In 2004-05, Advocates is mobilizing thousands of young people and training key youth leaders to demand their right to emergency contraception. Advocates is encouraging youth across the country to sign a petition, write letters to their Members of Congress and the Federal Drug Administration (FDA), and submit opinion editorials to their local newspapers. The current debate in the United States over EC access presents both an urgent need to marshal and demonstrate existing support for over-the-counter (OTC) status, and a window of opportunity to educate people- especially adolescents- about EC as a safe and effective emergency pregnancy prevention method.

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Training held to improve treatment of sexual assault victims in West Virginia

The Reproductive Freedom Project, together with the ACLU of Pennsylvania's Clara Bell Duvall Reproductive Freedom Project, sponsored a training this past winter for the West Virginia ACLU affiliate and its coalition partners on how to improve the treatment of sexual assault victims in West Virginia's emergency rooms. Under the guidance of RFP and the Duvall Project, the West Virginia ACLU affiliate, the state sexual assault coalition, and other reproductive rights advocates have recently begun a survey of ERs across the state to assess the level of care currently provided to rape victims. The coalition will then use the results to advocate for increased access to EC in the ER and other services.

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RESEARCH RESULTS AND UPDATES

Randomized trial in progress to evaluate effect of advance provision EC on pregnancy, STI risk

Family Health International, in collaboration with University of California at San Francisco, Planned Parenthood Mar Monte, and Planned Parenthood of Central North Carolina, have been conducting a randomized trial to determine the effect of advance provision of ECPs on pregnancy and STI risk. The trial is funded by the National Institutes of Health. In May, 2004, we completed enrollment of our target sample size of 1,490 women aged 14-24. Follow-up will be finished in June, 2005.

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Study being conducted to describe bleeding patterns following EC use

Family Health International is collaborating with Planned Parenthood League of Massachusetts on a study to describe bleeding patterns in the two months after use of the single dose levonorgestrel ECP regimen. The study will enroll 120 women who have used the regimen. It began on June 21, 2004 and will be completed in about 7 months.

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Analysis of DIAL EC data complete, published in Contraception

Family Health International has completed an analysis of data collected by the DIAL EC Project, which was initiated in February 2001 at Planned Parenthood of Central North Carolina. The results of our analysis were published in *Contraception* (Raymond EG, Spruyt A, Bley K, Colm J, Gross S, Robbins LA. The North Carolina DIAL EC Project: Increasing Access to Emergency Contraceptive Pills by Telephone. 2004;69:367-72.) The Project enabled North Carolina residents to obtain prescriptions for ECPs by telephone. In the first 29 months of the project, we issued 9,745 prescriptions to 7,774 callers. Forty percent of callers were teens. Only 16% of callers received more than one prescription. The service was initially free, but in the last 6 months, most callers were asked to pay \$40 per prescription. The fee resulted in a decline in the number of prescriptions issued, but the service became financially self-sustaining. This service proved to be an effective and efficient means for increasing access to ECPs in underserved areas.

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Levonorgestrel for emergency contraception: is treatment effective after 72 hours of unprotected intercourse?

A patient-based meta-analysis of two WHO trials (*Lancet* 1998; 352:428-33 and *Lancet* 2002; 360:1803-10) showed that the efficacy of LNG decreased significantly on third and fifth day compared to the first day after intercourse and that LNG prevents pregnancy up to the fourth day inclusive. LNG may still have an effect on the fifth day, although evidence is not strong due to the small number of women requesting EC on the fifth day. More research is needed to confirm effectiveness after the fourth day. The risk of pregnancy for successive days of delay was adjusted for trial and baseline characteristics of women. The prevented fraction was calculated using (pooled-recognizable) external conception probabilities.

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Study evaluates impact on risk taking behaviors among adolescents receiving advance provision of EC

A randomized trial was conducted at an urban, hospital-based adolescent clinic in Pittsburgh, PA from June 1997 to June 2002. The objective of this study was to determine whether adolescents given advance EC have higher sexual and contraceptive risk-taking behaviors compared to those obtaining it on an as-needed basis. 301 predominantly minority, low-income, sexually active adolescent women, age 15-20 years, not using long-acting contraception, participated in the study. At both one and six-month follow-up interviews, there were no differences between advance EC and control groups in reported unprotected intercourse within the past month or at last intercourse. At six-months, more advance EC participants reported condoms use in the past month compared to control group participants (77% vs 62%, $P=0.02$), but not at last intercourse (advance EC 83% vs control 78%, $P=0.34$). There were no significant differences by group in hormonal contraception use reported by advance EC or control groups in the past month (44% vs 53%, $P=0.19$) or at last intercourse (48% vs 58%, $P=0.20$). At the first follow-up, the advance group reported nearly twice as much EC use as the control group (15% vs 8%, $p=0.05$) but not at the final follow-up (8% vs 6%, $P=0.54$). Advance EC group participants began their EC significantly sooner (11.4 hours vs 21.8 hours, $P=0.005$). Providing advance EC to adolescents is not associated with more unprotected intercourse or less condom or hormonal contraception use. In the first month after enrollment, adolescents provided with advance EC were nearly twice as likely to use it and began EC sooner, when it is known to be more effective.

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Family Planning Council conducting five-year longitudinal EC study

A Second Chance with ECP: Reducing Unintended Pregnancy, funded by NICHD, is a five-year, longitudinal study currently being conducted by Family Planning Council, Inc. in Philadelphia, and Family Health Council, Inc. in Pittsburgh, PA. This study examines relationships between EC use and participants' demographics, access,

behaviors and psychosocial factors as well as their fertility and contraceptive histories. A total of 1093 women between the ages of 15 and 39 were enrolled, and primary data collection has been completed. Participants were asked to return a monthly page for 18 months to respond to a computer-generated survey regarding sexual and contraceptive behaviors. A random subsample of participants was asked to complete three in-depth interviews. Eight hundred thirteen women completed over 5,000 automated telephone surveys, while 475 completed the first in-depth interview, 363 another in-depth interview nine months later, and 315 completed the final interview 18 months after study enrollment. Preliminary data analyses indicate that approximately 24% of participants have used EC in the past. At enrollment, approximately 57% of EC users reported using EC because no other contraceptive was used, 32% said they used EC because of problems with condoms, 8% reported that problems with pills led to EC use, 3% reported sexual assault was the reason for EC use. Self-report data and medical chart data will be used to examine differences between EC users and nonusers in terms of STDs and pregnancies.

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Review of EC data: “Mechanisms of action of mifepristone and levonorgestrel when used for emergency contraception”

An emergency contraceptive method is used after coitus but before pregnancy occurs. The use of emergency contraception is largely under-utilized worldwide. One of the main barriers to widespread use is concern about the mechanism of action. Recently, treatment with either 10 mg mifepristone or 1.5 mg of levonorgestrel has emerged as the most effective hormonal method for emergency contraception with very low side effects. However, the knowledge of the mechanism of action of mifepristone and levonorgestrel in humans, when used for contraceptive purposes and especially for emergency contraception, remains incomplete. The objective of this review is to summarize available data on the effects of mifepristone and levonorgestrel on female reproductive functions relevant to the emergency use of the compounds. When summarized, available data from studies in humans indicate that the contraceptive effects of both levonorgestrel and mifepristone, when used in single low doses for emergency contraception, involve either blockade or delay of ovulation, due to either prevention or delay of the LH surge, rather than to inhibition of implantation. Hum Reprod Update. 2004 Jul-Aug;10(4):341-8. Epub 2004 Jun 10.

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ABOUT THE AMERICAN SOCIETY FOR EMERGENCY CONTRACEPTION

The American Society for Emergency Contraception (ASEC) is a voluntary collaboration of organizations that promote the availability of emergency contraception for women. Founded in 1997, ASEC has four mandates: 1) to serve as a source of information for the media and others who want information on emergency contraception; 2) to serve as a watchdog for inaccurate or biased articles in the press and respond with accurate letters to the editor, and to watch for abuses of reproductive rights related to emergency contraception, and draw attention to these problems; 3) to promulgate policies on emergency contraception and to support and disseminate the statements and guidelines of other organizations willing to endorse the method; and 4) to link the members of the emergency contraception field, primarily by sending out (in collaboration with the international Consortium on Emergency Contraception) this semi-annual electronic newsletter on recent events in emergency contraception and by organizing an annual meeting to share information with researchers, policy makers and the pharmaceutical industry.

ASEC is open to industry participation, although it will not endorse one method or regimen over others that are also safe and effective. Membership is free, and although the focus is primarily on the United States, international affiliates are welcome.

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ABOUT THE INTERNATIONAL CONSORTIUM FOR EMERGENCY CONTRACEPTION

The mission of the International Consortium for Emergency Contraception is to expand access to and ensure safe and locally appropriate use of emergency contraception worldwide within the broader context of family planning and reproductive health, with emphasis on developing countries. The Consortium now has 31 member agencies worldwide.

Materials Available: Single copies of the following publications can also be requested free of charge from the International Consortium:

- Five policy statements for use in local-country and international advocacy campaigns (published July 2003). The five topics covered include:
 1. Mechanism of Action
 2. Dosage and Timing of ECPs – Regimen Update
 3. Repeat Use of ECPs
 4. Increasing Access to ECPs
 5. EC and Abortion

- *Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs* (includes *Medical and Service Delivery Guidelines* as an appendix)

While contained in the above publication, the Consortium has also published: *Medical and Service Delivery Guidelines for Emergency Contraceptive Pills*, as a separate bound guide for use in training programs or for distribution to clinical staff. Single copies also available free of charge. Multiple copies can be purchased. An updated version of these guidelines, incorporating recent revisions on ECPs dosage and timing will be released in Summer 2003.

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