Bill as Introduced

2006 SESSION

06-2730
08/01

SENATE BILL ***343***

AN ACT relative to emergency contraception.

SPONSORS: Sen. Letourneau, Dist 19; Sen. Barnes, Dist 17; Sen. Boyce, Dist 4; Sen. Kenney, Dist 3; Sen. Morse, Dist 22; Sen. Martel, Dist 18; Rep. Dowd, Rock 5; Rep. Easson, Straf 3

COMMITTEE: Health and Human Services

ANALYSIS

This bill requires parents or legal guardians to give consent before pharmacists may dispense emergency contraceptives to minors.

This bill also establishes a pharmacist conscience clause which shields pharmacists refusing to fill emergency contraceptive prescriptions from civil liability and disciplinary action by the pharmacy board.

Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

06-2730
08/01

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Six

AN ACT relative to emergency contraception.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Parental Consent. RSA 318:47-e, VI is repealed and reenacted to read as follows:

VI.(a) Except as provided in subparagraph (b), a pharmacist shall not dispense emergency contraception to a child less than 18 years of age without the written consent of one of the child's parents or a legal guardian of the child.

(b) Parental consent shall be waived if:

(1) The minor is the victim of rape or incest, provided charges have been filed with the local authorities.

(2) The health care professional prescribing emergency contraception determines and submits documentation with the prescription stating that compliance with the parental consent requirement of this section may have an adverse effect on the welfare of the pregnant minor.

(3) The health care professional prescribing emergency contraception determines and submits documentation with the prescription stating that the pregnancy endangers the health or life of the pregnant minor in such a way that the requirement of parental consent may cause an untimely delay in the administration of emergency contraception, further endangering the health or life of the pregnant minor.

(c) A pharmacist dispensing emergency contraception to a child less than 18 years of age shall be guilty of a misdemeanor and shall be liable civilly to a parent or guardian who did not provide consent and for whom consent could not be waived in accordance with this section. A pharmacist shall not be held liable under this section if the pharmacist establishes by written evidence that the pharmacist relied upon evidence sufficient to convince a careful and prudent person that the representations of the pregnant minor regarding information necessary to comply with this section are bone fide and true.

2 New Paragraph; Pharmacist Conscience Clause. Amend RSA 318:47-e by inserting after paragraph VI the following new paragraph:

VII. Any pharmacist who states in writing an objection to emergency contraception on moral or religious grounds shall not be required to fill a prescription for a drug used as an emergency contraceptive. The refusal of the pharmacist to fill such prescription shall not form the basis of any claim for damages because of such refusal or for any disciplinary action under RSA 318. The written objection shall remain in effect until the person revokes it or terminates his or her association with the facility with which it is filed.

3 Effective Date. This act shall take effect January 1, 2007.

Committee Minutes

Health and Human Services Committee

Hearing Report

To: Members of the Senate

From: Joshua Chamberlain
Legislative Aide

Re: SB 343 - relative to emergency contraception

Hearing date: February 14, 2006

Members present: Sen. Kenney, Sen. Bragdon, Sen. Gallus, Sen. Estabrook, Sen. Fuller Clark

Members absent: Sen. Martel

Sponsor(s): Sen. Letourneau, Dist 19; Sen. Barnes, Dist 17; Sen. Boyce, Dist 4; Sen. Kenney, Dist 3; Sen. Morse, Dist 22; Sen. Martel, Dist 18; Rep. Dowd, Rock 5; Rep. Easson, Straf 3

What the bill does: This bill requires parents or legal guardians to give consent before pharmacists may dispense emergency contraceptives to minors. This bill also establishes a pharmacist conscience clause which shields pharmacists refusing to fill emergency contraceptive prescriptions from civil liability and disciplinary action by the pharmacy board

Who supports the bill: The sponsors, Rep. Souza, Joan Espinola, Patricia Kennedy, Rita Mistretta, Debbie Brand, Helen McPhillips, Peter Cataldo (Diocese of Manchester), Rev. Tad Pacholczyk (Bishop of Manchester), Dan Hogan,

Who opposes the bill: Sen. Martha Fuller Clark, Sen. Larsen, Sen. Burling, Sen. D'Allesandro, Sen. Hassan, Sara LeBoeuf, Mike Smith (Pharmacist), Sam Langley, Dr. Gary Sobelson (NH Medical Society), Barry Smith, Krishna Psoinos (Child and Family Services), Dawn Touzin (Planned Parenthood), Liza Dube (NARAL/Pro Choice NH), Valerie Marshall (New Beginning Crisis Center), Armand Grady (NH Coalition Against Domestic and Sexual Violence)

Summary of testimony received:

Senator Letourneau introduced the bill and said SB 30 (2005) did not address two fundamental rights: the right of parents to raise and care for their children and the right of a pharmacist to conscientiously object to dispensing emergency contraception. Section 1 of the bill requires parental consent before a child receives emergency contraception (EC). The bill also provides waivers if the minor is a victim of rape, incest, provided proper charges are filed with the authorities, 2) if parental consent may have an adverse

effect on the welfare of the pregnant minor, 3) if a health care professional determines and submits documentation stating the pregnancy endangers the life of the minor. The second part of the bill states that pharmacists do not have to perform duties that they believe are morally wrong.

Rep. Easton said EC is an amplified dose of hormones and parents should be aware of their child receiving such a massive dose.

Sen. Clegg said in a letter to the committee that he supports the bill with an amendment changing the age from 18 to 16. Changing the age 16 relieves some of the burden but none of the guilt of a girl who realizes she made a mistake. The girl will be able to take the pill within the effective time frame and be able to approach a mother figure to discuss the situation. Clegg said pharmacists are allowed to submit documentation if they feel the parental consent should be waived but that decision cannot be left to the pharmacists. Why would a girl who was raped feel comfortable telling this information to a pharmacist, he asked.

Senator Hassan said medical professional do provide treatment in emergency situations without parental consent. The bill ignores emotional differences between teens and their parents, differences that should not get in the way of an unintended pregnancy. Hassan said pharmacists take an oath to serve the health needs of their clients. EC does not disrupt a pregnancy rather than prevents a pregnancy. Hassan said she is not aware of other medications pharmacists are allowed to opt out of and warned that this would be a slippery slope in which pharmacists would opt out of dispensing other medications.

Senator D'Allesandro said SB 30 (2005) does three things: 1) improve access to healthcare, 2) reduces unintended pregnancies and abortions, 3) controls the cost of health care by supporting efficient models of care. He said exempting parental consent in cases of incest or rape only when charges have been filed is absurd because fast access to EC is the most important step. The young girl will be scared and traumatized, thus going to the authorities is not the easiest option. SB 343 goes against the original intent of SB 30 (2005) which passed both houses last year. At $40 a pill, teenagers will not use EC as their main form of contraception when birth control costs as little as $2 per pack. Senator D'Allesandro said SB 30 (2005) established a voluntary program in which pharmacists are not required to do anything.

Dr. Sobelson, NH Medical Society, opposes SB 343 and said the bill is not relevant to the abortion issue. EC has effectively worked for 40 years. Parental notification could seriously undermine timely access to EC and the collaboration between doctors and pharmacists on SB 30 (2005) is important. The American College of OB-Gyn has supported access of minors to EC based on science and the American Academy of Pediatrics issued a similar statement. While the FDA has not yet approved EC for over the counter use, its advisory panel has fully endorsed such a use. NH citizens should have full access to EC without personal views of pharmacists getting in the way.

Rep. Suza supports the legislation and said young women need parental guidance. The side effects of EC are considerable and the drug is abortive in nature because it prevents implantation. The policy at Brooks Pharmacy is that their pharmacists cannot deny anyone EC.

Barry Smith, OB-Gyn, opposes the legislation and said EC reduces abortions by 50%. EC prevents pregnancy by delaying ovulation and impeding sperm transfer. Smith said barriers should not be put in front of this therapy. Ideal parenting cannot be legislated, he said.

Dawn Touzin, Planned Parenthood, opposes SB 343 and said EC does not harm existing pregnancies nor does it increase or promote sexual activity. State and federal law recognize that while parental law is desirable, many minors will not seek services they need if they have to tell their parents. The good news is that 60% of teens tell their parents when they access sexual health services. Studies have also shown that only 7.6% of teens said they would stop having sex if parental notification were required for accessing sexual health services. 143 pharmacists have already been trained in the collaborative program.

Liza Dube, NARAL/Pro Choice NH, opposes the legislation and presented statements from a variety of medical academies, colleges and associations affirming that confidential care is critical to improving health.

Peter Cataldo, Diocese of Manchester, supports the legislation and said NH law allowing the distribution of EC to a child of less than 18 years of age is flawed and SB 343 will address the error. EC can cause abortions, thus parental consent and pharmacists' conscience provisions are necessary. EC may not suppress ovulation and prevent fertilization but may prevent implantation of already conceived embryo and therefore constitute a direct action against the life of a new human.

Rev. Tad Pacholczyk, Diocese of Manchester, supports the legislation and said the bill recognizes the proper order of things. To suddenly treat a child as an adult is not responsible and to treat a pharmacist as a machine who randomly dispenses medications disregards the lengthy training of pharmacists. It is not right to force pharmacists to dispense EC.

Future action: pending

Date: February 14, 2006
Time: 11:48 a.m.
Room: SH 100

The Senate Committee on Health and Human Services held a hearing on the following:

SB 343 relative to emergency contraception.

Members of Committee present: Senator Kenney
Senator Gallus
Senator Bragdon
Senator Estabrook
Senator Fuller Clark

The Chair, Senator Joseph D. Kenney, opened the hearing.

I'll open the hearing on SB 343 which is relative to emergency contraception. We ask the prime sponsor, Senator Letourneau, if you would speak to us about it this morning.

Senator Robert J. Letourneau, D. 19: Good morning Senator and Members of the Committee. I just want to say, welcome back Senator. We've missed you and we're glad you are home safe and sound.

Senator Joseph D. Kenney, D. 3: Thank you very much. I appreciate that.

Senator Robert J. Letourneau, D. 19: To the Members of the Committee, I am Senator Robert Letourneau, representing District #19, the Towns of Derry, Hampstead and Windham. I'm here today as the prime sponsor of SB 343.

Please see written testimony of Senator Robert Letourneau attached hereto and referred to as Attachment #1.

Now I received a letter from a concerned parent in one of the towns which is right close to me and I'm going to read part of the letter to you folks so that you will understand the reality of the situation. I'm going to leave the parents name out for privacy reasons.

"Dear Senator Letourneau,

Sir, this past summer my daughter had just turned 17 and she was given the morning after pill 4 times in less than 3 months. I had no idea at the time. She bled for 5 weeks and had one normal cycle and then not another cycle for 3 more months. She still is not sure if she has not wrecked her body and is afraid to go to the doctor. Please support this bill."

She goes on with some other information. So I wrote to the lady and I said, "Can you tell me how she got these drugs and under what circumstance?" She wrote back and said, "My daughter went to Planned Parenthood and a private doctor in a clinic in Manchester. They provide free care to teens without the contact with the parents or guardians. They are careful not to send any information to the residence. This way the secret stays with the teen and providers so that it provides a pseudo authority figure relationship allowing the teens to feel autonomous. In reality it makes them subject to the clinic workers. They are afraid to tell their parents that they have gone behind their backs and it is clever and devious. The worst of it is that this clinic is paid for by taxpayers without the slightest idea what is going on. The resulting promiscuity and following consequences are truly devastating."

This lady is a nurse and she is in the health care system and she understands what consequences could come of taking this particular drug. I have some information if the committee would care to have it. Some results from the Federal Drug Administration and some post market safety reviews and some other things if you are interested.

Please see U.S. Food and Drug Administration attached hereto and referred to as Attachment #2

Please see ODS Postmarketing Safety Review attached hereto and referred to as Attachment # 3

I also want to make one last statement that the Federal Drug Administration has not yet made this emergency contraceptive drug available for over the counter use. There is still some ongoing problems and legal problems that they are having by making this an over the counter drug. Primarily the Federal Drug Administration does not make a over the counter drug and a drug that is sold by prescription. The packaging can't be the same and it can't be the same drug. I think a good example would be some of the pain medicine that we take that is a stronger version, like Tylenol #3, you have to get a prescription for it. The regular Tylenol you can buy over the counter. That sort of thing. With that I close my testimony and open myself to any questions. Thank you.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Are there any questions of the committee? Senator Estabrook.

Senator Iris W. Estabrook, D. 21: Thank you Mr. Chairman. Thank you to the sponsor. I understand the spirit in which you brought this forward but I have some questions about some aspects of it that I think are highly problematic.

First of all, what constitutes documentation?

Senator Robert J. Letourneau, D. 19: It would probably be a form that would be drawn up in Rules when the rules would be made in the Rules Committee and what type of documentation would be required for the doctor to say, for example, that this is a life threatening situation for the minor. It had to go forward immediately. The same is if it was a case of incest. Proper charges would have to be filled. You couldn't just say that. It would have to be charged.

Senator Joseph D. Kenney, D. 3: Follow-up question.

Senator Iris W. Estabrook, D. 21: So you probably intended to make rulemaking ability, although it is not in the bill?

Senator Robert J. Letourneau, D. 19: Well, we always have rulemaking authority.

Senator Iris W. Estabrook, D. 21: Not unless you give it to them.

Senator Robert J. Letourneau, D. 19: Well, most of the time.

Senator Joseph D. Kenney, D. 3: Follow-up question?

Senator Iris W. Estabrook, D. 21: Yes. Another area that I think is problematic. You are exempting victims of rape or incest if they have filed charges with the local authorities. So in order for a rape or incest victim to have the benefit of a medical therapy, we are requiring them to move forward with a court case. First of all, I think there might be some other legal challenges to that kind of a requirement but how are the health professionals going to know whether legal proceedings are underway?

Senator Robert J. Letourneau, D. 19: Are you talking about the charges being filed under the first (inaudible) ? I would expect that any charge that had rape or incest and had to show up at a clinic for that, that would be a

first phone call. We have hospitals that have to call the police when they suspect child abuse. This would be the same thing. This would be child abuse.

Senator Iris W. Estabrook, D. 21: We have a separate bill on that, that is not yet law. Also throughout the bill you refer to pregnant minors. My understanding is that emergency contraception has nothing to do with someone who is pregnant. That when someone is pregnant this therapy won't help at all. So I would like to try and understand why you would need to tie this to a minor who is pregnant?

Senator Robert J. Letourneau, D. 19: That is what the contraception, emergency contraception is for, to prevent pregnancy.

Senator Iris W. Estabrook, D. 21: Prevent.

Senator Robert J. Letourneau, D. 19: This is the way the drafter wrote it up and this is the way it came to me. I'm certainly open to the change in the language to make sure that it fits the proper situation. We need to have some protection for minors. There has to be parental consent. Parents need to know what is going on in their child's life. They are responsible for them. They are responsible for the health and welfare of their minor children.

Senator Iris W. Estabrook, D. 21: One last practical piece of this, did you talk with anyone in the AG's office or any of the legal experts about any of the conflicts that this would create between state law and Title 20 or Medicaid and other federal legislation?

Senator Robert J. Letourneau, D. 19: No I haven't.

Senator Iris W. Estabrook, D. 21: Thank you.

Senator Joseph D. Kenney, D. 3: Are there any more questions of the committee? Senator Clark.

Senator Martha Fuller Clark, D. 24: Yes. I have some other questions again related to the context of this bill. One is that, how do you protect the privacy of a patient if you are requiring them to file with local authorities and then asking the pharmacist to have to check with that local enforcement agency? Is this not in violation of HIPPA?

Senator Robert J. Letourneau, D. 19: I don't know if it is a violation of HIPPA but if a minor teen has been raped or has incest, I would expect that

there would be formal charges filed. I would expect it. It is illegal. There should be charges filed.

Senator Joseph D. Kenney, D. 3: Are there any more questions of the committee? If not, thank you for your testimony and your service to the State of New Hampshire. Our next speaker will be co-sponsor, Representative Tim Easson.

Representative Tim Easson: Thank you Mr. Chairman and Members of the Committee. First of all Mr. Chairman, welcome back and thank you for your service to our nation. For that I'm proud to call myself one of your constituents.

Senator Joseph D. Kenney, D. 3: I appreciate that. Thank you very much.

Representative Easson: I signed on a co-sponsor of this bill. I'm sorry, for the record I am Representative Tim Easson. I represent Strafford County District #3.

The honorable Senator from Derry asked me to co-sponsor this bill and the reason I agreed to is, 1, what I see as one primary flaw with SB 30 as passed last year, that is, with emergency contraception you have an amplified dose of a hormone available without a prescription and I think because of that parents have the right and responsibility to be aware of that for the health of their children. That is the overriding reason why I think parental involvement needs to be secured in one form or another through this bill. Out of respect for the committee's long list of speakers following me, I will cut it off at that.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Senator Fuller Clark.

Senator Martha Fuller Clark, D. 24: Yes, I have a question. Are you aware that emergency contraception has been used in Europe for over 20 years for women of all ages with no adverse effect in terms of health and safety?

Representative Easson: Yes I am Senator. I am also aware that in this country we have laws stating that parent's are responsible for the health and well being of their children. I cannot speak intelligently regarding the laws of Europe.

Senator Joseph D. Kenney, D. 3: Thank you. Any other committee members wish to ask any questions? If not, thank you very much for your

testimony. I'd like to call forward the Majority Leader's, Senator Clegg's, assistant Katie Coburn.

Katie Coburn: On behalf of Senator Clegg:

Please see written testimony for Senator Clegg, read by Katie Coburn attached hereto and referred to as Attachment #4

Senator Joseph D. Kenney, D. 3: Thank you. Are there any questions of the committee? So Senator Clegg got off cheap here today. Thank you Katie for your excellent testimony. Our next speaker is Senator Peter Burling.

Senator Peter H. Burling, D. 5: Good afternoon Senator. Our side of the hall has been unbalanced with you gone. Glad to have you back, balance will return. For the record my name is Peter Burling. I represent Senate District #5. It has been my privilege to be part of this legislature for almost the entirety of the debate over a woman's right to choose. I am a strong believer in a woman's right to reproductive choice. I'm also a believer in the notion that there are major reasons why we should reduce the number of abortions that take place in this state. Passage of this bill will defeat both a woman's right to choose and the effort to reduce the numbers of abortions. It is a bad bill, poorly thought out which will have utterly negative consequences if it is passed. I am therefore firmly in opposition. Thank you.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Are there any questions from the committee members? If not, thank you. Our next speaker will be Senator Maggie Hassan.

Senator Margaret Wood Hassan, D. 23: Good afternoon. Welcome back. For the record my name is Maggie Hassan. I am honored to represent the people of District 23 in the State Senate. Thank you for hearing my testimony.

I just wanted to speak briefly on this bill because I am concerned that when we talk in abstract about parental rights and responsibilities, we sometimes blur the really important things. I think every parent in New Hampshire takes their rights and responsibilities extremely seriously but I think that they also know that their first responsibility is to protect their children's health. As much as we want to know what is going on with our children's lives, if I have to weigh between that knowledge and between a child's health I will choose the child's health. That is why in this state and throughout this country when our children need treatment for serious medical conditions such as sexually transmitted diseases or when they have been victims of an

accident and their parents can't be reached, medical professionals are allowed to provide that treatment without parental consent, without parental contact.

Our first job is to make sure that our children are healthy. Being able to prevent an unwanted pregnancy is an essential part of that task and for that reason I think this bill is very misguided.

I also think it is misguided because it ignores the very real emotional differences that teenagers, adolescents and teenagers have from adults. They perceive that their parents will react in certain ways that we may believe that we may not. I do not want a young teenager's perception that their parent's will be terribly disappointed them, will punish her or perhaps beat her to getting in the way of her getting medical treatment that could prevent an unwanted pregnancy. I think again, when we talk in the abstract about rights and responsibilities we forget very much the age group that we are dealing with and the way they perceive the world around them. They often find it much easier to talk to other adults about these very real challenges.

With all due respect to those who keep bringing it up in this context, the morning after pill is not the same thing as an ear piercing or tanning. If your parents deny you consent for ear piercing or for tanning, your health will be preserved. If they deny you consent for the morning after pill your health may not be. You may very well become pregnant and then you will be faced with even more health challenges whether you decide to continue the pregnancy or whether you decide to terminate it. I just don't think the analogy is well suited and I think it would be important for us to remember that.

With respect to the second section of the bill about pharmacists, my concern here is that pharmacists take an ethical, an ethical oath I guess I would call it to serve the health needs of their customers and clients. I understand that some may have moral objections to the morning after pill although certainly the studies that I have seen indicate that it does not interrupt a pregnancy, it only prevents a pregnancy. My concern here is that if we allow pharmacists to opt out, that we may in fact make the morning after pill inaccessible not only for minors but also for adult women everywhere. I think if pharmacists are uncomfortable with the fact that they may be dispensing the morning after pill, they need to make a job choice that will put them on duty at all times with the pharmacist who does not have that objection or, they need to think about another line of work. That is not because I disrespect their moral objection to it, but because of the type of work that they have chosen to do. Their first obligation is to the patients who come to them legally for the kind of help here that they need. The morning after pill, emergency contraception, is in fact an important piece of health care in the lives of women.

So that's my testimony. I would be happy to take any questions.

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? Senator Estabrook.

Senator Iris W. Estabrook, D. 21: Thank you Mr. Chairman. Thank you for your testimony. There were some good points. With regard to the section of the bill that allows pharmacists to opt out, I'm glad you brought that up. We haven't really focused on that piece at all. Are you aware of any other medications that pharmacists are allowed to opt out of filling prescriptions for? Part 2 of the question would be if we were to adopt this kind of provision based on what we understand is the moral objections of the pharmacist, wouldn't we then need to extend that to other medications that affect reproductive health?

Senator Margaret Wood Hassan, D. 23: As to the first part of your question, I'm not aware of any other medication that a pharmacist may choose not to dispense because of moral beliefs or judgments. As to the second one, I think that it does raise a question about whether they would then be allowed to opt out of other kinds of medications such as birth control pills.

Senator Joseph D. Kenney, D. 3: Are there any other questions of the committee? If not, thank you for your testimony. Our next speaker will be Senator D'Allesandro.

Senator Lou D'Allesandro, D. 20: Thank you Mr. Chairman and I echo the sentiments of my colleagues. Welcome back, great to see you. It is nice to have a full Senate.

I come to you opposed to this piece of legislation as the prime sponsor of the original bill that is currently in place. I also come to you as the father of two young women, they are older women now, and the grandfather of three younger women. So I have a vested interest in this piece of legislation.

This legislation was originally proposed for three purposes. The first, to improve access to health care. The second, to reduce unintended pregnancy and abortion and third, to control the cost of health care by supporting efficient models of care.

Preventing, placing any age restriction on this bill would be extremely detrimental to the overall goals of the bill which I've just stated. Young women under the age of 18 should not be denied over the counter access to

emergency contraception for a number of reasons. This age group, arguably, may be the group that experiences the most difficulty in obtaining emergency contraception through the current methods by prescription. It is not easy for this age group to make an appointment with a doctor to get to the doctor and get the prescription. How many of us have difficulty making an appointment with a doctor? They are not available.

The language in this bill which allows for parental consent to be waived in the event of rape or incest only if charges have been filed with local authorities is absurd. If a young woman is the victim of incest, the most important thing for her is to have fast and easy access to emergency contraception. Do you really believe that after being the victim of incest that a teenager is going to go straight to the authorities and admit what has just happened to her as easily as if her purse had been snatched? Do you have any idea how traumatic that experience is for a young woman? She is going to be scared, ashamed and most likely will have been threatened against telling anyone by the person who violated her.

After going through that kind of abuse and trauma, we should not be making it more difficult for that teen to gain access to emergency contraception. Emergency contraception is the most effective the sooner it is taken. How long do you anticipate the filing of formal charges and proof of that such action has occurred to take place? How long before the pharmacist has the proof he needs according to this legislation to dispense the pill? Too long. Then you end up with another unintended pregnancy which could result in another abortion.

This is not why we passed this legislation in the first place. We all want to reduce the number of abortions but placing restrictions on access to emergency contraception, you're taking counter productive actions. You're going against the original intent of the bill that passed both houses last year. By the way it passed both houses the year before.

If a young woman is the victim of rape or incest, she may not be willing or able to go to her physician for a prescription. As you know, timing is critical to the access of emergency contraception. After such a traumatic experience, it ought to be as simple and painless as possible for a young person to obtain emergency contraception.

In the event of a contraceptive failure, having over the counter access to emergency contraception provides a timely and effective backup solution that will ultimately reduce the number of unintended pregnancies amongst teenagers. While the cost of emergency contraception would be reduced by making it available over the counter, it is still more than your average

teenager could afford to spend on a regular basis. Therefore I don't see any validity to the concerns that this pill would promote promiscuity. At approximately $40 a pill, teenagers are not going to suddenly have unprotected sex and using emergency contraception as the main form of contraception. Not when regular birth control pills cost as little as $2 per pack. The cost of emergency contraception is hardly an incentive for anything but an emergency use. I say to you categorically, the intent of this piece of legislation is to do 3 basic things. Improve access to health care, reduce unintended pregnancy and abortion and eliminate the cost of health care by supporting efficient models of care. It appears to me that this piece of legislation goes a long way to unraveling those basic premises and actually doing something that will prove detrimental to the process.

I thank you for giving me the opportunity to testify before you and I'm happy to answer any questions that you might have.

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? If not, thank you for your testimony and thank you for your service to the state. Our next speaker is Senator Larsen, she had to leave. Senator Martha Fuller Clark.

Senator Martha Fuller Clark, D. 24: For the record I'm Senator Martha Fuller Clark. I represent District #24. That is Portsmouth and the 7 surrounding communities. I appear before you this morning in opposition to SB 343. I oppose this bill because denying access to important health care for young women under the age of 18 is the wrong thing to do. As you have heard, this is the very age when these young women may need such access the most.

You know and I know that contraceptive failure can occur at any time and at any age but when it happens to such a young and vulnerable individual, it can have a devastating impact. What emergency contraception does is as has been pointed out, it prevents pregnancy. It does not affect an existing pregnancy and we should make that contraceptive treatment available to these young girls. Drawing a line between 16 and 18 makes no sense to me. I have a daughter. I know my daughter and my daughters friends and their friends and they deserve, deserved in their adolescent years access to this type of prevention when failure would occur without the fear of parental or society disapproval and worse.

I also oppose this bill because it is flawed in not only its premise but in its application as you have heard. Federal law under Title X requires contraceptive services and other reproductive health care be available to

anyone who needs them regardless of age. So we would be flying in the face of federal law if we were to pass this bill.

Secondly, I think it is important to point out that the bill as it was passed last year, does not require all pharmacists to participate. It is a voluntary program where they receive through their choice, the education that they need in order to be in a position to be able to dispense emergency contraception.

I believe that our first responsibility as legislators and as parents is to protect the health and welfare of all our citizens, especially our adolescents and in this case, especially young women whose health and welfare will be put at risk, could be put at risk if they do not have the same right to access as older women.

Thank you.

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? Seeing none, thank you. Representative Souza, if I could sneak in Doctor Gary Sobelson. He has to leave shortly. If you don't mind?

Doctor Gary Sobelson, New Hampshire Medical Society: Thank you for that courtesy. As Senator D'Allesandro said about getting an appointment with you physician, as the clock turned I was getting more anxious about the opportunity and felt very responsible to my upcoming appointments.

For the record, my name is Doctor Gary Sobelson. I'm the Past President of the New Hampshire Medical Society and I'm here representing the New Hampshire Medical Society and its legislative task force. I do want to represent that the physicians of the New Hampshire Medical Society emerged from a process of deliberation which is somewhat broad. We bring down physicians from every specialty to regular monthly and bimonthly meetings to discuss the legislation that is relevant to health care in our state. We try and come up with a consensus positions and present those to our executive committee for approval. Our position in opposition to SB 343 does meet those criteria.

I would like to emphasize the points why the physicians in the State of New Hampshire are opposed to SB 343.

First of all, I premise that we don't take a position in the New Hampshire Medical Society on abortion. We see it as a controversial issue among our own membership as well as in the state. We do not see this as relevant to a bill on abortion. I think a number of the scientific studies that have looked at

the concept of emergency contraception have made it clear that while we don't understand entirely the scientific reasons why emergency contraception works, it has been effectively present for more than 40 years in our society, since birth control was available. Mostly, it works by preventing a pregnancy, not very clearly it is probably preventing effective ovulation when used properly.

Second thing has to do with our collaboration with pharmacists. As some of you may know, at times we are very protective at the New Hampshire Medical Society of our prerogatives and privileges as physicians. This is an area where we have felt that collaboration with co-professionals such as pharmacists is very important to improving the public health. In fact, do want to reach out with our co-professionals and working collaboratively as the original legislation brought forth.

But clearly, our reason for opposing this bill comes from our public health and scientific background. We clearly see emergency contraception as reducing unwanted pregnancies and the need for abortion services as has been stated. Frankly, there is clear evidence in literature that parental notification could severely undermine the public health benefits of emergency contraception access.

Physicians currently have broad rights as conducted through Title X but also through the Medical Practice Acts in the State of New Hampshire. To treat minors as well as their capacity to understand the ramifications for treatment is present, this collaborative bill would allow through very formal agreements that have been well outlined and designed by the Board of Pharmacy I might add, to extend that, not to over the counter access to emergency contraception as has been errantly cited, but to availability through a collaborative practice between physicians and pharmacists.

There is an American College of OB/GYN practice bulletin on emergency contraception that I'll submit and leave with you for duplication that addresses almost all of the scientific discussion in very thorough and very understandable terminology with lots of references and would support access of minors to emergency contraception on the basis of the science, best available.

Please see ACOG Practice Bulletin attached and referred to as Attachment # 5

There is a similar document available that I did not bring with me but I can provide at the New Hampshire Medical Society from the American Academy of Pediatrics advocating access for adolescents and teens to emergency contraception.

Furthermore as previously mentioned, while the FDA has not approved over the counter access to emergency contraception, the FDA Advisory Committee on Reproductive Drug Use, the committee commented on the safety of emergency contraceptive and fully endorsed over the counter access. In fact, the political ramifications of the failure of the FDA to support the findings of its advisory committee have led to significant resignations from that committee, again, are not based on the science of emergency contraception but more based upon political considerations.

With regard to the section on the personal views of pharmacists and the impact of this legislation, the New Hampshire Medical Society feels that with drug as well as with other legally available prescription and non-prescription medications, New Hampshire citizens should have full access to these without any barriers created by imposed personal views of pharmacists and I might add, of physicians as well.

Examples of this have been given. If one was to presume that the personal views of the pharmacists could be used for emergency contraception that would clearly be pharmacists of Catholic religious beliefs who might not be comfortable prescribing birth control pills. There might be pharmacists of the Church of Scientology, a recognized religion in our country, who wouldn't prescribe psychiatric medications. These are just the beginning of examples that could come forth if we look at that. We think this is especially important that the legislature certify the importance that our citizens should have access to legally available drugs in our pharmacies.

So in conclusion, we encourage defeat. We at the New Hampshire Medical Society encourage defeat of SB 343 to allow us to move forward with the collaborative process of last years legislation, preserve the public health and try to reduce the unintended pregnancies and the need for abortions in New Hampshire.

Thank you.

Senator Joseph D. Kenney, D. 3: Thank you for you testimony doctor. Are there any questions of the committee? If not, thank you.

Dr. Sobelson: I appreciate your courtesy.

Senator Joseph D. Kenney, D. 3: We have 11 more speakers. Honestly if there is anything that has been said that you wish to repeat, please don't repeat it. With that let's try to push this along as quickly as we can. Our next speaker would be Representative Souza.

Representative Kathleen Souza: Thank you Mr. Chairman and Members of the Committee. For the record, my name is Kathleen Souza representing Hillsborough District 11 which is Manchester's Ward 4. I am here to thank the sponsors of this bill and to plead for its passage. The first part of the bill concerning the young women. I very much feel that the young women getting these pills need parental guidance. Just like we have seen in the press where kids have been experimenting with Dramamine. Kids don't think through the consequences of what they are putting into their bodies and I think the parental role is very, very important here. I was the sponsor of the parental notification for abortion bill that was recently before the US Supreme Court and I feel just as strongly that this bill is extremely, extremely important.

If you go to the websites of the FDA you will see the scientific reasons that they did not give across the board, approval for across the board selling of this pill. It tells that they are very concerned with the effects on girls under 16, that it has not been proven safe for girls under 16. A lot of girls under 16 now can avail themselves of this pill.

If you go to the website of Barr Pharmaceuticals, the makers of Plan B, the name of this pill, it tells a little bit about how this pill works and the side effects. There are considerable side effects. Irregular periods, menstrual cramping, vomiting, etc. It talks about how the pill works. Both the FDA website and the Barr Pharmaceutical website explain that although it is called emergency contraceptive, it is abortive in nature also because one of the three ways it works also is to prevent implantation. Implantation of what? Implantation of a fertilized egg. Now, science has always held that life begins at the beginning, at fertilization. There has been an attempt by mostly people of the pro-abortion persuasion that life should be redefined as beginning at the implantation stage but scientifically it doesn't. It begins at the beginning, at fertilization. By working to prevent the implantation, that is an abortive method and so we are correct in saying that this bill is not only a contraceptive but it is an abortifation.

That is bringing me to the second part of the bill. Why a lot of pharmacists do not want to get involved in being forced to work with this bill. One of the previous speakers said that the pharmacists did have some latitude in freedom. But that isn't correct. I wish it were. I'm referring to the New Hampshire Sunday News of May 29th. I apologize I just couldn't get upstairs to get the copies made but I will make copies, I promise to the committee.

Please see "Pharmacist: Why I won't sell 'Plan B'" attached hereto and referred to as Attachment #6

There is a story of a pharmacist up in Laconia who had to leave his job and take another job because of his conscientious objections to Plan B, the morning after pill.

"I was taught that life begins at fertilization. When an egg is fertilized by the sperm, life begins at fertilization and this product will end that life so I can't dispense it."

There is a long story as you can see when I make the copies so I don't need to read it but this gentleman had to leave his job because of the conflict with his conscience in prescribing this pill. Another part of the story talks about how Brooks Pharmacy has a policy that the individual pharmacist cannot deny filling these prescriptions. Our pharmacists cannot deny care to any patients. They may be the exception. I don't know but this is just proof that this policy does exist among some of these stores, especially some of the small stores that don't have several pharmacy employees.

So on the two counts for the family integrity, for the right of parents to be involved in their child's health care, for the right of the girls or the benefit of the girls to have the involvement of their families. Parenthetically I know a woman who told me just last week, her daughter who has been missing her periods for several months and after some discussion they found out that the girl had taken 3 morning after pills within a very short period of several weeks. So the girl is going to end up at the doctors. There has been a lot of family disharmony because of this and the result that the people that oppose this bill, privacy and health care, is just being completely contradicted. This case, the family is upset, the daughter did something really stupid taking too many of these and now her health has been impacted. For the pharmacists, please be sensitive to their needs. They shouldn't have to go along with whatever legislation we pass despite their ethical and moral considerations. The history of this country is that we all have the right act on our conscience and pharmacists should not be singled out anymore than hospitals. Hospitals have the right not to do certain procedures and pharmacists should have these same rights. I thank you.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Any questions of the committee? Thank you. We're down to 10 speakers. Our next speaker would be Joan Espinola.

Joan Espinola: I really don't want to speak but I just want to hand these out that we signed on the way up that we are for this bill expect for sub paragraph b. Thank you.

Please see "We the undersigned" attached hereto and referred to as Attachment # 7

Senator Joseph D. Kenney, D. 3: Thank you very much. Our next speaker would be Helen McPhillips.

Helen McPhillips: I don't think I signed up to speak. Did I? I don't remember signing up to speak. I know my name is on the list but I guess I didn't check it.

Senator Joseph D. Kenney, D. 3: Ok. Debbie Brand wishes not to speak but is in favor, Sam Langley. Is Sam Langley here? No. Barry Smith?

Barry Smith: I recognize the fact that it is late and your time is short. I will try to not be too repetitive and try to answer I think a couple of the things that were raised. For the record, my name is Barry Smith. I am an Obstetrician/Gynecologist. I have practiced in New Hampshire for 36 years and I was the Chairman of (inaudible) at Dartmouth for the last long time until about a year ago when I retired from that position. I now work part time there in a quality assurance role.

Gary Sobelson spoke for the Medical Society although I sat in on all those hearings, so I am speaking really for the New Hampshire section of the American College of Obstetricians/Gynecologists which is the greater majority of OB/GYNS in the state, all those that are board certified and have chosen to join which is most of them.

I'm here to speak against the bill and against any legislation that would restrict emergency contraception. The points I would like to emphasize is that we have been using this for many years, long before it was FDA approved as an off label use and it has been FDA approved now for 8 years. It is extremely safe, extremely safe, you have heard others say how long it has been used outside of the country. It is an extremely effective method of preventing and I think the word preventing has to be emphasized, unwanted pregnancies. Up to 85-89% prevention of pregnancy if used in a timely and I think timely is the key when you are considering this bill, especially used within the first 24 but definitely in the first 72 hours after unprotected intercourse.

In my view and in the view of a large number of health professional organizations who try to care for women and children this is an outstanding therapeutic modality. Most of us agree that we want to lower the number of abortions and this method has been shown in several studies that it decreases abortions by at least 50%. Most scientific people, authorities feel

that this prevents pregnancy primarily by delaying ovulation or effecting sperm transport or sperm fertilization. We cannot 100% rule out obviously changes in the lining of the uterus however I would say, this is not a massive dose. There is what is called a massive dose of hormones, this is not a massive dose of hormone. We have to use 7-10 and sometimes 14 days of hormone to change the lining of the uterus in certain other therapeutic situations.

So there are many organizations that support this. I think it is important to emphasize that the American Academy of Pediatrics supports it for use in adolescents and I think that is a very, they have issued a state in 1995, excuse me, in 2005 overwhelmingly endorsing the use of this in adolescents.

We don't believe that any barriers should be put in the place of this therapy. The, all of these organizations if you have heard before have wondered why and are frustrated by the fact that it is, Plan B is not available over the counter at this point because of its proven safety record. Therefore we at this point do not want to put yet another barrier in the way of its use which by necessity has to be timely. The issues that have been raised earlier about massive hormones, it is not. The, it doesn't kill a pregnancy, it prevents pregnancy.

Unfortunately we can't legislate ideal parent child relations and these issues about them, we don't want to get involved in that. We would like to have it all be perfect. It doesn't work. We all know that. The questions raised about these individual cases about abnormal bleeding, it is more likely, much more likely that the emotional stress of whether a person was pregnant affected their periods than these two or four pills depending upon which ones you used. The stress involved in this, the stress on whether they can discuss this comfortably with their parents or other people we know can throw off their periods. It is like going away to camp in the summer for long periods. Therefore emergency contraception is safe, it is effective, it doesn't cause abortions, it prevents them and we also know from some of the recent studies in the last couple of years, where the questions have been asked, it doesn't increase promiscuity. I think that is something that we are all worried about but I think the studies have clearly shown that that is just not true. So we think it should be readily available and therefore as a group we strongly wish to oppose this bill. I would be happy to answer any questions.

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? There are not. Thank you very much for your testimony. Our next speaker would be Dawn Touzin.

Dawn Touzin, Planned Parenthood: Good afternoon Mr. Chairman. My name is Dawn Touzin and I am the Public Affairs Director for Planned Parenthood, Northern New England in New Hampshire. I have testimony and documents here that I will pass along but rather than go through them because so much has been covered, I will merely point to some of the items that are in there that might be informative for the committee.

I begin with, there have been discussions about emergency contraception and whether it is safe, whether it is contraception. What I have included is a copy of the federal register in which the Department of Health and Human Services speaks to emergency contraception. I have highlighted just for convenience where it talks about emergency contraception not being effective if a woman is pregnant, having no adverse effect on an established pregnancy and discussing also the fact that the commissioner has concluded that combined oral contraceptives taken initially within 72 hours of unprotected intercourse are safe and effective for post coital emergency contraception.

Please see Federal Register, Department of Health and Human Services attached hereto and referred to as Attachment #8

So this again scientific determination and evidence by the federal government, Health and Human Services, based on FDA information.

I've also in my testimony regarding the parental consent aspects refer to the federal register there but also some studies that have been done that would indicate, in New Hampshire for instance, we know that in 2003 according to the Health and Human Services website there were 825 pregnancies to teenagers. How many of those might have been prevented with greater access to emergency contraception we won't know but certainly that is what the program is about. How many abortions there were we don't know. How many of those could have been prevented is open to speculation but again, that is what the Emergency Contraception Collaborative Practice Program is all about.

There is also a study that would indicate that teenage girls have a higher risk of pregnancy complications and are less likely to obtain prenatal care. So EC does prevent teen pregnancies and the serious negative health consequences that impact teens lives and that also we in all of our various services in the state, then try to deal with. These can be prevented.

It has been mentioned and as a representative of an organization that receives Title X money as well as Medicaid money, we are under confidentiality requirements of the federal government. So how this would conflict with that is something that would really be very difficult. It would

certainly have to be resolved. Reading right from the program guidelines for the project grants that are put out by the federal government it says, "Title X requires that services be provided to adolescents regardless of ability to pay. Under Title X written consent of parents or guardians for provisions of services to minors may not be required prior to rendering service. Further, nor can parents or guardians be notified after a minor has requested and received family planning services."

I think so much of this goes to the fact that under New Hampshire law prior to this and federal law, minors should have access to confidential health care services when it comes to contraceptives really speaks to the wisdom of those policies, again, what we are trying to accomplish. We are not trying to keep parents and teens from communicating, in fact, we at Planned Parenthood have many programs that promote just that but we are trying to make sure that we have sound public policy that benefits us in the best way.

There have been no studies that would indicate what the result would be if parental involvement were required specifically for emergency contraception. There have been studies as to how it would affect teens access to contraception as a whole. There is some good news that we already know. 60% of the teens who went for contraceptive services, their parents already knew that they were there. Further, the study indicates that the younger teens, the younger teens are, the more likely that the parents know of their visit. So what we are concerned about are the 40% that go for services and don't tell their parents and what would the impact of imposing some type of parental notification or parental consent be on that. What we find is that 7.6% say that they would stop having sex, unfortunately all the rest say they would then engage in riskier sex behavior. We would not be helping them. We would in fact be pushing them to behaviors that would have a far worse impact on their health.

The bill was passed last year as Senator D'Allesandro said, it was passed the year before as well. Last year I was here to hear the activity in both houses and age restrictions were debated in both bodies and defeated and for a good reason. I would also add that we have already been implementing the Emergency Contraceptive Collaborative Practice Program here in the state. After the bill was passed last year, the Board of Pharmacy implemented regulations and based on those, the program has gone forward to a very strong reception among the pharmacy community. I'm told by the Board of Pharmacy that there are probably around 900 pharmacists in the type of setting for whom the Collaborative Practice Program would apply. 16% of those right off the bat went for the first trainings that were conducted in December. On a Saturday night and a Sunday morning, 143 pharmacists were trained. There will be another training session coming up in March and

from what we understand there will be another at least another 100 wanting to go there as well. That is an absolutely voluntary program that then has hours of training required on the part of the pharmacist. It requires informed consent forms that very clearly lay out what emergency contraception is about. It requires that the pharmacist advise a patient coming in as to what the ramifications are, what the side effects might be, what the pills do, how they should be used. It also requires at any health care provider that if the pharmacists has any indication that this is a result of an abusive situation, they are informed that the mandatory requirement is that they call the state authorities and report that. So the protections for teens are there to prevent abusive situations from continuing unaddressed and protective cautions are there so that the teens are advised as to what is going on when they access these pills. But they are and continue to be, the best way of preventing unwanted pregnancies and preventing the need for abortions.

In regards to the second part of the bill regarding the right of the pharmacist to refuse, our concern there is that it makes no provisions there at all to recognize a patients rights to lawfully prescribed medication. It does not recognize the medical judgment of the health care provider who prescribed the medication. It makes no protection for employers and reduces their right to freely contract with their employees and it singles out a highly effective method of preventing unplanned pregnancies and reducing the needs for abortions. A policy that discriminates against women.

Thank you. I would be glad to answer any questions.

Please see written testimony Planned Parenthood, Oppose Parental Consent attached hereto and referred to as Attachment #9

Please see written testimony Planned Parenthood, Refusing to Fill Prescriptions attached hereto and referred to as Attachment #10

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? If not, thank you for your testimony. Our next speaker would be Liza Dube.

Liza Dube, NARAL New Hampshire: Good afternoon. In the interest of time and because I know that many things have already been covered that I would have planned to have said, I'm going to try to keep this as possible for you all.

To begin, I am Liza Dube. I am the Political Director of NARAL Pro-Choice, New Hampshire. On behalf of our 2,800 members statewide we are expressing our opposition to SB 343. I believe most of the information that we really find to be the most prominent information in terms of our objection

to the parental consent for access to emergency contraception for the most part has been covered by Gary Sobelson and Dawn Touzin.

I would say however, that with the pharmacists refusal provision there are a few additional pieces of information that should be, you should be aware of. To begin with, to respond to Representative Souza's story about the pharmacist who was fired from his position in Laconia New Hampshire for refusing to dispense emergency contraception. That newspaper article much like this pharmacists refusal clause only covers half of the story and that is the pharmacists half of the story.

The other side of the story is the story of Suzanne Richards who is a 21 year old single mother who went to get a prescription for emergency contraception filled by that pharmacist. The pharmacist told Richards that he was morally opposed to filling prescriptions for the pills. Refused to transfer her prescription to another pharmacy and by the time she found a willing pharmacist to fill her prescription, the efficacy time had passed. There are other examples of stories of that happening with pharmacists who chose to refuse to dispense emergency contraception. Some of those stories grow even more disturbing than just the refusal to dispense, also the refusal to transfer but include pharmacists berating women or lecturing women in very public places about their moral objection to this particular medication. It is just something that we find particularly objectionable.

Our primary concern is really that the law does focus only on the pharmacists and not on the patient particularly because it does obstruct access to a basic health care need which is accessing emergency contraception as a last resort for preventing pregnancy.

Just a little bit more information for you. The American Public Health Association which has about 50,000 members nationwide and is the nations oldest and largest public health organization, states that when a health professional has prescribed contraception, the patient must be able to obtain the contraceptive in a timely manner at a licensed pharmacy without interference from those pharmacists who have personal objections to contraception. Any delay caused by such interference can endanger the patients health by increasing the risk of unintended pregnancy or exacerbating the other medical conditions for which contraceptives are sometimes prescribed.

The American Pharmacists Association, a national organization of equal size to the American Public Health Association in America, states that if a

pharmacist refuses to fill a prescription there should be established systems to ensure patient access to legally prescribed therapy.

So we are asking you to oppose SB 343 and in addition to written copies of my testimony which has a little bit more information than I just gave you, I do also have statements from, more expansive statements from the American Pharmacists Association about their objection to pharmacists refusals without protections for the patient as well as a statement from the American Public Health Association. Also a collection of statements from organizations like the American College of Obstetricians and Gynecologists and the Society for Adolescent Medicine on their support of teens access to confidential health care.

Please see NARAL Pro-Choice New Hampshire written testimony attached hereto and referred to as Attachment #11

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? Senator Bragdon.

Senator Peter E. Bragdon, D. 11: Thank you Mr. Chairman. I'm just, refresh my memory with regards to SB 40. Is that a voluntary participation right now on the part of the pharmacists?

Ms. Dube: That is a voluntary participation on the part of the pharmacists.

Senator Peter E. Bragdon, D. 11: Because they don't take this training.

Ms. Dube: That is correct. What we have learned from the other states that have already begun to have the collaborative agreements for emergency contraception is that in particular chain pharmacies but there have been no instances of a pharmacist or pharmacy owner forcing one of their employees to participate in the program.

Senator Peter E. Bragdon, D. 11: Thank you.

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Our next speaker would be Valerie Marshall. I believe I have three after this.

Valerie Marshall, New Beginnings Crisis Center: Good afternoon. My name is Valerie Marshall to briefly read a letter from New Beginnings Crisis Center in Laconia, New Hampshire.

Please see written testimony of New Beginnings attached hereto and referred to as Attachment #12

Senator Joseph D. Kenney, D. 3: Thank you for your testimony. Our next speaker would be Peter Cataldo.

Reverend Tad Pacholczyk: Peter had to leave and he wanted me to submit his testimony.

Please see written testimony of Diocese of Manchester attached hereto and referred to as Attachment #13

This is on behalf of the Catholic Bishop of Manchester.

Senator Joseph D. Kenney, D. 3: Thank you. Our next speaker would be Reverend Tad Pacholczyk.

Reverend Pacholczyk: Members of the committee, thank you again for hearing my testimony. This bill SB 343 I think raises some important issues in terms of understanding the prerogatives of parents. I think it is a very sensible kind of a legislation that we see formulated here. I'm speaking obviously in favor of this bill.

Our parents have such an important role in forming who the future individual is going to be. Almost every choice that ends up happening for our kids, our parents are intimately involved in. If you're talking about, are we going to be doing soccer or are we going to be doing baseball, it can even be at that level that there is a good deal of parental involvement in what the child ultimately ends up doing. Which kind of school, public or private? Again, this is a decision that is made with a heavy input if not an overarching input from parents. I know that when I was growing up even things like whether my sisters could date, that was determined by my dad. There was a date at which they could start dating and not prior. This represents the kind of area that is so important because it is dealing with the future formation of this human individual who then will be an autonomous member of society.

So allow for parental involvement to such a thorough degree even when you look at other health care areas as mentioned already. Issues such as tattoos and other forms of rather minor interventions do require parental permission. But if you look at surgery or something even bigger in that arena, who is it that signs the consent forms. Who gives informed consent? Again, it is the parents who stand in the place of the minor who cannot yet do this. So here we have a bill that is simply attempting to recognize that proper order of things. Say that when you are dealing now with something like emergency contraception which deals with the decision that affects the whole future of this individual to suddenly try to cordon that off and say that

now we're going to treat that child as if they are an adult and they should be able to move freely and do basically what they want. detach themselves from the familial contacts is simply not a reasonable understanding of what it means to be a responsible parent.

I think there have been some false dichotomies that have been presented here. People are saying that it is about health care for the kids. If it is a question of whether we are going to be knowing what the kids are doing versus providing health care, then I'm going to choose the health care. That is a false dichotomy and that represents a kind of abdication of the responsibility of what it is to be a parent, to be involved in these incredibly important choices. When you are dealing with issues of human sexuality and questions of the sexual choices and their consequences, parents have so much to contribute. They have been down these roads themselves. This tendency to sort of just sideline them and suggest that there is a kind of autonomy here that the minor should have, again is not a reasonable thing and it is not a recognition of the right order within a family. So our laws need to be safeguarded very much for those prerogatives of parents.

I want to say just a little bit about the conscience clause as well. I think that this is a very important area and I think there is again a great deal of misunderstanding of the basic kind of question that is at play here. We often hear that the first obligation to the pharmacist is toward the patient. The implication is that if the pharmacist is going to refuse to dispense something that the patient wants, that's not right. Even as stated earlier, if the doctor refuses to dispense something that the patient wants, that is not right. Well, that is missing the whole context of what we are talking about here. We're talking about the context of providing health care to the needy individuals.

In the health care context that means that there is an exchange between the health care provider, the doctor, the pharmacist and the patient. There is cross talk that is happening. This is ultimately oriented towards the health needs of the patient. So to suggest that the pharmacist should be nothing but a machine who stands there and randomly dispenses whatever comes to him based on something he receives from the physician is to fail to recognize how much training those pharmacists had to go through. How many years of study before they could get that pharmacists degree.

There are those pharmacists who recognize that emergency contraception as printed on the inserts within that drug that is included with that drug from the company, has this effect of rendering the uterine environment hostile to the arrival of an embryo so that simply providing this may indeed be involving you in an abortifacation effect, in other words a chemical abortion. These are obviously very serious grounds for a pharmacist to say this is

something that on conscience grounds I should not be forced to do. I should not have my hand twisted up against my back and be compelled to do something that is clearly morally objectionable to a large segment of our population.

So I think what is essential to realize here is that we are talking about a context, a very important context of health care. This bill simply recognizes that unfortunately now even within the health care setting there is some ambiguity about what the mission of the physician and the health care provider should be and whether it should include providing agents that cause the direct destruction of younger members of the human species sometimes as one of the modes of mechanism. So this bill is a very reasonable one, again recognizing this natural right of conscience that should always be safeguarded for individuals and for institutions.

So thank you very much.

Senator Joseph D. Kenney, D. 3: Thank you father for your testimony. Are there any questions:

Father Pacholczyk: Could I just mention briefly, not that this really matters but I always forget when I come up to give these kinds of testimonies, sometimes people are interested to know my background. I was a scientist before I became a priest. I worked as a neuroscientist. I have my PhD in neuroscience from Yale University. I did postdoctoral work at Harvard and I now serve as the Director of Education for the National Catholic Bioethics Center in Philadelphia. So these areas of bioethical concern, I think you can understand why I have such an interest in the proceedings that are happening here today.

Senator Joseph D. Kenney, D. 3: Father, you might run for office and we'll put you on the Science and Technology Committee.

Father Pacholczyk: Priests aren't supposed to run for office.

Senator Joseph D. Kenney, D. 3: Thank you very much for your testimony. Our final speaker is Dan Hogan.

Dan Hogan: My name is Dan Hogan and I am from Nashua, New Hampshire. I do not have the degrees that Father Tad has but I certainly do have the same interest in the subject. I spend a great deal of time thinking, working and reading and preparing to speak on this subject.

If I were to introduce a bill to dump all of the deicing fluid used at the Manchester Airport, untreated into the Merrimack River, you would be offended. Right? You would be offended. People are drinking that water downstream in Nashua. If I called it the Clean Water Act, you would be outraged.

Yes, this is analogous to what the New Hampshire supporters of the morning after pill have done. They have stated in the bill that approved the bill, that this product will be defined as a contraceptive. Wonderful. You can decide to define it as anything that you want but you can't argue with the facts. People are trying to do that.

Call the law the morning after pill a contraceptive is disingenuous and medically incorrect, only done to confuse the issue of when life begins which is what the medical community has always known, that new life always begins at conception. Now, this book, A Consensus Guide to the Pill by a pharmacist John Wilkes B Fram, an Australian pharmacist, explains it very well. How the definition was changed from what we have known for thousands of years when contraceptive, when conception took place. So in order to promote the pill they had to confuse the issue and say, "oh no. You are not pregnant until in fact the egg, the embryo, the fertilized egg, the zygote has implanted.

Now let's continue. This book gives the story of the myth of the morning after pill and says it certainly will interrupt a pregnancy.

I have another book with me. It is called A Child is Born. On page, it doesn't really matter what the numbers are, the effort is very clearly outlined in the picture of what can happen after intercourse in the instance where a pregnancy results. It is very simply done. I didn't have time to Xerox it and I wish I had but somebody who is involved in this would take the time to go duplicate these simple two pages.

Please see A Child is Born attached hereto and referred to as Attachment # 14

The book is simple enough to understand. Even I can understand. Even a pro-choice citizen will be able to understand this because it goes by hours and days.

Now when the original bill was being argued, I asked my legislator, a young woman from Nashua, New Hampshire, if she would give me that documentation which sold however she was going to vote to her because I was interested. I'm not going to ask you how you are going to vote. I simply want to know what is the documentation that convinced you that that was the

right way to go. She gave me a literature that was a study. A study was done on rhesus monkeys, it was done on rats, it was done on 28 Latino women who were told were already sterilized by tubal ligations. This is how we are going to determine the affect of a product like the morning after pill. I don't think so. She is a good legislator. I've heard her dealing in other instances. She must have had something more compelling than this. She certainly didn't provide it.

One last thing, emergency contraception by the numbers. This agency took the time to go through here and evaluate day by day, twenty eight days of a normal cycle, what could happen if an individual took this pill on each and every one of those 28 days. The conclusion is that in the majority of cases, the morning after pill would do nothing because there is not a time within that cycle when it would be activated. But when it does act, when it does act, 57% of the time it acts as an abortifation. The figures are here. If you would like to go through, day by day. If we are wrong, come back to us and say, "You were fine up to this point and here is where you went wrong." I doubt where you can find anywhere where medically we are incorrect in this.

Please see Emergency Contraception by the Numbers attached hereto and referred to as Attachment #15

We answer to a higher authority. We've got to tell the truth. All right. The evidence is here. If you would like I would be happy to answer any questions. I can provide you as the lady did who came up here day after day to try to get you to look at all of this information and to get you to vote intelligently on it. Was very disappointed when after perhaps 30 trips to Concord to work with people who were going to vote on this bill, the bill went the wrong way.

I'm a dad, a grandfather. I work with kids, coach at Nashua High, coach both boys and girls in the pole vault. I feel very, very strongly about what we are doing to our kids.

Our kids are told that they can't be executed. The Supreme Court said that they don't have the brain power. Their brain is not fully developed so therefore they can't make a rational decision that killing a person is seriously wrong. Therefore we can't condemn them to death. Now we hear people come here and say that these people are perfectly capable of making a decision. They don't need their parents to help them with this decision. Yet, we have women now who have had abortions who say, "The rest of my life has been like carrying a bag of rocks around. I have never gotten over the fact that I have killed my pre-born child." This is definitely something worth considering. When we are told by the last young lady who was here, 1 in 7 young women are victims of sexual assault. What does that tell you. The

governor is concerned. He wants penalties. Put an individual who performs sexual assault into prison for 25 years. We are creating these people. We are creating, they start off as innocent pre-born's. They were born. They become 2 year olds. They move on. They get an education that says that they have a right to have sex. They can do it with anyone they want at any time. Then we are surprised when somebody rejects them and they get violent about this thing that they then become victims of sexual assault. I don't find it strange. I think it is pretty logical with the training that they have.

We are told that 825 teenage pregnancies were in New Hampshire and we don't know how many abortions we had. We have tested this bill every single year. We want a record of all abortions. It is the death of an individual. Who fights us? It is the same people that are opposed to this bill now. We can't reveal who the doctor was who performed that abortion. He might be gunned down and yet that same doctor from Bedford has a video tape made of him called, Live Free or Die and he shows it on public television all over the country with his picture and his home and his address and his family. Then his wife comes in and she says, "Oh he can't allow his name to be put out there because somebody might shoot him and we're so concerned about publicity." It can't be both ways.

Let's be serious about this. We're all intelligent human beings. Which way is it?

The last point. Title X. Minors and the rules and the parents are cut out. That lady is right. She is right. That is the way that the federal law for Title X is written. That is where the emphasis has to be placed. We've got to go back to Washington and say, "You are killing our kids." Dr. Meg Neither, Dr. Meg Neither is a pediatrician. In her book and she has written two of them, both called Epidemic. She said, the first one the subtitled, Epidemic, Teenage Sex is Killing Our Kids. She said, "When I graduated from medical school I thought the best thing I could do going into the ghetto was put all these young ladies on birth control." She said, "I've now been a pediatrician for 20 years and have 4 daughters of my own. I recognize now that was the worst thing I could have possibly done to those young people."

We have the evidence, we know it is right, we know it is right. The kids know it is right. Unless you want them to come back and tell you, "I have carried this weight of killing my unborn child around on my back for the rest of my life because no one told us the truth." All we're asking for is that we tell we truth. Let's stop lying to these kids.

Are there any questions?

Senator Joseph D. Kenney, D. 3: Are there any questions of the committee? There aren't. Thank you so much for your testimony and your passion.

Mr. Hogan: If you want copies of the book I can tell you where they came from.

Senator Joseph D. Kenney, D. 3: If you have anything for the committee.

Mr. Hogan: I came to testify on two other bills today. I had not originally intended to be involved here. When I was I grabbed those things that were easily available. I think that this particular two pages, if you could send somebody to Xerox it now and the analysis of the 28 day cycle.

Senator Joseph D. Kenney, D. 3: Is there anyone else who wishes to speak on SB 343? If not, we'll go ahead and close the hearing.

Hearing closed at 1:25 p.m.

Respectfully submitted,

Pamela Manocchi

Pamela Manocchi
June 20, 2006

Attachments

Attachment #1

Senator Bob Letourneau
30 South Avenue
Derry, New Hampshire 03038
e-mail: robert.letourneau@leg.state.nh.us

February 14, 2006

TESTIMONY ON SB 343 (EMERGENCY CONTRACEPTION)
Before Health & Human Services Committee

I am pleased to be here today as the prime sponsor of SB 343. Last year, the legislature passed a law (SB 30) allowing pharmacists to dispense emergency contraception. But that law neglected to address two fundamental rights which cannot be separated out from the emergency contraception issue. This bill is intended to fix those problems.

The first section of the bill concerns the fundamental right of parents to raise and care for their children.

Under the New Hampshire emergency contraception law, a pharmacist is allowed to give a minor child emergency contraceptive drugs without any input from the child's mother or father.

In New Hampshire, no child under 18 can have body piercing done without the consent of a parent or guardian. No child under 18 can use a tanning booth without the consent of a parent or guardian. **But New Hampshire currently allows emergency contraceptive drugs - a massive dose of hormones - to be given to a child without the parent's consent or even knowledge.**

This is wrong. It is up to the parents, not a pharmacist, to counsel a child concerning the decision to use this drug. It is for the parents, not a pharmacist, to counsel their child concerning the "emergency" situation which prompted the child to seek out this drug. And it is the parent, not the pharmacist, who will be with the child after the drug is

taken and who needs to be aware of what has happened in order to be on the watch for any side effects.

Thus, Section 1 of this bill requires parental consent of a parent or guardian before a child receives emergency contraception.

This bill also provides waivers for extreme circumstances. 1) If the minor is the victim of rape or incest, provided proper charges are filed with the authorities. 2) If the health care professional determines and submits documentation that parental consent may have an adverse effect on the welfare of the pregnant minor. 3) The health care professional determines and submits documentation stating that the pregnancy endangers the health or life of the pregnant minor in such a way the requirement of parental consent may cause an untimely delay of emergency contraception further endangering the health or life of the pregnant minor.

The second part of this bill addresses the rights of pharmacists who conscientiously object to dispensing emergency contraceptives.

If conception has occurred before emergency contraception drugs are administered, then these drugs have the effect of killing that human embryo. In the eyes of some pharmacists, therefore, dispensing these emergency contraception drugs is actually the same as assisting in an abortion. As a result, some pharmacists around the country, and it will certainly happen here in New Hampshire, because of their moral opposition to abortion, have refused to dispense emergency contraception.

Doctors who perform abortions do so by their own choice. No state law forces doctors to perform abortions. We should not require pharmacists to perform acts which they believe are morally wrong. Thus, Part 2 of this bill is intended to protect against the firing or disciplining of pharmacists who exercise their conscience with respect to dispensing emergency contraception. Thank you for your time and consideration

I urge this committee to vote ought-to-pass on SB 343

U.S. Food and Drug Administration

FDA Statement

FOR IMMEDIATE RELEASE
Statement
August 26, 2005

Media Inquiries:
Suzanne Treviño, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Takes Action on Plan B
Statement by FDA Commissioner Lester M. Crawford

Thank you for coming today.

We are announcing the action we took today of sending a letter to Barr Labs concerning their application to allow Plan B to be sold over-the-counter.

I want to start by making sure everyone is clear on what this drug is. Also, it's important that we define what the FDA has been asked by Barr Labs to address with respect to this drug.

Plan B has been referred to as emergency contraception. It contains one of the same active ingredients used in ordinary prescription birth control pills -- only in the case of Plan B -- each pill contains a much higher dose and is taken in a different way.

Like ordinary birth control pills, Plan B is currently available to all women as a prescription drug. There is a second drug called Preven that is similar to Plan B. That drug is also sold with a prescription. Preven was first introduced on the market before Plan B.

The question we have been asked to address is whether Plan B should be available without a prescription on a pharmacy shelf, similar to the way other over-the-counter medicines like some cough syrups and allergy pills are sold, for women age 16 and older, and remain prescription-only for those under the age of 16.

The issues that we were asked to resolve, and the proposal that was put forward by Barr Labs, presented us with many difficult and novel policy and regulatory issues.

In some cases, the questions we were asked to answer were unprecedented for this agency. In particular:

Can age be used as a criterion on which we decide whether a drug should be prescription or over-the-counter, as has been proposed in this case?

Can the prescription and over-the-counter version of the same drug be marketed in a single package?

In addition, if we do use age as the only criterion on which we decide whether a drug is sold as a prescription product, or an over-the-counter product, how, as a practical matter, would such a limitation be enforced?

These are profound regulatory decisions that cut to the heart of our work. The answers to these questions can establish very broad and far-reaching policies that could have a significant effect on the way FDA regulates many different drugs.

In fact, the answers to these questions could establish pathways that could make many more products available as over-the-counter drugs.

That could be a positive public health step, and one that I would support as the agency's Commissioner if it means we could safely make many more effective medicines more easily available.

We believe these novel regulatory issues should be considered in an open, public process.

Rather than answering these questions in the context of a decision on a single drug, we need to have an open process to solicit public comment.

These regulatory and policy questions are too profound and cut across too many different products to be made behind closed doors.

And so today we are also announcing that we are taking the action of publishing an advance notice of proposed rulemaking to initiate an open public process to consider these important regulatory and policy questions.

This notice will speak only to the regulatory and policy issues raised by this application.

The resubmitted supplemental new drug application that the FDA was asked to review provides for a switch from prescription only status to Over the Counter status only for women ages sixteen years and older.

Plan B would remain prescription only for women under sixteen years of age.

The FDA's drug center, the Center for Drug Evaluation and Research or CDER, completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but only for women who are 17 years of age and older.

What we are saying today is that the Agency is unable at this time to reach a decision on the approvability of the application because of these unresolved regulatory and policy issues that relate to the application we were asked to evaluate.

We need to resolve these policy and regulatory questions before we can reach a final decision on the underlying science that was presented to us.

FDA is both a scientific and a regulatory agency. And what we are saying today is that there are unique regulatory issues that need to be addressed before we can take a final action on the application.

We are beginning a process that will address the regulatory questions today, but we believe we can only decide these issues in an open, public process.

Through this process, all interested parties can weigh in on the questions of whether a drug may be both prescription and over the counter based on uses by different subpopulations and whether the prescription and over the counter versions of the drug may be marketed in a single package.

There is precedent for this kind of careful, public policy making inside FDA and inside many federal agencies. This action ensures that the rules that an Agency like ours sets are done so in an open fashion. These rules have lots of implications that aren't always easy to anticipate at first blush.

Today I am making the commitment that we will work with our stakeholders to make sure that this process is expeditious and thorough.

Before I close, I want to step back and give you a little more detail on the regulatory pathway that led us to our current action.

And I want to help explain why the question of whether a drug can be sold simultaneously both over the counter and as a prescription product, in the same dosage, for the same indication, and in the same package, and with age as the only deciding criteria, is so profound.

FDA used to prohibit products from being both over the counter and prescription at the same time. They had to be one or the other. The idea was that if an active ingredient was safe and effective without a practitioner's supervision it had to be over-the-counter. If it needed a prescription for one group of people, then it needed a prescription for all people.

That was FDA's practice for a very long time.

In the late 1970s, FDA formed a task force to undertake a formal process to consider changing that policy, to determine whether a drug could be sold prescription and over-thecounter in different settings, for example, for different medical indications.

But ultimately, this task force rejected changing the policy, and so the policy continued. And from the 1950s until the 1980s, drugs were either only prescription or only over-thecounter.

There was no molecule that existed on the market as both a prescription drug and an over-the-counter product.

Then in the 1980s, the agency was challenged on an application. FDA decided to allow the molecule to be sold as a prescription product for one use and an over-the-counter product for another.

Since then, there have been only a small number of ingredients approved as both prescription and over-thecounter and in these cases there was a meaningful difference in the way the two products are used.

In the Plan B application, we are grappling not with the same question but with a different question: whether we can have the same molecule exist as both a prescription and over-thecounter product for the SAME indication?

And if FDA were to attempt to limit sale of an over-thecounter product to a particular sub population, would FDA be able to enforce such a limitation as matter of law, and could it do so as practical matter and then how?

Moreover, we are being asked to determine whether a product can be labeled for over-the-counter and prescription us and be sold in the same package.

I am committed to expediting this rule-making process, and in order to do so, I have ordered a 60-day comment period instead of the usual 90 to 120 day comment period. FDA will process and post the comments as they come in to us and finalization of this regulatory and policymaking process will be a personal priority of mine.

The action FDA took today underscores the Agency's commitment to public health and safety.

As an agency and as its Commissioner personally, I want to say that FDA remains committed to making safe and effective contraceptive products available to women and men who choose to use them.

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FDA Letter to Sponsor
Federal Register Document [PDF 17KB]

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville, MD 20587

NDA 21-045/S-011

Duramed Research, Inc.
Attention: Joseph A. Carrado, M.Sc., R.Ph.
Senior Director, Regulatory Affairs
One Belmont Ave, 11 th floor
Bala Cynwyd, PA 19004

Dear Mr. Carrado:

Please refer to your supplemental new drug application dated April 16, 2003, received April 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Plan B ® (levonorgestrel) Tablets, 0.75 mg.

We acknowledge receipt of your submissions dated April 16, July 25 (3), and 31, August 8 (2), September 4, 8, 9, and 15, October 6, 10, 15 (2), 17, 21, 24, 29, 30, and 31, December 3, and 9, 2003, January 9, and 30, February 6, 10, 13, 20, and 24, March 11 and 26, May 6 and 11, June 30, July 21, 2004, and January 6, 12, 13, 14, 18, 19 and 21, 2005.

Your submission of July 21, 2004 constituted a complete response to our May 6, 2004 Not Approvable action letter.

The resubmitted supplemental new drug application provides for a switch from Rx only status to Over the Counter (OTC) status for women ages sixteen years and older. Plan B would remain Rx only for women under sixteen years of age. In addition, you have proposed that both the Rx and OTC version of Plan B be marketed in a single package.

The Center for Drug Evaluation and Research (CDER) has completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product, but only for women who are 17 years of age and older. However, the Agency is unable at this time to reach a decision on the approvability of the application because of unresolved issues that relate to your NDA discussed below.

Your application has presented us with three difficult and novel issues. Specifically, you have proposed that Plan B be marketed in a single package, and sold either as Rx or OTC, depending on the age of the patient. While the Agency has allowed the same active ingredient to be marketed both Rx and OTC based on indication, strength, dosage form and route of administration, the Agency has never determined whether a drug may be both Rx and OTC based on the age of the individual using the drug. A related concern is how, as a practical matter, an age-based distinction could be enforced. In addition, we have never been confronted with whether the Rx and OTC versions of the same active ingredient may be marketed in a single package.

As you may be aware, questions have arisen over the years about whether there are any conditions under which an active ingredient may be simultaneously marketed in both a prescription drug product

and an OTC drug product. Notwithstanding our having allowed the practice in those rare instances where there is a meaningful difference in the indication, strength, dosage form or route of administration of the two products, we recognize that FDA's interpretation of section 503(b) of the Act has not been explicitly set forth in any of the regulations that discuss the process by which FDA classifies (or re-classifies) drugs as OTC or prescription. See 21 CFR 310.200 and 310.201.

In this case, we have decided that the appropriate course is to ask for public comments on whether we should initiate a rulemaking to codify our interpretation of section 503(b) regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product. To this end, we have decided to publish an advance notice of proposed rulemaking in the Federal Register. In addition, the notice will seek public comments on questions related to the marketing of Rx and OTC versions of the same active ingredient in a single package.

At this time, the drug product may not be legally marketed OTC. In the future, you will be notified in writing regarding changes in the status of your application.

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference to discuss what steps need to be taken before the application may be approved .

Sincerely,

Lester M. Crawford, DVM, PhD
Commissioner of Food and Drugs

Attachment #3

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH	ODS POSTMARKETING SAFETY REVIEW	
TO: Daniel Shames, M.D., Director Division of Reproductive and Urologic Health Products (DRUDP), HFD-580	**FROM:** Sarah J. Singer, R.Ph., Safety Evaluator Division of Drug Risk Evaluation (DDRE) HFD-430	**ODS PID#, DATE:** D030586 October 31, 2003

DESIRED COMPLETION DATE: October 31, 2003 **DATE RECEIVED BY ODS:** September 30, 2003	**REQUESTOR:** Daniel Shames, M.D.	
DRUG: Plan B® (levonorgestrel)	**NDA #:** 21-045	**SPONSOR:** Women's Capital Corporation, Barr Laboratories

EVENT: All events, with an emphasis on ectopic pregnancies

EXECUTIVE SUMMARY:

As background information for an upcoming advisory committee meeting on a proposed OTC switch for Plan B®, DRUDP requested AERS information and information from the United Kingdom on adverse events reported in association with the use of postcoital levonorgestrel. The division indicated they would be most concerned about deaths (if any) and ectopic pregnancies.

Neither AERS nor the U.K.'s database contained any reports of death in women using postcoital levonorgestrel.

AERS contained 28 unduplicated cases of ectopic pregnancy (none from the United States) in users of postcoital levonorgestrel. Four of the cases had been published.

Most of the other reported events were nonserious and already are described in the product labeling. However, there were ten cases of hypersensitivity reactions, seven of which were considered life-threatening. The current Plan B® labeling does not address hypersensitivity reactions.

REASON FOR REQUEST/REVIEW:

As background information for an upcoming advisory committee meeting on a proposed OTC switch for Plan B®, DRUDP submitted a consult request but did not state what information they wanted ODS to provide. Daniel Davis, M.D., the medical officer for Plan B®, was contacted and indicated that he would be most interested in cases involving death (if any) and/or ectopic pregnancies. Information on other events reported to the FDA could be presented in tabular format.

Dr. Davis also asked if ODS could obtain information from the United Kingdom on adverse reactions to Levonelle and Levonelle-2 (the U.K. equivalents of Plan B®). He later requested U.K. utilization data as well.

USAGE INFORMATION:
****Information from IMS HEALTH, INC. is copyrighted and cannot be used outside the FDA without prior clearance from IMS HEALTH.****

The utilization databases usually used by ODS were deemed inadequate to determine the use of Plan B®, which is often dispensed by family planning clinics rather than outpatient pharmacies or office-based physicians. Accordingly, sales data were requested from the IMS HEALTH INC. National Sales Perspectives™ database, which captures sales to U.S. non-retail outlets such as clinics, as well as retail pharmacies. The data show that approximately 314,000 Plan B® kits were sold in the United States between the approval of the drug in July, 1999 and the end of August, 2003. There is no way of knowing what percentage of the sold kits have actually been distributed to patients.

At the request of HFD-580, ODS has also requested utilization data from the United Kingdom. If the U.K. is willing to provide it, we have asked that it be sent directly to DRUDP.

SEARCH DATE: October 9, 2003	**DATABASE SEARCHED:** Adverse Event Reporting System (AERS)

SEARCH CRITERIA:

A typical AERS search using the drug active ingredient (generic name), levonorgestrel, would capture all the Norplant® cases as well as those associated with Plan B®. Thousands of Norplant® cases have been received in association with class action lawsuits. Therefore, AERS was searched using only the trade name Plan B and various verbatim reported names such as foreign trade names (Levonelle, Levonelle-2, Postinor, Postinor-2). The search retrieved all AERS cases with any of those drug names listed as suspect products.

SEARCH RESULTS:

The search identified 130 cases, all of which were retrieved for hands-on analysis. After eliminating duplicate reports, a total of 116 unduplicated cases remained. There were no reports involving death.

Most of the reports involved nonserious expected (labeled) events and are tallied below. The other cases will be presented in the sections that follow.

Unintended pregnancy (no other event)[1]:	**21**
Delayed menstruation:	**3**
Menstrual dysfunction:	**2**
Vaginal bleeding:	**26**
Additional events:	
Cramps, pain, &/or backache:	8
Diarrhea:	1
Dizziness:	1
Headache:	1
Passing clots:	3
Nausea &/or vomiting:	3
Nausea and/or vomiting (no bleeding):	**8**
Additional events:	
Cramps or pain:	3
Dizziness:	2
Headache:	1
Mood swings:	1

[1] Three additional patients had unintended pregnancies resulting in spontaneous abortions, and a fourth had a missed abortion. See **POSSIBLE FETAL EFFECTS**.

ECTOPIC PREGNANCIES:

Number of cases, country of origin:

The AERS search identified 29 cases. During hands-on review, only one definite duplication was identified, so this analysis will be presented as covering 28 unduplicated cases[2].

None of the 28 cases occurred in the United States.

Twelve cases were reported from Gedeon Richter in Hungary without information on the actual country of origin. Levonelle-2 was listed as the drug in eight of the 12 cases, and Postinor-2 in the other four. Ten of the cases provided demographic information; among those ten cases, there does not appear to be duplication of a case reported from another country.

There were ten cases from the United Kingdom, one of which had been published:
Fabunmi L, Perks N. Caesarean section scar ectopic pregnancy following postcoital contraception. J Family Planning Repro Health Care **2002**;28:155-6.

Three cases came from Israel and had also been published:
Sheffer-Mimouni G, Pauzner D, Maslovitch S, Lessing JB, Gamzu R. Ectopic pregnancies following emergency levonorgestrel contraception. Contraception **2003**;67:267-9.

There was a single case from Sweden and a case from a Chinese study, as well as a literature case (see footnote 1) in which the country of origin could not be determined.

Characteristics of the cases:

The patients ranged in age from15 to 38 years (N=23).

The drug used for postcoital contraception was reported as Levonelle-2 in 18 cases, Postinor-2 in 8 cases, and "two-dose levonorgestrel" in 2 cases.

Most of the reports provided no information other than that an ectopic pregnancy had occurred. However, tubal pregnancies were specified in eight cases, and the published case from the United Kingdom presented a pregnancy occurring in the surgical scar from an earlier Caesarean section.

The event was considered life-threatening in 15 cases. Fifteen patients were stated to have been hospitalized, and surgery was performed in ten cases.

One patient was stated to have a history of three prior ectopic pregnancies, unassociated with postcoital contraception. Two patients (including the U.K. literature case mentioned above) had histories of prior Caesarean sections. One patient had undergone a D&C for a first-trimester termination of pregnancy 2 to 3 weeks before the unprotected intercourse for which she received levonorgestrel. Two patients were stated to have had histories of normal pregnancies.

Concomitant medications were only listed in three cases: mebeverine (an antispasmodic) and ranitidine in a patient with irritable bowel syndrome; topical erythromycin + zinc in a 15-year-old patient; and oral contraceptives, which had been discontinued two months before the unprotected intercourse, in the third patient. Six patients were specifically stated not to be taking any concomitant medications.

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[2] Four of the 28 cases contained very little information (no demographic information) and therefore could be duplicates of more completely documented cases. One of the four is a literature report:
von Hertzen H et al for the WHO Research Group on Post-ovulatory Methods of Fertility Regulation. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet **2002**;360:1803-10.
It mentions one patient in the two-dose levonorgestrel group who experienced an ectopic pregnancy requiring unspecified surgical treatment. The trial was conducted in China, Sweden, and the United Kingdom (among other countries). AERS contains reports of ectopic pregnancies from each of those countries, so this case may be a duplicate.

POSSIBLE FETAL EFFECTS:

A 14-year-old in the U.K. had been taking Microgynon (levonorgestrel/ethinyl estradiol) for contraception. For an unstated reason she was also given Levonelle-2 for postcoital contraception. Several conflicting reports were provided on the case, but the most recent followup indicates that conception had occurred 10 days before the use of Levonelle-2. She received x-rays for abdominal pain "at approximately 12/40 gestation (pregnancy was not diagnosed until 14/40)". At an unspecified time, major fetal anomalies were discovered: extensive abdominal wall defects, thoracic wall defects, amputation of left arm, loss of bony rib cage, and scoliosis. The reports do not provide the outcome of the pregnancy.

A 36-year-old woman in the U.S. reported that she had received Plan B® a year earlier, and had later determined that she had been pregnant at the time. She experienced 3 weeks of continuous spotting, so an ultrasound was performed. The fetus was detached from the uterine wall. A D&C was performed.

A 30-year-old woman received Levonelle-2 as postcoital contraception; erythromycin was started the same day and continued for a week (indication not stated). An unintended pregnancy occurred, and a baby with translocated Down syndrome was later born.

A 29-year-old woman who had received Levonelle-2 experienced an intrauterine death at 15 weeks' gestation. The fetus was found to have "possible Edward's syndrome (trisomy) on triple testing".

Three patients (none from the United States) had unintended pregnancies resulting in spontaneous abortions, and a fourth patient had a missed abortion.

CONVULSIONS:

The AERS search identified three unduplicated cases of convulsions. One occurred in the United States. The patient, of unstated age, reported that she had taken her first dose of Plan B® at 7 or 8 AM, and the second dose 12 hours later. The following morning a family member went to wake her and found her in bed "shaking with her eyes rolling back in her head". She was hospitalized and claimed that a physician had confirmed she had a grand mal seizure. However, an MRI and unstated blood tests had "appeared" normal. She had no history of seizures and was on no other medications.

The two other cases both involved Levonelle-2. One patient had no previous history of epilepsy. She experienced convulsions the day she took Levonelle-2, and was hospitalized. The report stated that she was also on Minulet (ethinyl estradiol/gestodene). The second patient had a long history of epilepsy, which was stated to have been well-controlled with carbamazepine. The reporter indicated that a drug interaction had been involved.

HYPERSENSITIVITY:

The AERS search identified ten unduplicated cases of hypersensitivity reactions, three of which occurred in the United States. Events ranged from minor rashes to urticaria, whole-body rashes and edematous reactions involving dyspnea. Seven of the cases were considered life-threatening. The time to onset was stated in 8 reports and ranged from four hours to two days after taking the drug. The current labeling for Plan B® does not mention hypersensitivity reactions.

MISCELLANEOUS (Single cases):

Thrombocytopenia:

Two days after taking Plan B®, the U.S. patient of unstated age noticed bruising and petechiae and had epistaxis. She was hospitalized with a platelet count of 1000. She was treated with immune globulin and prednisone and her platelet count rose to 9000 two days later. Two months later her platelet count was up to 146,000 and she was off prednisone. She had a history of a similar event occurring following a rubella vaccination several years earlier, but five months before using Plan B® her platelet count had been "in the mid-200,000 range".

Other events:

The other cases were:

- Numbness/tingling of the fingers, jaw tightening, shakiness, sore throat, nausea
- Breast soreness, tiredness, loss of appetite
- Urinary frequency/urgency/pain, breast tenderness, headache
- Abdominal bloating, cramping, extreme fatigue
- Ruptured corpus luteum cyst
- Headache, disorientation, dizziness

UNITED KINGDOM POST-MARKETING ADVERSE EVENT DATA:

The Medicines and Healthcare products Regulatory Agency (MHRA) sent printouts to ODS from the Adverse Drug Reactions Online Information Tracking (ADROIT) database of all events reported for Levonelle and Levonelle-2 since their approval in the United Kingdom. There were 45 total reports for Levonelle and 243 for Levonelle-2[3]. There were no deaths reported for either drug.

The printouts showed 5 reports of ectopic pregnancy with Levonelle and 16 with Levonelle-2.

Copies of the printouts have been provided to DRUDP.

SUMMARY:

A search of the Adverse Event Reporting System on October 9, 2003 identified 130 cases with Plan B® or a foreign equivalent as the suspect drug. Hands-on review of the cases eliminated 14 duplicates, leaving 116 unduplicated cases which were analyzed for this document.

There were no deaths.

The event of most concern to DRUDP was ectopic pregnancy. AERS contained 28 unduplicated cases (none from the United States) of ectopic pregnancy in users of postcoital levonorgestrel. Four of the cases had been published.

Most of the other reported events were nonserious and already are described in the product labeling. However, there were ten cases of hypersensitivity reactions, seven of which were considered life-threatening. The current Plan B® labeling does not address hypersensitivity reactions.

REVIEWER'S SIGNATURE / DATE:	**DIVISION DIRECTOR SIGNATURE / DATE:**
/S/ 10/31/03	/S/ 10/31/03
Sarah J. Singer, R.Ph.	Mark Avigan, M.D., Acting Director

[3] Presumably, any AERS reports from the United Kingdom are duplicates of cases in the ADROIT database.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sarah Singer
10/31/03 11:54:17 AM
DRUG SAFETY OFFICE REVIEWER

Mark Avigan
10/31/03 05:00:17 PM
DRUG SAFETY OFFICE REVIEWER

Attachment # 4

Testimony for Senator Clegg, read by Katie Coburn:

I am here today to speak in favor of this bill, with an amendment which changes the age from 18 to16. I feel that the age which requires parental consent to obtain this morning after pill should be 16. I would rather have a 16 year old girl who thinks she is in love and makes a mistake one night in the back of a car learn from her mistake early, and feel the effects from the pill, rather than have to deal with the choice of an abortion 2 or 3 months down the road.

When a female takes the morning after pill, three things happen. Incredible nausea and cramping take place, as well as a fear that the pill may not work, and that she may become pregnant. Dramamine can help the nausea, however one way to ease that incredible fear would be to allow a girl who has made a mistake to make sure she can remedy that mistake before pregnancy occurs. If a minor is required to obtain parental consent to get this pill, the arguing and conflict that results in her asking her parents may last longer than the 24 hour period when the morning after pill is most effective. So on top of the horrible nausea and the cramping and the fear of the pill not working, the girl now has to deal with the stress of disappointing her family. This stress can also possibly lead to the delay of the pill working, as stress often stunts menstruation, which has to occur in order for the pill to have worked. By allowing the age to be changed to 16, we are relieving some of the burden, but none of the guilt of a girl who realizes she has made a mistake. The girl will be able to take the pill within the effective time frame, and be able to approach a mother-figure more comfortably to discuss the situation, knowing that she is not pregnant.

These girls who use the morning after pill are not all promiscuous girls. These are the girls you see in your church, the girls you see on the honor roll in the high schools, and the girls you see in the supermarkets shopping with their parents. Not every girl who uses the pill is promiscuous, and usually after one dose of the morning after pill, will not make the same mistake again.

I understand that the pharmacists are allowed to submit documentation if they feel parental consent should be waived, but that decision cannot be left to pharmacists. If a girl who has been raped by a stranger or family member, and does not feel comfortable going to a stranger to file charges, why would she feel comfortable disclosing that information to a pharmacist?

After speaking to a young woman who has used the morning after pill, who knows other young women who have also used the pill, I urge you to reconsider the age requiring parental consent. Pharmacists who choose to distribute this emergency contraception are trained to provide adequate information to these girls. A constituent told me, "After feeling the effects of the drug first hand, I can honestly say that I will never made the same mistake again, and I can tell you that several other young women I know would certainly say the same thing. The 24 hours following taking the pill are painful and the next 3-7 days waiting for the pill to complete its course is not something I would ever want to risk experiencing again."

Attachment #5

ACOG PRACTICE BULLETIN

[PDF format]

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS
NUMBER 69, DECEMBER 2005

(Replaces Practice Bulletin Number 25, March 2001)

Emergency Contraception

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins — Gynecology with the assistance of Elizabeth Raymond, MD, MPH. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Emergency contraception, also called the morning-after pill *and* postcoital contraception, *is therapy used to prevent pregnancy after an unprotected or inadequately protected act of sexual intercourse. Women seeking emergency contraception typically are younger than 25 years, have never been pregnant, and have used some form of contraception in the past (1â€"3). Common indications for emergency contraception include contraceptive failure (eg, condom breakage, missed doses of oral contraceptives) and failure to use any form of contraception (2, 4, 5). Although oral emergency contraception was first described in the medical literature decades ago, this therapy is still not widely used in the United States to reduce unintended pregnancy. The results of a 2003 survey of 800 U.S. women aged 18â€"49 years indicate that only 6% reported having ever used emergency contraception (1). Many women are unaware of the existence of emergency contraception, misunderstand its use and safety, do not have convenient and prompt access to it, or do not use it when a need arises. Increasing emergency contraception awareness, knowledge, and access are important prioities in the effort to reduce*

the incidence of unintended pregnancy.

Methods of emergency contraception include administration of progestin-only or combination estrogenâ€"progestin oral contraceptives, synthetic estrogens and conjugated estrogens, or antiprogestins and the insertion of a copper intrauterine device (IUD). This bulletin addresses the progestin-only and combined oral contraceptive medical methods, which are the most frequently used and the only methods currently approved by the U.S. Food and Drug Administration (FDA) specifically for emergency contraception, and briefly addresses the IUD because of its use as long-term contraception in addition to emergency contraception.

Background

Research on the postcoital use of contraceptive steroids began in the 1960s. The first oral regimen, which used a widely available brand of combined estrogenâ€"progestin oral contraceptive pills, was published in 1974 by Yuzpe and colleagues (6). Research on progestin-only regimens for occasional postcoital use by women having infrequent intercourse also began about that time (7).

Regimens

The two most commonly used oral emergency contraception regimens are the progestin-only regimen, which consists of a total of 1.5 mg levonorgestrel, and the combined estrogenâ€"progestin regimen, which consists of two dosesâ€"each containing 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrelâ€"taken 12 hours apart. Both regimens are available in many countries as products labeled specifically for use as emergency contraception, but the levonorgestrel-only product (Plan B) is the only dedicated emergency contraception product currently marketed in the United States. Both regimens also can be made from a variety of standard oral contraceptives (Table 1), although data exist only for regimens containing levonorgestrel, norgestrel (levonorgestrel plus an equal amount of the inactive enantiomer dextronor-gestrel), and norethindrone.

The package insert of Plan B instructs patients to take one 0.75-mg levonorgestrel pill as soon as possible after unprotected intercourse and to take the second 0.75-mg pill 12 hours after the first dose. However, randomized trials have shown that taking both pills at the same time (8, 9) or taking each 0.75-mg pill 24 hours apart (10) is as effective as taking them 12 hours apart and does not increase the risk of side effects.

Method of Action

No single mechanism of action has been established for emergency contraception; rather, the mode of action varies according to the day of the menstrual cycle on which intercourse occurs and emergency contraception is administered (11â€"14). Both the combined regimen and the levonorgestrel-only regimen have been shown to inhibit or delay ovulation (15â€"21). Earlier studies documented histologic and biochemical changes in the endometrium after administration of the combined regimen, suggesting that emergency contraception may alter the receptiveness of the endometrium and inhibit implantation of a fertilized egg (6, 18, 22â€"24). However, several more recent studies have not supported these findings (16, 19, 21, 25â€"28), and the endometrial changes that have been observed may not be sufficient to prevent implantation. Interference with sperm transport or penetration (7, 29) and impairment of corpus luteum function (18, 30)

have been proposed as other possible mechanisms of action, but there is no direct clinical evidence to support these theories. However, it is statistically unlikely that emergency contraception could be as effective as it is for preventing pregnancy if interference with ovulation is its only method of action (31).

Emergency contraception is sometimes confused with medical abortion (32). However, whereas medical abortion is used to terminate an existing pregnancy, emergency contraception is effective only before a pregnancy is established. Emergency contraception can prevent pregnancy during the 5 or more days between intercourse and implantation of a fertilized egg, but it is ineffective after implantation. Studies of high-dose oral contraceptives indicate that emergency contraception confers no increased risk to an established pregnancy or harm to a developing embryo (33).

Side Effects

Plan B is available only by prescription. However, in 2003 a combined panel of the FDAâ€™s Advisory Committee on Reproductive Health Drugs and the Advisory Committee on Nonprescription Drugs concluded that the safety of the levonorgestrel-only emergency contraception regimen has been sufficiently demonstrated to warrant approval for nonprescription status.

No deaths or serious complications have been causally linked to emergency contraception (34). Short-term side effects include the following:

- Nausea and vomiting: The levonorgestrel-only regimen is associated with significantly lower incidences of nausea and vomiting than the combined regimen (35, 36). Nausea and vomiting, respectively, occur in about 18% and 4% of women using levonorgestrel-only emergency contraception (8, 9, 36) and in approximately 43% and 16% of women using the combined regimen (37).
- Irregular bleeding: After emergency contraception use, the menstrual period usually occurs within 1 week before or after the expected time (36). Some patients experience irregular bleeding or spotting in the week or month after treatment; one recent trial of the levonorgestrel-only regimen found that 16% of women reported nonmenstrual bleeding in the first week after use (9). Irregular bleeding associated with emergency contraception resolves without treatment.
- Other side effects: Some patients have reported experiencing short-term side effects, such as breast tenderness, abdominal pain, dizziness, headache, and fatigue (38).

Table 1. Twenty-one Brands of Oral Contraceptives That Can Be Used for Emergency Contraception in the United States

Brand	Company	Pills per Dose*	Ethinyl Estradiol per Dose (µg)	Levonorgestrel per Dose (mg)â€
Plan Bâ€¡	Barr	1 white pill	0	0.75
Ovral	Wyeth-Ayerst	2 white pills	100	0.50
Ogestrel	Watson	2 white pills	100	0.50
Cryselle	Barr	4 white pills	120	0.60

Levora	Watson	4 white pills	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white pills	120	0.60
Low-Ogestrel	Watson	4 white pills	120	0.60
Levlen	Berlex	4 light orange pills	120	0.60
Nordette	Wyeth-Ayerst	4 light orange pills	120	0.60
Portia	Barr	4 pink pills	120	0.60
Seasonale	Barr	4 pink pills	120	0.60
Trivora	Watson	4 pink pills	120	0.50
Tri-Levlen	Berlex	4 yellow pills	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow pills	120	0.50
Enpresse	Barr	4 orange pills	120	0.50
Alesse	Wyeth-Ayerst	5 pink pills	100	0.50
Lessina	Barr	5 pink pills	100	0.50
Levlite	Berlex	5 pink pills	100	0.50
Lutera	Watson	5 white pills	100	0.50
Aviane	Barr	5 orange pills	100	0.50
Ovrette	Wyeth-Ayerst	20 yellow pills	0	0.75

*The treatment schedule is one dose as soon as possible after unprotected intercourse, and another dose 12 hours later. However, recent research has found that both doses of Plan B or Ovrette can be taken at the same time.

â€ The progestin in Cryselle, Lo/Ovral, Low-Ogestrel, Ogestrel, Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each tablet is twice the amount of levonorgestrel. Levonorgestrel regimens also can be formulated by substituting double the amount of norgestrel as is indicated for levonorgestrel.

â€¡Plan B is the only dedicated product specifically marketed for emergency contraception in the United States. Preven, a combined emergency contraception pill, is no longer available on the U.S. market.

www.NOT-2-LATE.com: the emergency contraception website. Princeton University Office of Population Research. Princeton (NJ): Office of Population Research; 2005. Available at: http://ec.princeton.edu/questions/dose.html. Retrieved October 13, 2005.

Effects on Pregnancy

No studies have specifically investigated adverse effects of exposure to emergency contraception during early pregnancy. However, numerous studies of the teratogenic risk of conception during daily use of oral contraceptives (including older, higher-dose

preparations) have found no increase in risk to either the pregnant woman or the developing fetus (39).

Existing data indicate that use of emergency contraception does not increase the chance that a subsequent pregnancy will be ectopic. Emergency contraception, like all other contraceptives, actually reduces the absolute risk of ectopic pregnancy by preventing pregnancy overall (40).

Drug Interactions

Although no evidence exists regarding the interaction between emergency contraception and other medications, it is biologically plausible that any drug interactions involving emergency contraception would be similar to those interactions observed with use of combined estrogenâ€"progestin oral contraceptives. A detailed discussion of adverse interactions involving oral contraceptives is beyond the scope of this bulletin, but several resources are available on this topic (41â€"45). Medications and herbal supplements that may decrease the effectiveness of oral contraceptives (including but not limited to rifampicin, St. Johnâ€™s wort, certain anticonvulsants, and certain antiretrovirals) also may reduce the efficacy of emergency contraception.

Awareness and Access

Recent surveys have documented that a large number of women are unaware of the existence of emergency contraception or have insufficient knowledge to allow them to use it effectively (46â€"50). The results of a 2003 survey of Californians between the ages of 15 and 44 years indicate that 35% did not know of any way to prevent becoming pregnant after sex, and 43% were not aware that emergency contraception is available in the United States (1). Many health care providers are poorly informed about this method (51â€"53), and access to emergency contraception through health care providers, pharmacies, student health centers, urgent care centers, and other sources is limited (54, 55). A study of 320 pharmacies in Pennsylvania found that only 35% could fill a prescription for emergency contraception on the same day it was requested (56). Data from a nationally representative sample of female sexual assault victims seen in U.S. emergency departments in 2002 indicated that only 21% of eligible women received emergency contraception (57).

A prominent concern among both women and health care providers is that making emergency contraception more readily available could encourage irresponsible sexual behavior, which would increase the risks of both unintended pregnancy and sexually transmitted diseases (58). However, numerous studies have shown that this concern is unfounded. At least seven published randomized trials have evaluated the policy of providing emergency contraception to women at the time of a routine gynecologic visit, so that they will have the medication immediately available if a contraceptive mishap occurs (4, 59â€"64). These trials compared this policy of advance provision with a policy of instructing women to contact a clinician if emergency contraception is needed. All but one (63) of these trials showed no difference between groups regarding self-reported frequency of either unprotected intercourse or use of contraception. In all the trials, use of emergency contraception was substantially more common in the group that was provided emergency contraception in advance, and one trial found that providing emergency contraception in advance of need resulted in earlier use of the treatment (4).

Clinical Considerations and Recommendations

- ***Who are candidates for emergency contraception?***

Emergency contraception should be offered to women who have had unprotected or inadequately protected sexual intercourse and who do not desire pregnancy. Some emergency contraception studies have excluded women with specific contraindications to oral contraceptives, but no evidence demonstrates that emergency contraception is unsafe for women with these contraindications or for those with any particular medical conditions. Similarly, although some product package inserts list contraindications similar to those accepted for regular use of oral contraceptives, these precautions likely do not apply to emergency contraception because of the short duration of use. The World Health Organizationâ€™s "Medical Eligibility Criteria for Contraceptive Use" include no conditions in which the risks of emergency contraception use outweigh the benefits (65). These criteria note specifically that women with previous ectopic pregnancy, cardiovascular disease, migraines, or liver disease and women who are breastfeeding may use emergency contraception. No data specifically examine the risk of using hormonal methods of emergency contraception among women with contraindications to the use of conventional oral contraceptive preparations; nevertheless, emergency contraception may be made available to such women. In addition, no rationale exists for denying emergency contraception to women with undiagnosed genital bleeding. Although existing pregnancy is not a contraindication for emergency contraception use in terms of risk of adverse effects, emergency contraception is not indicated in women with confirmed pregnancy because it will have no effect.

- ***What screening procedures are needed before provision of emergency contraception?***

No clinical examination or testing is required before emergency contraception is provided. Emergency contraception should not be withheld or delayed in order to test for pregnancy, nor should it be denied because the unprotected coital act may not have occurred on a fertile day of the menstrual cycle. Emergency contraception generally should be provided any time unprotected or inadequately protected intercourse occurs and the patient is concerned that she is at risk for unwanted pregnancy.

- ***When should emergency contraception be initiated?***

Treatment should be initiated as soon as possible after unprotected or inadequately protected intercourse, because efficacy seems to decline substantially with time (9, 66). Several studies have shown that both combined and progestin-only regimens are more effective the closer dosing is to the time of intercourse (9, 35, 36, 67). However, a few studies have not observed this time effect with the combined regimen (68, 69). Because earlier studies demonstrated that both regimens are effective when initiated up to 72 hours after intercourse (6, 36), some product package instructions advise use only within that time frame. More recent studies have shown that emergency contraception is still moderately effective when the first dose is taken up to 120 hours after intercourse. Therefore, emergency contraception should be made available to patients who request it up to 120 hours after intercourse (9, 59, 69â€“72). There currently are no data evaluating the efficacy of emergency contraception when treatment is initiated more than 120 hours after intercourse.

- ***How effective is emergency contraception in preventing pregnancy?***

In the ideal setting, the effectiveness of a preventive therapy is best measured by comparing the probability that the condition will occur if the therapy is used with the probability that it will occur without treatment. For emergency contraception, efficacy is defined as the number of pregnancies observed after treatment divided by the estimated number of pregnancies that would occur without treatment. When this proportion is

subtracted from one, the resulting statistic is the â€œprevented fraction,â€□ which represents the estimated percentage of cases averted by the treatment. Calculation of this statistic in clinical observation involves many assumptions that are difficult to validate. The numerator may become artificially inflated because preexisting pregnancies and those resulting from subsequent acts of intercourse are difficult to distinguish from pregnancies resulting from emergency contraception treatment failure. In addition, calculation of the denominator requires that estimates of the timing of ovulation be compared with data about the daily probability of conception that may not be appropriate for the study populations. Therefore, reported figures on the efficacy of emergency contraception vary considerably and are imprecise.

Six studies comprising a total of more than 8,000 women who used the levonorgestrel-only regimen calculated prevented fractions ranging from 60% to 94%, meaning that the regimen reduced womenâ€™s chances of pregnancy by that amount (8â€“10, 35, 36, 73). Similarly, eight studies including a total of more than 3,800 women who used the combined regimen yielded prevented fractions ranging from 56% to 89%; a meta-analysis of pooled data from these studies concluded that the regimen prevents at least 74% of expected pregnancies (74).

Other data suggest that the levonorgestrel-only regimen is more effective than the combined regimen. The first of two randomized trials that directly compared the two regimens found no statistically significant difference in efficacy between failure rates of the levonorgestrel-only regimen and the combined regimen (2.4% versus 2.7%, respectively) (35). However, a second larger trial reported that the levonorgestrel-only regimen was significantly more effective for preventing pregnancy than the combined regimen (85% versus 57%, respectively) (36). Estimates based on combined data from these two studies show a reduced relative risk of pregnancy (0.51, 95% confidence interval, 0.31â€“0.83) with the levonorgestrel-only regimen (75). Therefore, the levonorgestrel-only regimen is preferred to the combined estrogenâ€“progestin regimen, if available.

- ***Are antiemetics useful as an adjunct to treatment?***

Because the incidence of nausea and vomiting is low with the levonorgestrel-only regimen, prophylactic antiemetics are probably not necessary. With the combined regimen, antiemetic pretreatment may be beneficial because the incidence of nausea is reported to be 30â€“60% (76). A single dose of an antiemetic taken 1 hour before the first dose of emergency contraception has been shown to decrease the incidence or severity of nausea (37, 77). Taking emergency contraception with food does not appear to affect the risk of nausea (37, 78). No evidence exists that vomiting within 3 hours of taking the dose is associated with an increased failure rate; how-ever, no studies were designed specifically to measure this effect. Many experts recommend that the dose should be repeated if vomiting occurs within 2 hours of taking a dose. If severe vomiting occurs, emergency contraception may be administered vaginally. Studies of vaginally administered combined oral contraceptive pills suggest that the hormones are effectively absorbed through the vaginal epithelium (79, 80).

- ***Is emergency contraception safe if used repeatedly?***

Data are not available on the safety of current regimens of emergency contraception if used frequently over a long period. However, experience with similar regimens (81) and with high-dose oral contraceptives suggests that the likelihood of serious harm from at least moderate repeat use is low. Therefore, emergency contraception may be used even if the woman has used it before, even within the same menstrual cycle. Information

about other forms of contraception and counseling about how to avoid future contraceptive failures should be made available to women who use emergency contraception, especially those who use it repeatedly.

Emergency contraception is less effective than most other available methods for long-term contraception. In addition, continued use would result in exposure to higher total levels of hormones than those of either combined or progestin-only oral contraceptives, and frequent use also would result in more side effects, including menstrual irregularities. Therefore, emergency contraception should not be used as long-term contraception.

- ***What clinical follow-up is needed after use of emergency contraception?***

No scheduled follow-up is required after use of emergency contraception. However, the woman should be advised that if her menstrual period is delayed by a week or more, she should consider the possibility that she may be pregnant and seek clinical evaluation. A woman also should seek follow-up care for persistent irregular bleeding or lower abdominal pain because these symptoms could indicate a spontaneous abortion or an ectopic pregnancy. Women also should be advised about available resources if they need ongoing contraceptive or other services, such as testing for sexually transmitted diseases, at the time emergency contraception is provided or at some convenient time thereafter.

- ***When should regular contraception be initiated or resumed after use of emergency contraception?***

Treatment with emergency contraception may not protect against pregnancy in subsequent coital acts (9); in fact, because emergency contraception may work by delaying ovulation, women who have taken emergency contraception are at risk for becoming pregnant later in the same menstrual cycle. Therefore, all women should begin using barrier contraceptives to prevent pregnancy (eg, condoms, diaphragms, and spermicides) immediately after taking emergency contraception. Short-term hormonal contraceptives (eg, pills, patches, and rings) may be started either immediately (with a backup barrier method) or after the next menstrual period. Long-term hormonal methods should be started after the next menstrual period, when it is clear that the patient is not pregnant.

- ***How can access to emergency contraception be facilitated?***

To maximize the effectiveness of treatment, women should be able to obtain emergency contraception quickly when the need arises. Providing an advance prescription or supply of emergency contraception, educating staff who may be in contact with the patient about its availability, and prescribing it by phone without requiring an office visit will facilitate access (82).

- ***When is an intrauterine device appropriate for emergency contraception?***

Use of a copper IUD for emergency contraception, first reported in 1976 (83), has been studied in prospective cohort trials with pregnancy rates of 0â€“0.1% (84). In these trials, the IUD was inserted up to 5 days after unprotected intercourse. A more recent report of 1,013 women who underwent insertion of a copper IUD for emergency contraception, including 170 nulliparous women, found a pregnancy rate of 0.2% (85). One advantage of the copper IUD for emergency contraception is that it can be retained for continued long-term contraception. The same study found 86% of parous women and 80% of nulliparous women maintained the IUD for contraception. No randomized controlled trials

have compared IUD insertion with medical regimens for emergency contraception. A recent meta-analysis concluded that the IUD is very effective for emergency contraception but that further comparative studies are needed (86).

The copper T380A is appropriate for emergency contraception in women who meet standard criteria for IUD insertion and is most effective if inserted within 5 days after unprotected intercourse. This method is particularly useful for women who desire long-term contraception and who are otherwise appropriate candidates for IUD use.

Summary of Recommendations and Conclusions

The following recommendations are based on good and consistent scientific evidence (Level A):

- Emergency contraception should be offered or made available to women who have had unprotected or inadequately protected sexual intercourse and who do not desire pregnancy.
- The levonorgestrel-only regimen is more effective and is associated with less nausea and vomiting; therefore, if available, it should be used in preference to the combined estrogenâ€"progestin regimen.
- The 1.5-mg levonorgestrel-only regimen can be taken as a single dose.
- The two 0.75-mg doses of the levonorgestrel-only regimen are equally effective if taken 12â€"24 hours apart.
- To reduce the chance of nausea with the combined estrogenâ€"progestin regimen, an antiemetic agent may be taken 1 hour before the first emergency contraception dose.
- Prescription or provision of emergency contraception in advance of need can increase availability and use.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Treatment with emergency contraception should be initiated as soon as possible after unprotected or inadequately protected intercourse to maximize efficacy.
- Emergency contraception should be made available to patients who request it up to 120 hours after unprotected intercourse.
- No clinician examination or pregnancy testing is necessary before provision or prescription of emergency contraception.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- No data specifically examine the risk of using hormonal methods of emergency contraception among women with contraindications to the use of conventional oral contraceptive preparations; nevertheless, emergency contraception may be made available to such women.
- Clinical evaluation is indicated for women who have used emergency contraception if menses are delayed by a week or more after the expected time or if lower abdominal pain or persistent irregular bleeding develops.
- Information regarding effective contraceptive methods should be made available either at the time emergency contraception is prescribed or at some convenient time thereafter.
- Emergency contraception may be used even if the woman has used it before, even within the same menstrual cycle.

Additional Resources

Emergency Contraception Hotline: 1-888-NOT-2-LATE

World Wide Web Pages:

- The American College of Obstetricians and Gynecologists: www.acog.org
- Emergency Contraception: http://www.not-2-late.com
- International Consortium for Emergency Contraception: http://www.cecinfo.org
- Pastillas Anticonceptivas de Emergencia: http://www.en3dias.org.mx

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2005. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

The American College of Obstetricians and Gynecologists

I Evidence obtained from at least one properly designed randomized controlled trial. II-1 Evidence obtained from well-designed controlled trials without randomization. II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group. II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories: Level A—Recommendations are based on good and consistent scientific evidence. Level B—Recommendations are based on limited or inconsistent scientific evidence. Level C—Recommendations are based primarily on consensus and expert opinion.	**409 12th Street, SW, PO Box 96920** **Washington, DC 20090-6920** 12345/98765 Emergency contraception. ACOG Practice Bulletin No. 69. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005; 106:1443–52.

Rep Souza

Pharmacist: Why I won't sell 'Plan B'

By SHAWNE K. WICKHAM
Sunday News Staff

A pharmacist who refused to dispense emergency contraception to a woman last September because of his personal beliefs no longer works at the Brooks Pharmacy in Laconia.

Todd Sklencar told the Sunday News he left that job in October and now works at Wal-Mart in Rochester. He said Wal-Mart pharmacies do not stock the "Plan B" product, an elevated dose of birth control often called the "morning-after pill" because it can prevent pregnancy when taken within several days of unprotected sex.

And Sklencar said that makes Wal-Mart "a better fit" for him. "It's nice to not have it be an issue."

Emergency contraception is becoming more of an issue around the country, as other pharmacists do what Sklencar did. Their objection is based on the possibility that the medication, if taken after an egg already has been fertilized, can prevent implantation.

And that's what Sklencar told a woman when she asked him to fill her prescription for the drug last fall, he said.

"I was taught that life begins at fertilization," he told the Sunday News yesterday. "When an egg is fertilized by the sperm, life begins at fertilization, and this product will end that life so I can't dispense it."

"I said one sentence, and I tried to back out of it a couple times. I never mentioned ethical, I never mentioned moral, I never mentioned religion."

"I was taught that life begins at fertilization. When an egg is fertilized by the sperm, life begins at fertilization, and this product will end that life so I can't dispense it."

TODD SKLENCAR
pharmacist

Sklencar said press reports about the incident failed to note that he offered to transfer the woman's prescription to another pharmacy just a few miles away. "It was refused twice."

Instead, he said the woman came back later that same night with her father and again tried to get him to fill the prescription. "They wanted to force the issue, force me to do this."

Sklencar said his employer at the time, Brooks pharmacy in Laconia, backed him "behind the scenes," but "not publicly."

Sklencar said the store did make "an accommodation" for him, allowing him to refer any requests for the Plan B prescription to another pharmacist on duty. But he said he felt he was "being targeted" after the publicity surrounding the September incident: "As in, somebody that wanted to do this while I was on duty would come in and test it."

Sklencar said he would like the State Board of Pharmacy to adopt some sort of "conscience clause" that would allow pharmacists to follow their personal beliefs in such matters.

And that would be especially important, he said, now that the Legislature has approved a program that will allow women of all ages to obtain Plan B directly from participating pharmacists without having to first get a prescription from a doctor.

Sklencar said he wishes the Legislature had set some age limits for the program. And he would like to see the medical information that accompanies the medication explain the biological process involved. "The company promotes it as not ending a pregnancy, and I guess by the current definitions that would be true."

But he said, "Somewhere between fertilization and implantation, if that life has started, this product would end that life, and the person that picks up the emergency contraception should be made aware of that."

Attachment #6

Public hearings part of rule-making process

Pill

Continued From Page A1

fore they join the program.

And that process will likely put off the program until next year.

Unresolved issues

Paul Boisseau, executive secretary for the State Board of Pharmacy, called the language of SB 30 "very vague." He wants the Attorney General's office to clarify some legal issues before his board begins the rule-making process.

Among them:

- Can the board establish minimum age or parental notification requirements?
- What legal obligations does a participating pharmacist have to notify officials if a woman reports being the victim of a rape?
- What liability does a pharmacist have for a possible adverse outcome after dispensing ECPs?
- Can the board include a "conscience clause" so a pharmacist could refuse to dispense the medicine to a customer for ethical reasons?

Medical experts say emergency contraception, which works by preventing ovulation, fertilization or implantation of a fertilized egg, can work within five days after unprotected sex but is most effective when taken as early as possible. That is what is driving states to allow programs like the New Hampshire Legislature just approved.

Boisseau said the board of pharmacy will take up the issue at its next meeting on June 15; he plans to contact other states with successful programs to see what has worked elsewhere.

Maine is the only other Eastern state with such a program; laws also have passed in Alaska, California, Hawaii, New Mexico and Washington.

The New Hampshire Legislature passed a similar measure last year, but then-Gov. Craig Benson vetoed it.

Legislative intent

Sen. Lou D'Allesandro, D-Manchester, who sponsored SB 30, told the Sunday News he does not believe the board of pharmacy can include in its rules an age limit or parental consent clause, even for the youngest children. He said the legislative intent is clear.

When the measure came before the House last Wednesday, a floor amendment to limit the program to women 18 and older, and require parental consent for younger teens, failed by a 141-225 vote.

"They tried to amend the bill so that those parameters could be put in but they were rejected," D'Allesandro said.

Ann Larney, chief of the civil bureau for the state Attorney General's office, told the Sunday News on Friday that the legislative history of the measure would be "an important factor" her office would consider in advising the pharmacy board.

"The Legislature is the policy maker, and the agencies ... are there to carry out the policy that is contained in the law," she said.

"The purpose of a rule is to implement and interpret the statute, not to add or subtract from it."

Lynch spokesperson Pamela Walsh also said the House action makes legislative intent clear. "I would think if the Legislature has considered something and rejected it, it would be hard to write administrative rules that contradict legislative intent."

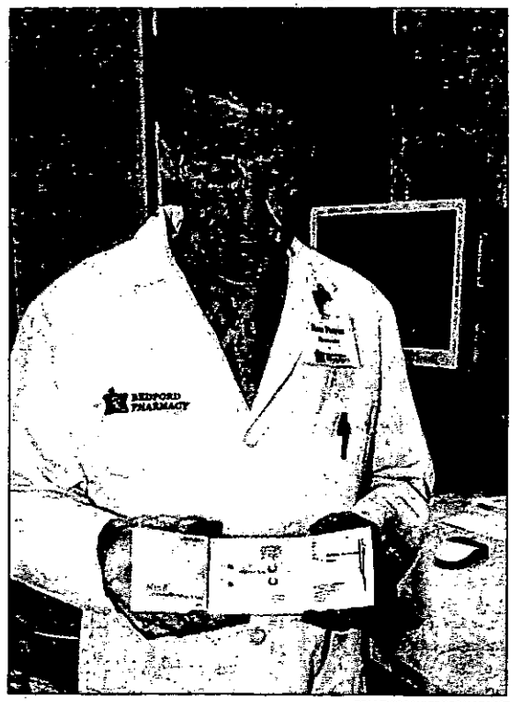
Limits for young girls

Asked if the governor personally favors any age limit at all for such a program, Walsh said, "He believes families should talk about this issue and he hopes that they do, but that you can't legislate family communication."

"We don't have an age limit on selling other forms of birth control, like condoms," she added.

However, a young girl would have to see a medical practitioner to get a prescription for birth control pills. The new emergency contraception program puts the burden on the pharmacist for dispensing the higher dosage of the pills.

And that makes some pharmacists uneasy.



TOM THIBEAULT/UNION LEADER

Ronald L. Petrin, owner of Bedford Pharmacy, holds a pack of Plan B pills. He serves on the state board of pharmacy, which is charged with drafting rules for a program to allow women to obtain emergency contraception like Plan B from a pharmacist without a doctor's prescription.

Pharmacist misgivings

Ken Gillis, owner of Ken's Pharmacy in Manchester, said he would like to see the board draft rules that contain an age limit. "If I had my say, I would prefer not to dispense it to minors without permission from their parents," he said.

"Children are precious," Gillis said. "You don't want to take care of someone else's child or do something to someone else's child without the permission of their parents."

Boisseau said he understands such misgivings. "It's difficult. What's the age that you really question this? When do you really have a concern or a moral obligation that you just can't continue without doing a parental notification?"

"So without having a minimum age requirement I think it'll make it very difficult to develop rules that pharmacists would be somewhat comfortable with," Boisseau said.

Don Messina, president of the New Hampshire Pharmacists Association, said he would like the board to include what's known as a "conscience clause" in its rules, allowing a pharmacist to refuse to dispense ECPs to someone if he has a moral or ethical objection. "It gives us an option to say yes or no," he said.

The organization Pharmacists for Life International, which opposes emergency contraception and labels it "chemical abortion," has been pushing for states to adopt conscience clauses, to allow practitioners to exercise their own moral judgment in such matters.

Making choices

But D'Allesandro stressed that while participation in the emergency contraception program in New Hampshire will be voluntary, once a pharmacist agrees to participate, he cannot decline to offer the medication to certain customers. If someone has a moral concern about dispensing to minors, for instance, "Then the pharmacist shouldn't participate, because there is no age limit in the bill."

Gillis expects some pharmacists will in fact choose not to participate. "I suppose that's a way out: If you don't want to dispense it or be forced to dispense it to a minor, you just don't dispense it to anybody."

But Messina said pharmacists make ethical choices all the time in everyday practice. And he believes that's how the emergency contraception program will work as well.

"I think each individual case is going to warrant consideration," he said.

"They can tell us OK, that's going to be the situation and spell it out and all the rest of it. But when it comes right down to the situation, I think the pharmacist is going to be able to make a good judgment call as to yea or nay."

A community asset

Ron Petrin is the owner of Bedford Pharmacy and one of five pharmacists who serve on the state board. He said he hasn't made up his mind, but leans toward not putting age limits on the program.

"Would I be comfortable with a 13-year-old? Probably not. But if a 13-year-old is having sex, it might be wiser to not get pregnant than to turn into a 13-year-old mother," he said.

Petrin sees the new program as "a good opportunity" for pharmacists. "We are one of the most readily accessible health care practitioners out there, and I think with adequate knowledge and training we can be an asset to the community, particularly with something as timely as this."

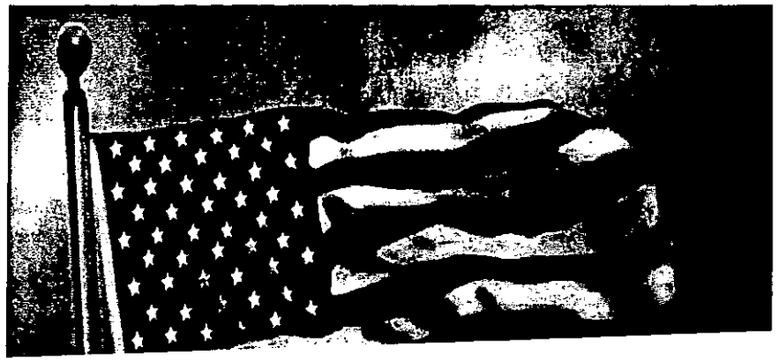
Public participation

Once the board writes its proposed rules, it will hold a public hearing. Then the rules go to the Joint Legislative Committee on Administrative Rules (JLCAR).

Any changes from the JLCAR are reviewed by the pharmacy board, and then go back to the committee for another public hearing, Boisseau said. And based on public input, "The proposed rules could be further amended."

Boisseau said the new program could be in place by the beginning of next year — but that's only if the rule-making doesn't hit a snag.

"We always say that rulemaking takes longer than getting laws passed in this state," he said. "It is a lengthy and cumbersome process."



Pharmacies' policies vary on dispensing 'Plan B' pills

By SHAWNE K. WICKHAM
Sunday News Staff

Independent pharmacists in New Hampshire can choose whether to stock and dispense emergency contraception and other medications that could raise ethical issues.

But those who work for some chain drugstores may not have a choice.

Helene Bisson, a spokesman for Brooks Pharmacy, said by company policy, "Our pharmacists cannot deny care to any patients."

She sent the Sunday News a press release issued last month that states, "Our pharmacists must ensure that patients receive their prescription needs regardless of any religious, political or moral beliefs."

The statement notes Brooks Pharmacy stores have traditionally carried the "Plan B" emergency contraception product "and will continue to provide it."

Jody Cook, spokesman for Rite Aid, which has about 40 pharmacies in New Hampshire, said the company's policy allows for pharmacists to act on their moral or ethical principles.

"The first step is they need to find another pharmacist in the store to fill the prescription. If that's not possible, they need to refer the patient to a nearby Rite Aid to have it filled. They have to work with the patient and either refer them to a nearby Rite Aid or contact another Rite Aid and have the prescription brought to their store."

And if neither of those options is feasible, the pharmacist has to refer the customer to any other nearby drugstore, Cook said.

Mike DeAngelis, manager of corporate communications for CVS, which has 27 stores in New Hampshire, also said the decision of whether to participate in such a program would be left up to an individual CVS pharmacist.

He provided the Sunday News a copy of the company's "dispensing policy," which states, "It is our policy to fill prescriptions for all legally prescribed medications."

"If a pharmacist wanted an accommodation for a sincerely held religious conviction, we would work to accommodate that pharmacist while ensuring that all customer needs are promptly and completely satisfied."

Attachment 7

SB343, February 14, 2006

We the undersigned agree with SB343 requiring parents or legal guardians to give consent before pharmacists may dispense emergency contraceptives to minors and establishing a pharmacist conscience clause which shields pharmacists refusing to fill emergency contraceptive prescriptions from civil liability and disciplinary action by the pharmacy board, without sub para (b)

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Rita Mistretta
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Helen McPhillips
Londonderry, NH

Attachment #8

federal register

Tuesday
February 25, 1997

Part V

Department of Health and Human Services

Food and Drug Administration

Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0492]

Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Commissioner of Food and Drugs (the Commissioner) has concluded that certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as postcoital emergency contraception, and requests submission of new drug applications (NDA's) for this use. This notice is intended to encourage manufacturers to make this additional contraceptive option available.

ADDRESSES: Submit NDA's to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Room, 12229 Wilkins Ave., Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa D. Rarick, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

SUPPLEMENTARY INFORMATION:

I. Background

Combined oral contraceptives, which contain an estrogen and a progestin, were first approved in the United States in 1960 and in many other countries shortly thereafter. When taken daily for 3 weeks followed by a week without medication, these drugs provide effective contraception. They have become one of the most widely employed methods of pregnancy prevention, currently used by an estimated 11 million American women. In the period since the introduction of combined oral contraceptives, the amounts of estrogen and progestin have been reduced and explicit labeling guidance for safe use has been developed in response to extensive medical research. Consequently, combined oral contraceptives are now accepted as remarkably safe and effective when used as directed. There are more than 30 brands of FDA-approved oral contraceptives on the American market that contain estrogens and progestins. These products contain estrogens and progestins in different amounts and have some differences in labeling, but all are considered to be safe and effective.

For several decades, estrogens and progestins have also been used, either separately or in combination, to prevent pregnancy in women who have unprotected intercourse as a result of rape, contraceptive failure, or lack of planning. Such drugs, when used for this purpose, are known as emergency contraceptive pills, or postcoital pills, or morning-after pills.

The best researched regimen for emergency contraceptive pills was first described in 1974 by Professor A. Albert Yuzpe of Canada (Ref. 18). The regimen consists of two tablets, each tablet containing 0.05 milligram (mg) of ethinyl estradiol and 0.50 mg of norgestrel, taken within 72 hours after unprotected intercourse; a second identical dose is to be taken 12 hours after the first dose. When used in this manner, the treatment is 75 percent effective in preventing pregnancy.

This regimen and the very similar regimens described below are widely used. The specific regimen described by Yuzpe is approved for use by the drug regulatory agencies of the United Kingdom, Germany, Sweden, Switzerland, and New Zealand. The approved products used in this regimen contain ethinyl estradiol and, as the progestin, either norgestrel or levonorgestrel.

The Yuzpe regimen and similar regimens have been used extensively in the United States in the last two decades, even though no products are approved and labeled for this use. The drugs are prescribed by hospital emergency rooms, reproductive health clinics, and university health centers. They are also prescribed, although less widely, by physicians in private practice. On February 14, 1996, the Reproductive Health Technologies Project established a hotline number (1-800-584-9911) to inform women about this contraceptive method and about providers in their local area.

Since the United Kingdom approved emergency contraceptive pills in 1984, more than 4 million prescriptions have been recorded. However, the actual use is much greater because providers have found it less expensive to provide tablets of identical drugs taken from products packaged as combined oral contraceptives. The use of combined oral contraceptives for emergency contraception in the United States can only be estimated because they are not approved for this indication, but the results of a Kaiser Family Foundation survey reported at the June 28, 1996, meeting of FDA's Advisory Committee for Reproductive Health Drugs (the Advisory Committee) suggest that approximately 225,000 American women have used the method. A further indication of the extent of use is that over 25,000 calls were made to the hotline number (cited above) in the first 5 months of operation.

In November 1994, the Center for Reproductive Law & Policy filed a citizen petition asking FDA to require manufacturers of certain combined oral contraceptive products to amend their labeling and patient package inserts to include information regarding the use of these products for postcoital emergency contraception. Although FDA indicated that it had the authority to require that certain conditions of use be included in a product's labeling, it declined to exercise its discretion in this case to require the relabeling of these products for emergency contraception, and denied the petition. However, the agency decided to present the issue of the safety and effectiveness of combined oral contraceptives for postcoital emergency use to the Advisory Committee. The Advisory Committee met on June 28, 1996, to consider this issue and unanimously concluded that the four regimens below are safe and effective for postcoital emergency contraception. For the reasons described in section II. below, FDA agrees with this conclusion.

The four regimens for postcoital emergency contraception are as follows:

(1) For tablets that contain 0.05 mg of ethinyl estradiol and 0.50 mg of norgestrel, take 2 tablets within 72 hours after unprotected intercourse, then take 2 more tablets 12 hours after the first dose;

(2) For tablets that contain 0.03 mg of ethinyl estradiol and 0.30 mg of norgestrel, take 4 tablets within 72 hours after unprotected intercourse, then take 4 more tablets 12 hours after the first dose;

(3) For tablets that contain 0.03 mg of ethinyl estradiol and 0.15 of levonorgestrel, take 4 tablets within 72 hours after unprotected intercourse, then take 4 more tablets 12 hours after the first dose; and

(4) For tablets that contain 0.03 mg of ethinyl estradiol and 0.125 mg of levonorgestrel, take 4 tablets within 72 hours after unprotected intercourse, then take 4 more tablets 12 hours after the first dose.

The appendix to this notice provides information concerning the use of emergency contraceptive pills that might be useful to sponsors in drafting

physician and patient labeling for these products for this use.

II. Discussion

A. Safety

Experience with the approved products in Europe and New Zealand has demonstrated the regimens to be safe. At the Advisory Committee's June 28, 1996, meeting, Elizabeth Barden presented information from the British Medicines Control Agency that only six serious adverse reactions associated with these products for this use were reported to it from 1984 to 1996. Of these, only one occurred close enough to the time of administration to indicate that the reaction might be drug related.

Emergency contraceptive pills are not effective if the woman is pregnant; they act by delaying or inhibiting ovulation, and/or altering tubal transport of sperm and/or ova (thereby inhibiting fertilization), and/or altering the endometrium (thereby inhibiting implantation). Studies of combined oral contraceptives inadvertently taken early in pregnancy have not shown that the drugs have an adverse effect on the fetus, and warnings concerning such effects were removed from labeling several years ago. There is, therefore, no evidence that these drugs, taken in smaller total doses for a short period of time for emergency contraception, will have an adverse effect on an established pregnancy.

B. Effectiveness

There are numerous published articles that support the effectiveness of oral contraceptive pills for emergency use (Refs. 1, 3, 4, 7 through 14, 16 and 18 through 21). In 1996, Trussell, Ellertson, and Stewart reported a meta-analysis of 10 published articles on clinical trials of emergency contraceptive pills in which the number of pregnancies among women with regular menstrual cycles who used emergency contraception was compared to the expected number of pregnancies based on the cycle day of intercourse and published estimates of conception probabilities by cycle day (Ref. 9). Defining effectiveness as the percent reduction in the likelihood of pregnancy occurring, the authors found a range of effectiveness of 55.3 percent to 94.2 percent, with an average effectiveness of 74.0 percent. In other words, if 100 women have unprotected intercourse once during the second or third week of their menstrual cycle, about 8 will become pregnant, but if the same women use emergency contraception after intercourse, only 2 will become pregnant.

III. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bagshaw, S. N., D. Edwards, and A. K. Tucker, "Ethinyl Oestradiol and D-Norgestrel Is an Effective Emergency Postcoital Contraceptive: A Report of Its Use in 1,200 Patients in a Family Planning Clinic," *Australian and New Zealand Journal of Obstetrics and Gynecology*, 28:137-140, 1988.

2. Delbanco, S., "1995 Kaiser Family Foundation Surveys on Emergency Contraceptive Pills: Knowledge and Attitudes among American Adults and Obstetrician/Gynecologists," Testimony before the FDA Reproductive Health Drugs Advisory Committee, June 28, 1996.

3. Fasoli, M., F. Parazzini, G. Cecchetti, and C. La Vecchia, "Post-coital Contraception: An Overview of Published Studies," *Contraception*, 39:459-468, 1989.

4. Glasier, A., "Postcoital Contraception," *Reproductive Medicine Review*, 2:75-84, 1993.

5. Glasier, A., et al., "Mifepristone (RU486) Compared with High-Dose Estrogen and Progestogen for Postcoidal Emergency Contraception," *New England Journal of Medicine*, 327:1041-1044, 1992.

6. Haspels, A. A., and M. R. Van Santen, "New Aspects in Post-coital Contraception," in "Future Aspects in Contraception," edited by B. Runnebaum, T. Rabe, and L. Kiesel, MTP Press Limited, Boston, 1985.

7. Ho, P. C., and M. S. W. Kwan, "A Prospective Randomized Comparison of Levonorgestrel with the Yuzpe Regimen in Post-coital Contraception," *Human Reproduction*, 8:389-392, 1993.

8. Percival-Smith, R. K. L., and B. Abercrombie, "Postcoital Contraception with dl-Norgestrel/Ethinyl Estradiol Combination: Six Years Experience in a Student Medical Clinic," *Contraception*, 36:287-293, 1987.

9. Trussell, J., C. Ellertson, and F. Stewart, "The Effectiveness of the Yuzpe Regimen of Emergency Contraception," *Family Planning Perspectives*, 28:58-87, 1996.

10. Trussell, J., and F. Stewart, "The Effectiveness of Postcoital Hormonal Contraception," *Family Planning Perspectives*, 24:262-264, 1992.

11. Trussell, J., et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, 24:269-273, 1992.

12. Tully, B., "Postcoital Contraception—A Study," *British Journal of Family Planning*, 8:119-124, 1983.

13. Van Look, P. F. A., and H. von Hertzen, "Emergency Contraception," *British Medical Bulletin*, 49:158-170, 1993.

14. Van Santen, M. R., and A. Haspels, "Interception II: Postcoital Low-Dose Estrogens and Norgestrel Combination in 633 Women," *Contraception*, 31:275-293, 1985.

15. Webb, A., "Safety and Medical Contraindications," in "The Provision of Emergency Hormonal Contraception," edited by D. Paintin, ch. 4, RCOG Press, London, 1995.

16. Webb, A., J. Russell, and M. Elstein, "Comparison of Yuzpe Regimen, Danazol, and Mifepristone (RU486) in Oral Postcoital Contraception," *British Medical Journal*, 305:927-931, 1992.

17. Webb, A., and D. Taberner, "Clotting Factors After Emergency Contraception," *Advances in Contraception*, 9:75-82, 1993.

18. Yuzpe, A. A., et al., "Post Coital Contraception—A Pilot Study," *Journal of Reproductive Medicine*, 13:53-58, 1974.

19. Yuzpe, A. A., R. Percival Smith, and A. Rademaker, "A Multicenter Clinical Investigation Employing Ethinyl Estradiol Combined With dl-Norgestrel as a Postcoital Contraceptive Agent," *Fertility and Sterility*, 37:508-513, 1982.

20. Yuzpe, A. A., and W. J. Lancee, "Ethinylestradiol and dl-Norgestrel as a Postcoital Contraceptive," *Fertility and Sterility*, 28:932-936, 1977.

21. Zuliani, G., U. F. Colombo, and R. Molla, "Hormonal Postcoital Contraception with an Ethinylestradiol-Norgestrel Combination and Two Danazol Regimens," *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 37:253-260, 1990.

IV. Conclusions

The Commissioner has concluded that combined oral contraceptives, taken initially within 72 hours of unprotected intercourse and providing a total of 0.10 or 0.12 mg of ethinyl estradiol and 0.50 or 0.60 mg of levonorgestrel in each of 2 doses separated by 12 hours, are safe and effective for use as postcoital emergency contraception. The Commissioner bases this conclusion on FDA's review of the published literature concerning this use (listed above), FDA's knowledge of the safety of combined oral contraceptives as currently labeled, and on the unanimous conclusion that these regimens are safe and effective made by the agency's Advisory Committee for Reproductive Health Drugs at its June 28, 1996, meeting. Because such combined oral contraceptives have not been labeled for this use or this dosage regimen, the Commissioner finds that these products are new drugs as defined in section 201(p)(1) and (p)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)(1) and (p)(2)). Accordingly, approved NDA's are required as a condition of marketing.

FDA is prepared to accept NDA's for combined oral contraceptives appropriately labeled for use as postcoital emergency contraception under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)) and part 314 (21 CFR part 314). Because of the publicly available safety and effectiveness data documenting the drugs' use, the safety and effectiveness requirements of § 314.50 may be met by citing the

published literature listed in the references in section III. of this document. The Commissioner advises that it is unnecessary to submit copies and reprints of the data cited in section III. of this document. Both the safety and effectiveness data upon which the Commissioner bases the above conclusions and the minutes of the Advisory Committee meeting are on file for public inspection in the Dockets Management Branch (address above). The Commissioner invites applicants to submit any other pertinent studies and literature of which they are aware.

Dated: February 20, 1997.

David A. Kessler,

Commissioner of Food and Drugs.

Appendix

Use of Emergency Contraceptive Pills (ECP's)

ECP's consist of two doses of regular birth control pills containing estrogen and progestin. Taking ECP's provides a short, strong, burst of hormone exposure. Depending on where you are in your cycle and when you had unprotected intercourse, using ECP's may prevent ovulation, disrupt fertilization, or inhibit implantation of a fertilized egg in the uterus.

How To Use ECP's

The oral contraceptive pills that can be used as ECP's are listed below. Take only one type of pill, not all of them. For example, if you use Ovral, you do not need Nordette. If you are getting your ECP's from a regular pack of birth control pills containing 28 pills (1 for every day), remember that the last 7 (green or pink) pills do not contain any hormones.

Brand Name	Pill Color	Number of pills to swallow within 72 hours after unprotected sex	Number of pills to swallow 12 hours later
Ovral	white	2	2
Lo/Ovral	white	4	4
Nordette	light orange	4	4
Levlen	light orange	4	4
Triphasil	yellow	4	4
Tri-Levlen	yellow	4	4

1. Swallow the first dose no later than 72 hours after having unprotected sex. Remember that the second dose must be taken 12 hours after the first dose. Taking the first dose at 3 p.m. would mean taking the second dose at 3 a.m. So take the first dose at a time that will make it convenient to take the second dose 12 hours later.

2. Swallow the second dose 12 hours after taking the first dose. Do not swallow any extra ECP's. More pills will probably not decrease the risk of pregnancy any further and will increase the risk of nausea.

Side Effects of ECP's

About half the women who take ECP's have temporary nausea. It is usually mild and should stop in a day or so. The risk of nausea may be reduced if you take a long-acting nonprescription antinausea medicine (such as meclizine) 30 minutes to 1 hour before taking each of the two doses of ECP's. About 20 percent of women who take ECP's vomit. If you vomit within an hour after taking either dose of ECP's, call your clinician to discuss whether to repeat that dose or to take antinausea medicine.

Before Taking ECP's

If you think you might have gotten pregnant last month, see your clinician before taking ECP's. Early pregnancy symptoms can include breast tenderness, nausea, or a previous period that was not quite normal.

If you have a serious medical problem, talk to your clinician before using ECP's.

After Taking ECP's

Your next menstrual period may start a few days earlier or later than usual. If your period does not start within 3 weeks, see your clinician for an exam and pregnancy test. If ECP's fail, or if you were already pregnant when you took ECP's, the fetus would be exposed to hormones. Studies of women who continued to take birth control pills after they unknowingly became pregnant do not show any evidence of harm to the fetus.

ECP's may not prevent an ectopic pregnancy (in the tubes or abdomen). Ectopic pregnancy is a medical emergency. In ectopic pregnancies, spotting and cramping pain usually begin shortly after the first missed menstrual period. See your clinician immediately if you experience these symptoms.

After taking ECP's, get started as soon as you possibly can with a method of birth control you will be able to use every time you have sex. ECP's are meant for one-time, emergency protection. ECP's are not as effective as other forms of birth control. If you want to start or resume use of birth control pills after taking ECP's, consult your clinician. Protect yourself from Acquired Immune Deficiency Syndrome (AIDS) and other sexual infections as well as pregnancy. Use condoms every time you have sex if you think you may be at risk.

Source: Adapted (with permission) from Trussell, J., F. Stewart, F. Guest, and R. A. Hatcher, "Emergency Contraceptive Pills: A Simple Proposal To Reduce Unintended Pregnancies," *Family Planning Perspectives*, 24:269–273, 1992.

[FR Doc. 97–4663 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

Attachment 9

Planned Parenthood® of Northern New England

SERVING MAINE, NEW HAMPSHIRE AND VERMONT

SB 343 an act relative to emergency contraception

Position: OPPOSE – PARENTAL CONSENT
Committee: Senate Health & Human Services
Hearing Date: February 14, 2006
Contact: Dawn Touzin, Public Affairs Director

This bill would require parents or legal guardians to give consent before pharmacists may dispense emergency contraceptives to minors.

SB 343 would prevent or delay many teens from accessing emergency contraception, a form of hormonal birth control that can prevent unwanted pregnancy and abortion.

EMERGENCY CONTRACEPTION IS RECOGNIZED AS A SAFE AND EFFECTIVE METHOD OF PREVENTING PREGNANCY

Based on the *"FDA's review..., the FDA's knowledge of the safety of combined oral contraceptives currently labeled, and on the unanimous conclusion that these regimens are safe and effective made by the agency's Advisory Committee for Reproductive Health Drugs at its June 28, 1996, meeting"* emergency contraception is considered an acceptable oral contraceptive by the Department of Health & Human Services.

Federal Register/ Vol. 62, No. 37/ Tuesday, February 25, 1997/ Notices
http://opa.osophs.dhhs.gov/titlex/pis/opa97-2_attach2.pdf
DHHS letter to Regional Health Administrators, April 23, 1997
http://opa.osophs.dhhs.gov/titlex/pis/opa97-2.pdf

EMERGENCY CONTRACEPTION WILL NOT HARM AN EXISTING PREGNANCY

*"**Emergency contraceptive pills are not effective if the woman is pregnant**...*
Studies of combined oral contraceptives inadvertently taken early in pregnancy have not shown that the drugs have an adverse effect on the fetus, and warnings concerning such effects were removed from labeling several years ago. ***There is, therefore, no evidence that these drugs, taken in smaller total doses for a short period of time for emergency contraception, will have an adverse effect on an established pregnancy.***"

Federal Register/ Vol. 62, No. 37/ Tuesday, February 25, 1997/ Notices
http://opa.osophs.dhhs.gov/titlex/pis/opa97-2_attach2.pdf

WIDESPREAD USE AND AVAILABILITY OF EMERGENCY CONTRACEPTION COULD PREVENT MORE THAN HALF OF ALL UNINTENDED PREGNANCIES AND ABORTIONS IN THE U.S.

Forty-three million, or 7 in 10 women of reproductive age, are sexually active and do not want to become pregnant. Yet nearly half of America's six million annual pregnancies are accidental; and half of them are terminated by an abortion.

In 2000, an estimated 840,000 U.S. teenage women aged 15-19 became pregnant. At least three-quarters were unintended.

Widespread use of emergency contraception could potentially prevent an estimated 1.5 million unintended pregnancies and 800,000 abortions each year. In 2000, an estimated 51,000 abortions were prevented through the use of emergency contraception; moreover, ECPs were responsible for approximately 43 percent of the decrease in total abortions between 1994 and 2000.

ACCESS TO EMERGENCY CONTRACEPTION IN COULD PREVENT UNWANTED TEEN PREGNANCIES IN NEW HAMPSHIRE

In 2003, the latest year for which NH DHHS shows statistics, there were 825 teenage births. (NH DHHS. Health Statistics & Data Management) **Emergency contraception, according to the FDA, is 75% effective if taken within 72 hours after unprotected sex.**

EMERGENCY CONTRACEPTION DOES NOT INCREASE OR PROMOTE SEXUAL ACTIVITY

Studies have found that EC does not hasten the onset of sex. Does not increase the frequency of sexual intercourse. Does not increase the number of sexual partners. Does not increase the likelihood of unprotected sex

Douglas Kirby, The National Campaign to Prevent Teen Pregnancy, *Emerging Answers: Research Findings on Programs to Reduce Teen Pregnancy*, at 95 (2001)
Melanie Gold et al., *The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors*, 17 J. Pediatric & Adolescent Gynecology 87, 91-95 (2004)

EC does prevent teen pregnancies and the serious negative health consequences and impact on teens' lives.

Teenage girls have a higher risk of pregnancy complications and are less likely to obtain prenatal care.
Stephanie J. Ventura & Sally C. Curtin, *Recent Trends in Teen Births in the United States*, STAT. BULLETIN – Metropolitan Life Ins. Company, Jan. 1, 1999, at 1

STATE AND FEDERAL LAW DESIGNATE CIRCUMSTANCES WHERE MINORS MUST HAVE CONFIDENTIAL ACCESS TO HEALTH CARE SERVICES

Under current New Hampshire Law:

Mature minors can consent to medical care.

Any minor who is mature enough to understand the nature and consequences of the proposed medical or surgical treatment may consent.

Any minor over the age of 13 can consent to STD services.

Any minor over the age of 11 can get treatment for alcohol and/or drug abuse.

RSA 318-B:12-a, RSA 141-C:18

Under Federal Law:

Title X requires that services be provided to adolescents regardless of ability to pay. Under Title X, written consent of parents or guardians for the provision of services to minors may not be required prior to rendering service. Nor can parents or guardians be notified after a minor has requested and received family planning services.

The Program Guidelines for Project Grants for Family Planning Services (January 2001)
http://opa.osophs.dhhs.gov/titlex/2001guidelines/2001_ofp_guidelines_complete.pdf

Medicaid also requires that family planning services be provided on a confidential basis to sexually active minors who desire them.

THESE LAWS AND POLICIES ARE RECOGNITION ON THE PART OF LAWMAKERS THAT WHILE PARENTAL INVOLVEMENT IS DESIRABLE, MANY MINORS WILL NOT SEEK SERVICES THEY NEED IF THEY HAVE TO TELL THEIR PARENTS.

This recognition by lawmakers that mandating parental notification will have ultimately negative consequences was verified by a recent study published in the Journal of the American Medical Association.

[Note: this study focused on the affect of parental notification on teens accessing prescription contraceptives from family planning clinics. There have not been studies of the affect of parental notification or parental consent on teens accessing emergency contraception. However, because the effectiveness of emergency contraception is dependent upon the timeliness in which it is taken, any mandates that cause a teen to avoid or delay access to EC will result in teenage pregnancies that could have been avoided.]

The survey asked 1526 female adolescents, in 33 states, from May 2003 to Feb 2004, if their parent/ legal guardian knew they were seeking birth control or other sexual health services, and how they would react if parents/ legal guardians were told in writing when teenagers receive prescription birth control.

The good news:

60% of parents were aware that their teen was accessing sexual health services even without a parental notification requirement.

Further, younger teenagers were more likely to have parents that knew of the visit.

The bad news:

Of the 40% whose parents did not know were accessing sexual health services,
70% said they would not attempt to access those same sexual health services if parental notification was required.

Instead:

63% would use condoms or some other OTC method
19.5% would use the rhythm method, or withdrawal
9.2% would use no method of birth control
Only 7.6% would stop having sex.

Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception
JAMA, January 19, 2005 – Vol 293, No. 3 pp 340-348

The concern that mandated parental notification would place teens at greater risk for unintended pregnancy and STDs is also supported by research showing that after an Illinois county began requiring parental involvement for minors seeking contraceptive services, the proportion of births to teenagers younger than 19 years in the county increased while it decreased in nearby counties that had similar racial and economic profiles. Zavodny M. Fertility and parental consent for minors to receive contraceptives. Am J Public Health. 2004;94:1347-1351.

ACCORDING TO THE INTENT OF THE LEGISLATURE WHEN IT PASSED SB 30 LAST YEAR, THE NH PHARMACY BOARD AND NH PHARMACY COMMUNITY HAVE SUCCESSFULLY IMPLEMENTED EC COLLABORATIVE PRACTICE

The Emergency Contraception Collaborative Practice bill, SB 30, was passed by this legislature (in the Senate on March 31, 2005, and in the House on May 25, 2005) with an effective date of August 15, 2005. Since that time, the NH Board of Pharmacy developed regulations under which the program has been implemented.

Already, 143 pharmacists (16% of those in relevant practice settings) have been trained in the program, in two education sessions conducted this past December. These sessions were developed and presented through a coalition effort by the NH Board of Pharmacy, NH Pharmacists Association, NH Coalition Against Domestic and Sexual Violence, NH Reproductive Health Association, Naral Pro-Choice NH, and Planned Parenthood of Northern New England.

Due to the enthusiastic response from the pharmacy community, an additional training is planned for March. A 'Train the Trainer' class will also be conducted to increase the number of qualified trainers. The goal is to ensure that training programs are more accessible to pharmacists in the more rural areas where women may now find it difficult to obtain emergency contraception in a timely manner.

It is important to note that as the pharmacists' scope of practice increases when they voluntarily participate in the EC Collaborative Practice program, so do their responsibilities. As a result, a required component of the EC Collaborative Practice training curriculum includes information and role playing on domestic and sexual violence, minors, and mandatory reporting issues. This aspect of the training has been developed by the NH Coalition Against Domestic and Sexual Violence and the NH Sexual Assault Nurse Examiner Program (SANE).

Attachment #10

Planned Parenthood® of Northern New England

SERVING MAINE, NEW HAMPSHIRE AND VERMONT

SB 343 an act relative to emergency contraception

Position: OPPOSE – REFUSING TO FILL PRESCRIPTIONS
Committee: Senate Health & Human Services
Hearing Date: February 14, 2006
Contact: Dawn Touzin, Public Affairs Director

This bill also establishes a pharmacist conscience clause which shields a pharmacist refusing to fill emergency contraceptive prescriptions from civil liability and disciplinary action by the pharmacy board.

SB 343, in allowing a pharmacist to refuse to fill a lawful prescription runs counter to the NH Code of Ethics and the position of the American Pharmacists Association.
"A licensed pharmacist shall: (1) Hold the health and safety of patients to be of first consideration and render to each patient the full measure of his/her ability as an essential health practitioner." Code of Ethics Ph501.01 Standards of Conduct (b)(1)
"APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy..."
Approved by the APhA House of Delegates

SB 343 provides no protections for the patient and fails to recognize the patient's right to access lawfully prescribed medication.

SB 343 fails to recognize the medical judgment of the health care provider who prescribed the medication.

SB 343 fails to recognize the pharmacist's obligation to ensure that a patient's health and safety are protected.

SB 343 also provides no protections for employers and reduces their right to freely contract with their employees.

SB343 singles out a highly effective method of preventing unplanned pregnancies and reducing the need for abortions, a policy that discriminates against women.

Please vote "No" on SB 343

Attachment #11

NARAL
Pro-Choice New Hampshire

To: Senate Health & Human Services Committee
From: Liza Dube, NARAL Pro-Choice New Hampshire
Date: February 14, 2006
Re: SB 343

Mr. Chair and Members of the Committee:

My name is Liza Dube and I am Political Director of NARAL Pro-Choice New Hampshire. On behalf of our 2,800 members statewide, I'd like to express our opposition to SB 343. In addition to the procedural challenges presented for pharmacists by this legislation, the philosophy of both the provisions in the bill constitute poor public health policy.

Regarding the first provision in SB 343, requiring parental consent for women under 18 seeking emergency contraception with or without a prescription: Many people believe that mandatory parental involvement laws would help guarantee that young people engage in safe sex or abstain from sexual activity altogether. In truth, without confidential access to contraception, young people are more likely to engage in risky and unsafe sex, causing increased rates of unintended pregnancy and sexually transmitted diseases.

Although we believe young people should involve their parents in their decision-making about when and whether to have sex, and how to prevent unintended pregnancy and sexually transmitted diseases, we also recognize that not all families choose to discuss these issues openly.

It's important to be clear that emergency contraception (EC) is an effective final chance to prevent pregnancy *after* contraceptive failure, unprotected sex and sexual assault. It does not cause abortion, and it will not interfere with an established pregnancy. And, as you know, the New Hampshire legislature passed a law last year allowing pharmacists to *voluntarily* dispense EC, through a partnership with a licensed prescriber. In December, nearly 15% of all registered pharmacists in the state voluntarily participated in the first training held for this program.

Access to contraception that works to prevent pregnancy following sex or sexual assault is most important for young women, who are more likely to experience the conditions under which EC is indicated. In recognition of the importance of preventing unintended teen pregnancy in New Hampshire, and the potential for EC to positively affect that goal, both the New Hampshire House and Senate rejected age restrictions for pharmacy access to EC during floor debate last year.

It is also important to note New Hampshire's history of ensuring confidential health care for young women. New Hampshire law already allows young women the ability to access confidential reproductive health care. The "mature minor" provision in New Hampshire

statue currently guarantees that women deemed mature enough to understand the nature and consequences of a proposed medical or surgical treatment may consent.

Our opposition to the pharmacist refusal provision stems from a disregard for the patient seeking access to legal medication with a valid prescription; particularly because the medication in question is one used solely by women to prevent and treat conditions endured only by women.

Our primary concern, however, is that the proposed law would protect only the interests of the individual pharmacist without any consideration for the patient. Because of the time-sensitive nature of EC, refusals obstruct access to a medication used as a last resort to prevent pregnancy – a basic health care need. And, SB 343 allows pharmacists to refuse to dispense a prescription even if a woman's life or health is in danger or would be endangered by pregnancy.

As the American Public Health Association – the nation's oldest and largest public health organization – states "When a health professional has prescribed contraception, the patient must be able to obtain the contraceptive in a timely manner at [a] licensed pharmacy, without interference from those pharmacists who have personal objections to contraception. Any delay caused by such interference can endanger the patient's health by increasing the risk of unintended pregnancy or exacerbating the other medical conditions for which contraceptives are sometimes prescribed."[i] Similarly, the American Pharmaceutical Association states that if a pharmacist refuses to fill a prescription, there should be established "systems to ensure patient access to legally prescribed therapy."[ii]

When a woman and her doctor have made the decision that a prescription for birth control is in her best interest, a third party should not override that decision, without protections in place for the patient. Pharmacies have a duty to dispense and have an ethical obligation not to endanger their patients' health by withholding basic health care.

Senate bill 343 would build significant barriers to the time-sensitive contraceptive women are responsibly seeking in order to prevent unintended pregnancy, a contraceptive option that can reduce the need for abortion in our state. Please recommend inexpedient to legislate for SB 343.

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[i] American Public Health Association Policy, Ensuring that Patients are Able to Have Contraceptive Prescriptions Filled at Pharmacies, APHA Governing Council (adopted Dec. 13, 2005).

[ii] Policy adopted by the APhA House of Delegates in 1998. A spokesman for the APhA said: "A pharmacist is like any doctor, nurse or other health-care professional who has a right to have a conscience. . . . But we also support the establishment of systems by the pharmacy so that [the] patient can access their legally prescribed medication." *Pharmacists' Right to Refuse Challenged,* THE DALLAS MORNING NEWS, Apr. 1, 2004.

NARAL
Pro-Choice New Hampshire

STATEMENTS ON TEEN ACCESS TO CONFIDENTIAL CARE

American College of Obstetricians and Gynecologists: "The potential health risks to adolescents if they are unable to obtain reproductive health services are so compelling that legal barriers and deference to parental involvement should not stand in the way of needed health care for patients who request confidentiality. Therefore, laws and regulations that are unduly restrictive of adolescents' confidential access to reproductive health care should be revised." **(Access to Reproductive Health Care for Adolescents, 2003)**

Society for Adolescent Medicine: "Confidentiality protection is an essential component of health care for adolescents because it is consistent with their development of maturity and autonomy and without it, some adolescents will forgo care... Health care professionals should support effective communication between adolescents and their parents or other caretakers. Participation of parents in the health care of their adolescents should usually be encouraged, but should not be mandated... Laws that allow minors to give their own consent for all or some types of health care and that protect the confidentiality of adolescents' health care information are fundamentally necessary to allow health care professionals to provide appropriate health care to adolescents and should be maintained." **(Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine, 2004)**

American Academy of Family Physicians: "Concerns about confidentiality may discourage adolescents from seeking necessary medical care and counseling, and may create barriers to open communication between patient and physician. Protection of confidentiality is needed to appropriately address issues such as...unintended pregnancy." **(Adolescent Health Care, 2001)**

American Academy of Pediatrics: "Health care professionals have an ethical obligation to provide the best possible care and counseling to respond to the needs of their adolescent patients...This obligation includes every reasonable effort to encourage the adolescent to involve parents, whose support can, in many circumstances, increase the potential for dealing with the adolescent's problems on a continuing basis...At the time providers establish an independent relationship with adolescents as patients, the provider should make...clear to parents and adolescents [that]...confidentiality will be preserved between the adolescent patient and the provider. **(Confidentiality in Adolescent Health Care, 2004)**

American College of Physicians: "In the care of the adolescent patient, family support is important. However, this support must be balanced with confidentiality and respect for the adolescent's autonomy in health care decisions and in relationships with health care providers." **(Ethics Manual: Fourth Edition, 1998)**

American Medical Association: "Our AMA...reaffirms that confidential care for adolescents is critical to improving their health... When in the opinion of the physician, parental involvement would not be beneficial, parental consent or notification should not be a barrier to care." **(Confidential Health Services for Adolescents, 2004)**

NARAL
Pro-Choice New Hampshire

Pharmacist Refusals for Emergency Contraception Interfere With Patient's Rights to Valid Prescriptions for Legal Medication

Despite the small but vocal minority of anti-choice pharmacists supporting so-called "conscience clauses", pharmacists statewide are enthusiastically volunteering to be a part of the new collaborative practice for emergency contraception program. In December 2005, just 6 months after the passage of SB 30 (allowing pharmacists to dispense emergency contraception directly to women through voluntary partnerships with licensed prescribers), 15% of the total registered pharmacists in New Hampshire signed up to be a part of the first training weekend offered for the program.

Additionally, in July of 2005, the American Pharmacists Association, the national professional society of pharmacists with over 50,000 members nationwide, reinforced their position that policies that allow pharmacists to refuse to dispense treatments based on moral or religious convictions must also develop strategies to ensure the patient has access to the prescribed medications. They may "step away", but not "step in the way."

"Common systems that are used to balance a pharmacist's moral or religious objections and a patient's needs include staffing the pharmacy so that another pharmacist in the same pharmacy can dispense the prescription, and referring a new prescription or transferring a refill prescription to a different pharmacy...Similar to the situation where a medication is simply out of stock on any given day, if the pharmacist is unable to dispense the prescription, then the patient must be made aware of the options available to them to fulfill his or her medication needs. The pharmacist should not use their position of power to berate the patient, to share their own personal beliefs, or obstruct patient access to therapy—such as refusing to return a patient's legally valid, clinically appropriate prescription"[i]

Proposed NH legislation regarding pharmacist refusal is in direct opposition to that policy position as it focuses solely on the rights of the pharmacists without recognizing the responsibility of their role as community health care providers.

Finally, the American Public Health Association (over 50,000 members nationwide) "takes the position that the patient's health and well-being must come first in health care delivery and in the formulation of health policy. When a health professional has prescribed contraception, the patient must be able to obtain the contraceptive in a timely manner at licensed pharmacy, without interference from those pharmacists who have personal objections to contraception."[ii]

Both the APhA and the APHA agree: responsible public health policy should always recognize the rights of the patient seeking access to health care.

---

[i] Testimony of the American Pharmacists Association, Linda Garrelts Maclean, RPh, CDE; Before the Small Business Committee United States House of Representatives (July 25, 2005).

[ii] American Public Health Association Policy, Ensuring that Patients are Able to Have Contraceptive Prescriptions Filled at Pharmacies, APHA Governing Council (adopted Dec. 13, 2005).

Attachment #12

New Beginnings

Domestic Violence Support Line: 1.866.644.3574 Sexual Violence Support Line: 1.800.277.5570

February 14, 2006

Honorable Senators of the Health and Human Services Committee:

My name is Laurie Grasso Dunleavy and I am writing to you on behalf of New Beginnings – a Domestic Violence and Sexual Assault Crisis Center located in Laconia, New Hampshire. I am the Direct Service Coordinator for the agency. Part of my role is to make sure services are provided to those whose lives have been affected by domestic and sexual violence and stalking in an appropriate and effective manner. I have been with the agency for 6 years and enjoy working with survivors during their journey to a new, more peaceful life.

New Beginnings opposes SB 343.

New Beginnings Crisis Center works with survivors of all ages who have been sexually assaulted in the State of New Hampshire. National statistics show that each year 32,000 women become pregnant as a result of rape and approximately 50% of these pregnancies end in abortion. Young women experience sexual assault at some of the highest rates. Many of these young women report these crimes to law enforcement and receive services from hospitals and medical providers. Those young survivors who choose to access emergency contraception through their pharmacists will be screened and referred to hospitals and crisis centers for post-assault services. If SB 343 were to pass, the lives, health and well being of young survivors of sexual assault may be at risk. Young women who are survivors of sexual assault should not be subjected to re-victimization and withheld essential medical services that could prevent a potential pregnancy.

According to the Journal of the American Medical Association, **most young people (60%) inform a parent when they seek reproductive health services.** Twenty percent of these young people say they would **not seek** those services if parental notification were required. Seventy percent of young people who choose not to inform a parent said they would not seek prescription contraception if they were required to involve a parent.

Considering these statistics, as well as the fact that one in seven women in New Hampshire will be the victim of a sexual assault; it is of utmost importance that emergency contraceptives are available to all women in New Hampshire.

For the above reasons I hope you will find this bill Inexpedient to legislate.

Laurie Grasso Dunleavy
Advocate
New Beginnings Crisis Center
Laconia NH

Attachment #13

Diocese of Manchester
Office of Public Policy

153 Ash Street - Box 310
Manchester, NH 03105-0310
(603) 669-3100
Fax: (603) 669-0377

February 14, 2006

The Honorable André A. Martel
Chairman
Health and Human Services
Room SH100
Legislative Office Building
Concord, NH 03301

RE: SB 343

Dear Senator Martel and Committee Members:

As an authorized representative of the Roman Catholic Bishop of Manchester (the Diocese of Manchester), I write and appear today before your Committee to express the **support** of Bishop John B. McCormack and the Diocese of Manchester for the parental consent and pharmacist conscience provisions of Senate Bill 343.

The Diocese of Manchester does not support the use of any "emergency contraceptives" for minors or adults without proper testing for reasons outlined below. Having said this, in light of RSA 318:47-e, which allows the distribution of "emergency contraception" to a child less than 18 years of age without the written consent of one of the child's parents or a legal guardian of the child, the Diocese believes that SB 343 will improve a flawed statute.

The Diocese supports the parental consent and pharmacist conscience provisions of SB 343 for two specific reasons that are related to the fact that emergency contraceptives can have an abortifacient effect; i.e. they can cause abortions. First, the bill requires parental or legal guardian consent for an act that has the potential of producing an abortifacient effect. Second, the bill allows a pharmacist to refuse to comply with a request to fill a prescription for emergency contraceptives (who may object to the request on the basis of the drug's possible abortifacient effect). Both provisions in the bill are important safeguards of life and conscience.

Depending upon the ovulation phase of a woman taking emergency contraceptives, these drugs may not suppress ovulation and prevent fertilization but may prevent the implantation of an already conceived embryo. This constitutes a direct action against the life of a new human individual who is the proper subject of human rights.

Without proper ovulation phase testing of a female seeking emergency contraception, neither the female nor the pharmacist can know with adequate certainty that the drugs will not have an abortifacient effect. Simply put, emergency contraception may cause abortions.

It is also important to recognize the fundamental rights of parents in the raising of their children. Considering the importance of the decision whether to take an emergency contraceptive, as well as the circumstances which may surround that decision (for instance, the Board of Pharmacy's administrative rules on dispensing emergency contraception require the pharmacist to provide the patient with referral information for domestic violence and sexual assault), it is essential that parents have the ability to participate in this decision. This bill properly advances parental rights in this important area.

The support of the Diocese should not be misconstrued as support for the abortifacient effect that may occur in those instances where parental consent is waived pursuant to the provisions of this bill. However, to the extent that SB 343 improves on the existing law, which makes no provision for parental involvement at all, and at least partially ensures prior consent from parents or legal guardians, the Diocese supports this change. Any opportunity that this consent procedure allows for parents and legal guardians to help children take adequate measures to prevent an abortifacient effect from emergency contraception are helpful.

The Diocese also supports SB 343 because the bill protects the rights of conscience of a pharmacist who may, for sound ethical reasons, feel unable to comply with a request for a drug that may take the life of a new human individual who has been conceived but has not yet implanted in the womb of its mother. Protection of the sanctity of conscience in matters of life and death is indispensable for public policy and for securing the common good.

Because SB 343 provides some protection of parental consent and conscience with respect to the potentially life-ending drug of emergency contraception, and given that current law provides no such protection, we support SB 343 as described above. If I can be of further assistance to the Committee regarding this important matter of public policy, you may contact me at 603-624-0200 or pjcataldo@comcast.net.

Sincerely yours,

Peter J. Cataldo, Ph.D.

Lt Col Dan Hogan, USAF (Retired)
71 Watson Street, Nashua, NH 03064
Abstinence Education Advisor
Pres, Abstinence Ed. Resource Institute

Nashua HS Track&Field Pole Vault Coach, Volunteer

Phone:(603)880-8157

E-mail:flyingparson@aol.com

From A Child is Born

$35.00 U.S./$49.95 Can.

Dan Hogan's Testimony

Attachment #14

1 day

Cell division

Deep in the Fallopian tube the original cell divides, becoming two precisely identical cells.

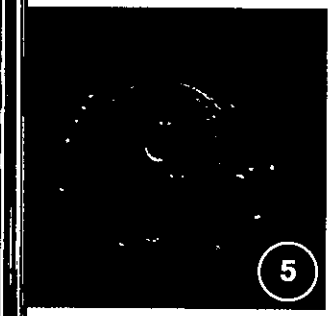
2 days

Four cells

The fertilized egg, still surrounded by nutrient cells, on its way through the Fallopian tube.

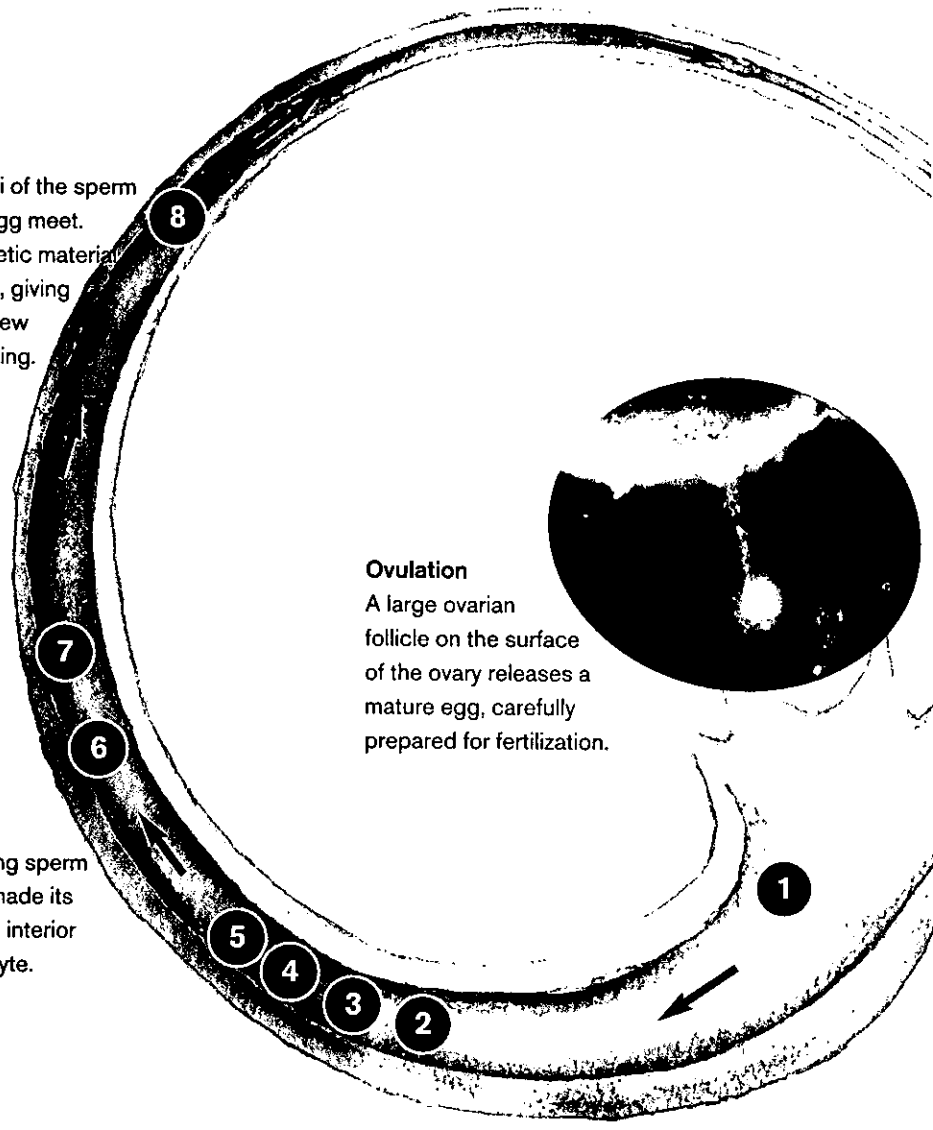
3–4 days

18 hours



Fusion

The nuclei of the sperm and the egg meet. Their genetic material combines, giving rise to a new human being.



Ovulation

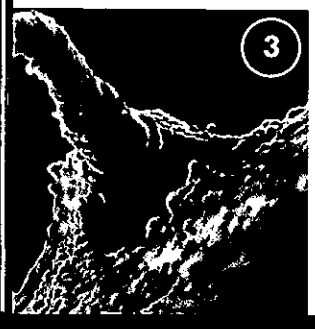
A large ovarian follicle on the surface of the ovary releases a mature egg, carefully prepared for fertilization.

10 hours

Success

The winning sperm has now made its way to the interior of the oocyte.

6 hours



Last lap

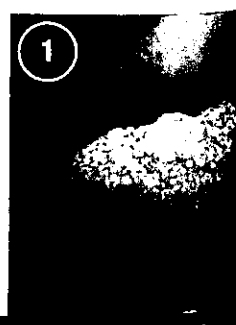
The sperm have reached the egg and are trying to penetrate the shell (right)—the winner may be visible on the left.

5 hours

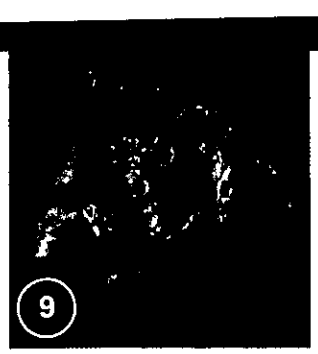
1 hour

Waiting

The egg, surrounded by nutrient cells, in the outer part of the Fallopian tube.



Expanding berry
The fertilized egg (morula) looks like a mulberry. All the cells are still the same size.

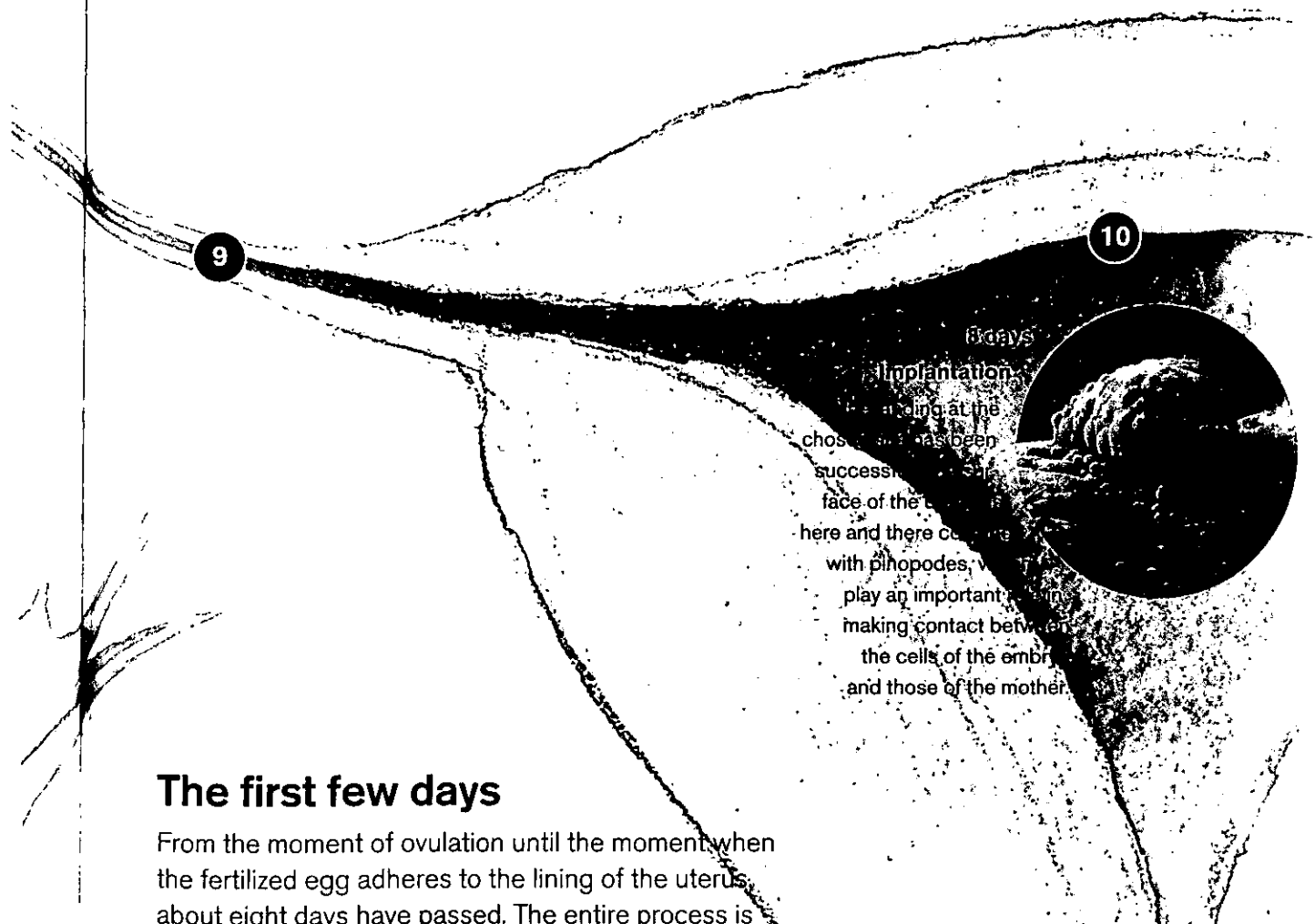


5 days

Tight squeeze
The fertilized egg navigates a narrow part of the Fallopian tube just before reaching the uterus.

In the uterus
The embryo leaves its shell and tries to adhere to the wall of the uterus.

6–7 days



The first few days

From the moment of ovulation until the moment when the fertilized egg adheres to the lining of the uterus, about eight days have passed. The entire process is completed in the wide outer reaches of the uterine tube, known as the ampulla, where the egg remains for about three days before migrating toward the uterus. Throughout the journey the fertilized egg retains its protective shell, but upon its arrival the shell must break to enable the sticky surface of the embryo to attach to the mucous membrane of the uterus.

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Pres, Abstinence Ed. Resource Institute

Nashua HS Track&Field Pole Vault Coach, Volunteer

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Analysis of operation of Attachment #15
Morning After Pill
with Dan Hogan's Testimony

Emergency Contraception By the Numbers

Conclusion:

Emergency contraception that "prevents" pregnancy will do so at least 57 percent of the time, not by pre-venting ovulation, but by preventing implantation.

Basic Facts:

1. A woman ovulates approximately once every 28 days. Therefore the chance that a woman will ovulate on any randomly selected day is 3.57 percent.
2. When a woman ovulates, the egg is able to be fertilized for 12–24 hours (1 day).
3. When sperm enters the woman's body, it remains alive and able to fertilize an egg for 1–5 days.
4. It takes emergency contraception from 12–24 hours to be effective (1 day).
5. Emergency Contraception remains effective for at least 10 days.
6. It takes a fertilized egg 5–7 days after ovulation to implant in the woman's womb.

Let us assume that a man and woman have sex on the 12th of the month (it could be any day). Let us also assume that the Emergency Contraception is taken sometime from 1-3 days after sex. Therefore, the EC is taken on the 13th, 14th or 15th. The time period of interest is 6 days—the 11th through the 17th. EC is only involved if the woman ovulated during these six days. There is a 21.4 percent chance that the woman ovulated during these six days.

Therefore,

A. In 78 percent of the cases, taking Emergency Contraception is unnecessary because the woman could not have conceived a child. Thus, EC only becomes a factor in a possible pregnancy 22 percent of the time.

B. Let's took at how EC will work during those 22-percent situations in which it becomes a factor.

i. Case one—if the woman ovulated on the 10th, the egg would die before sperm could reach it and no pregnancy would be possible. EC would have no effect.

ii. Case two—if the woman ovulated on the 11th, her egg could have been fertilized on the 12th. Taking EC will have no effect on ovulation and its only effect would be to prevent implantation on the 16th–18th. (NOTE: Under this earliest of scenarios, if EC is taken 72 hours after the sex act, it would be taken on the 15th and begin to work on the 16th. Thus, the requirement that EC be taken within 72 hours. If it is not, it will be too late to stop implantation of the fertilized egg from this earliest possible scenario.)

iii. Case three—If the woman ovulated on the 12th, her egg could have been fertilized on the 12th or 13th. Taking EC will have no effect on ovulation and its only effect would be to prevent implantation on the 17th–19th.

iv. Case four—If the woman ovulated on the 13th, her egg could have been fertilized on the 13th or 14th. Even if EC were taken on the 13th, it would not stop the ovulation. Therefore, its only effect would be to prevent implantation on the 18th–20th.

v. Case five—if the woman would have ovulated on the 14th and EC were taken on the 13th, it could stop the ovulation. If EC were taken on the 14th or 15th , its only effect would be to prevent implantation on the 19th–21st.

vi. Case six—if the woman would have ovulated on the 15th and EC were taken on the 13th or 14th, it could stop ovulation. If it were taken on the 15th, its only effect would be to prevent implantation on the 20th–22nd.

vii. Case seven—if the woman would have ovulated on the 16th and EC were taken by the 15th, it is possible that the EC could prevent ovulation.

viii. Case eight—if the woman would have ovulated on the 17th and EC were taken by the 15th, it is possible that the EC could prevent ovulation.

ix. Case nine—if the woman would have ovulated on the 18th, the sperm would already have died and EC does nothing to prevent pregnancy.

C. Thus, even under ideal conditions, it would only be possible for EC to work by preventing ovulation in:

i. zero percent of case two

ii. zero percent of case three

iii. zero percent of case four

iv. 33 percent of case five

v. 66 percent of case six

vi. 100 percent of case seven

vii. 100 percent of case eight

This means EC could possibly prevent ovulation only 43 percent of the time. Its method of "preventing pregnancy"

would be by preventing implantation at least 57 percent of the time.

D. Another look at this same data shows:

i. If EC is taken within 24 hours, there is a 57 percent chance it will prevent pregnancy by preventing ovulation.

ii. If EC is taken in 24–48 hours, there is a 43 percent chance it will prevent pregnancy by preventing ovulation.

iii. If EC is taken in 48–72 hours, there is a 29 percent chance it will prevent pregnancy by preventing ovulation.

Stated inversely:

EC TAKEN WITHIN 24 HOURS WILL "PREVENT" PREGNANCY AT LEAST 43 PERCENT OF THE TIME BY KILLING A HUMAN BEING.

EC TAKEN BETWEEN 24 AND 48 HOURS WILL "PREVENT" PREGNANCY AT LEAST 57 PERCENT OF THE TIME BY KILLING A HUMAN BEING.

EC TAKEN BETWEEN 48 AND 72 HOURS WILL "PREVENT" PREGNANCY AT LEAST 71 PERCENT OF THE TIME BY KILLING A HUMAN BEING.

E. A final, summary statement that can be supported by the facts presented is that,

Emergency Contraception that "prevents" pregnancy will do so at least 57 percent of the time, not by preventing ovulation, but by preventing implantation.

We hope this information will aid you in preparing letters-to-the-editor, talks, and getting out the truth about emergency contraception.

Denver Post Castigates PP

The following opinion piece appeared on the editorial page of the *Denver Post* on November 14, 1999.

Straw men at Planned Parenthood

By Al Knight
Denver Post Columnist

It is very common to find straw men arguments in the popular press. Straw men are, after all, easy to erect and easier still to knock down.

Yet there ought to be some limit on the reliance that an individual organization can place on this logical fallacy. A good first step would be to somehow require Planned Parenthood, one of the worst offenders, to advance better justifications for its programs and positions, justifications which at least contain an element of logic.

Two different Planned Parenthood officials last week engaged in debates over a congressionally authorized abstinence training program and, in each case, sent straw men into battle.

The abstinence program provides $50 million annually to local organizations that actually supervise the abstinence training. The program was motivated by a congressional realization that the more typical safe-sex training programs offered in public schools weren't exactly producing the desired results. The federal grants, which will run for five years, were intended to see that there is some competition between abstinence-based programs and those that might include distribution of condoms and other birth control materials.

Planned Parenthood doesn't much like the federal program and has condemned it at every opportunity. That's to be expected, but what is not to be expected is the terribly shallow way in which these condemnations are delivered.

Kate Reinisch, a spokeswoman for Planned Parenthood, was quoted in last Sunday's *Denver Post* as follows:

"How many teenagers are going to believe instruction by Congress that sex outside of marriage will make you crazy and physically harm you?" she asked. "Our fear is that many of these programs are based on religion, not public health. People will be learning fear and shame instead of responsibility. They'll be taught that a wedding ring will protect more than a condom."

That's not just a straw man. That's a battalion. Congress has not said that sex "outside of marriage" will make anyone crazy or by itself "physically harm" someone. Nor does it much matter what Planned Parenthood might fear. No evidence was offered that the abstinence programs are based on "fear and shame."

In fact, when Planned Parenthood finds it convenient, it says it favors "abstinence based" training itself. As for Reinisch's final reference to the relative protection offered by condoms and wedding rings, it must be assumed that she thinks condoms are the obvious choice.

Reinisch's comments in no way respond to the central question of whether abstinence-based instruction might be more effective with a certain age and population group than, say, the more familiar safe-sex instruction. Instead she maligns congress, maligns the abstinence instructors, maligns religion and suggests the intent of all concerned is to keep young people both ignorant and pregnant. But if Reinisch was bad, the Planned Parenthood spokeswoman who appeared

Speakers

SENATE
HEALTH & HUMAN SERVICES COMMITTEE

Date: **02/14/06** Time: 10:45 a.m. Public Hearing on **SB 343**

relative to emergency contraception

Please check box(es) that apply.

	SPEAKING	FAVOR	OPPOSED	NAME (Please print)	REPRESENTING
1.	☐	☑	☐	SEN. JOHN S. BARNES, JR.	17
2.	☑	☑	☐	Joan Espinola	Self
3.	☐	☑	☐	Patricia Kennedy	
4.	☐	☑	☐	R Ha Mistretta	
5.	☑	☑	☐	Sen. Bob Letourneau	DIST-19
6.	☐	☑	☐	Debbie Brand	Self
7.	☑	☑	☐	Helen McPhillips	Self
8.	☑	☐	☑	SAM LANGLEY	SELF
9.	☑	☒	☐	Sen. Clegg PLEASE CALL KATY Coburn	Dist 14
10.	☒	☐	☒	Sen Peter Burling	
11.	☒	☐	☒	Sen Maggie Hassan	Dist 23
12.	☒	☒	☐	Rep. Tim Eaton (Co-sponsor)	Stratford 3
13.	☒	☐	☒	DR. GARY SOBELSON	NH MEDICAL SOCIETY
14.	☑	☐	☑	Sen Odell	Dist #2 NH Adv
15.	☒	☐	☒	Barry D. Scott	
16.	☐	☐	☒	Rhonda Bowles	Child + Family Service
17.	☒	☐	☒	Dawn Touzin	Planned Parenthood
18.	☑	☐	☑	Liza Dube	NARAL Pro Choice NH
19.	☑	☐	☑	Valerie Marshall	on behalf of New Beginnings Crisis Center
20.	☐	☐	☑	Amand Brady	NHCADSV

SENATE
HEALTH & HUMAN SERVICES COMMITTEE

Date: **02/14/06** Time: 10:45 a.m. Public Hearing on **SB 343**

relative to emergency contraception

Please check box(es) that apply. SPEAKING	FAVOR	OPPOSED	*NAME (Please print)*	*REPRESENTING*
✓1. ☑	☑	☐	Peter Cataldo	Roman Catholic Bishop of Manchester
✓2. ☑	☑	☐	Rev. Tad Pacholczyk	RC Bishop of Manchester NCBC
✓3. ☑	☑	☐	Dan Hogan	Self
✓4. ☑	☑	☐	Rep Kathy Souza	
5. ☐	☐	☐		
6. ☐	☐	☐		
7. ☐	☐	☐		
8. ☐	☐	☐		
9. ☐	☐	☐		
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13. ☐	☐	☐		
14. ☐	☐	☐		
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SENATE
HEALTH & HUMAN SERVICES COMMITTEE

Date: **02/14/06** Time: 10:45 a.m. Public Hearing on **SB 343**

relative to emergency contraception

Please check box(es) that apply. SPEAKING	FAVOR	OPPOSED	*NAME (Please print)*	*REPRESENTING*
1. ☐	☐	☑	Sarah LeBoeuf	Self
2. ☐	☐	☑	Mike Smith	NH Pharmacist
3. ☒	☐	☑	Sen. Sylvia Larsen	Dist 15
4. ☑	☐	☐	Dan Hogan	Self
5. ☑	☒	☑	Sen. Martha Fuller Clark	Dist 24
6. ☐	☐	☐		
7. ☐	☐	☐		
8. ☐	☐	☐		
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SENATE
HEALTH & HUMAN SERVICES COMMITTEE

Date: **02/14/06** Time: 10:45 a.m. Public Hearing on **SB 343**

relative to emergency contraception

Please check box(es) that apply. SPEAKING	FAVOR	OPPOSED	*NAME (Please print)*	*REPRESENTING*
1. ☐	☐	☒	Rep Mary Cooney	Grafton 7
2. ☐	☐	☒	Rep Jessie L-Osborne	Concord Merrimack #12
3. ☒	☒	☐	Rep Dan Itse	Rock, Dist 9
4. ☐	☐	☒	Claire Ebel	NHCLU
5. ☐	☐	☐		
6. ☐	☐	☐		
7. ☐	☐	☐		
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Emergency Contraception Collaborative Practice

Frequently Asked Questions

LEGISLATION PROVIDING FOR COLLABORATIVE PRACTICE AGREEMENTS FOR EMERGENCY CONTRACEPTION IS IN PLACE. Participation in the program is **voluntary** between pharmacists and authorized prescribers and requires the completion of a one-time, 2-hour, live training program. The program is approved for continuing education credits. Call the Board office at (603) 271-7842 for more program information.

WHAT ARE COLLABORATIVE PRACTICE AGREEMENTS?

- Collaborative Agreements refer to the practice whereby prescribers authorize participating pharmacists to initiate emergency contraception drug therapy according to protocols.
- The partnering pharmacist and prescriber will collaborate in establishing an agreement based on rules adopted by the NH Board of Pharmacy.

WHY SHOULD PHARMACISTS PARTICIPATE IN COLLABORATIVE PRACTICE AGREEMENTS?

- Collaborative agreements provide an opportunity for expanding the scope of practice for community and institutional pharmacists.
- Current national trends indicate that increased access to health care will include more options for collaborative agreements between pharmacists and prescribers including disease state overview and medication management.

WHY COLLABORATIVE PRACTICE AGREEMENTS FOR EMERGENCY CONTRACEPTION?

- Emergency contraception (EC) is a concentrated dose of regular birth control pills that can be up to 89% effective in preventing pregnancy when taken immediately after contraceptive failure, unprotected sex, or sexual assault.
- Because of the time-sensitive nature of EC, pharmacies are an ideal access point for women who cannot get timely appointments with providers or do not have primary health care

- With few to no contraindications for taking EC, pharmacists may confidently prescribe under the authority of their partnering prescriber, and make referrals for ongoing contraceptive care.

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CHAPTER 1000 EMERGENCY CONTRACEPTION

PART Ph 1001 COLLABORATIVE PRACTICE FOR EMERGENCY CONTRACEPTION

Ph 1001.01 Collaborative Practice Authorized.

Not withstanding any other provisions of law, a licensed pharmacist who has completed the training required in Ph 1001.02 may initiate emergency contraception drug therapy in accordance with standardized, board approved procedures and protocols developed by the pharmacist and an authorized prescriber who is acting within the prescriber's scope of practice.

Ph 1001.02 Education and Training.

(a) Any pharmacist exercising prescriptive authority for emergency contraception drug therapy shall complete a minimum of 0.2 CEU's (2 didactic hours) of approved training and education prior to participating in the delivery of emergency contraception drug therapy.

(b) Programs for training and education, referenced in (a) above shall be:

1. Accredited by the Accreditation Council for Pharmacy Education (ACPE); or
2. Approved by the board of pharmacy according to Ph 403.01(b).

(c) Programs for training and education, as referenced above, must include study materials and instruction in the following content areas:

1. Mechanisms of action, contraindication, drug interaction, and monitoring of emergency contraception drug therapy;
2. Current standards for prescribing emergency contraception drug therapy;
3. Identifying indications for use of emergency contraception drug therapy;
4. Interviewing patient to establish need for emergency contraception drug therapy;
5. Counseling patient regarding the safety, efficacy and potential adverse effects of drug products for emergency contraception;
6. Evaluating patient's medical profile for drug interaction;
7. Referring patient follow-up care with primary healthcare provider;
8. Informed consent;
9. Record management;
10. Management of adverse events, including identification, appropriate response, documentation and reporting;
11. Management and response to negative public opinion; and
12. Medical/forensic implications of sexual attack.

Ph 1001.03 Emergency Contraception Collaborative Agreement.

(a) Each arrangement between a licensed pharmacist and an authorized prescriber relating to the distribution to a patient of emergency contraception drugs shall be documented in a signed collaborative agreement in accordance with form Ph EC-1, which may be obtained from the office of the board identified in Ph 103.03.

(b) By executing the collaborative agreement, both the pharmacist and the authorized prescriber agree and acknowledge that:

1. The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, and follow-up contraceptive care;

2. The collaborative agreement shall be effective for a period of two years unless rescinded in writing earlier by either the pharmacist or the authorized prescriber, with written notice to the other, or unless the board of pharmacy invalidates the agreement or changes the terms of the agreement. At the time the collaborative agreement expires or is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with an authorized prescriber is completed;

3. Each drug therapy prescription authorized by the presciber and dispensed by the pharmacist shall be documented in a patient profile.

(c) Additionally, the collaborative agreement between the licensed pharmacist and the authorized prescriber shall include:

1. The name, address, phone number and signature of the licensed pharmacist;

2. The name, address, phone number and signature of the authorized prescriber;

3. The purpose of the collaborative agreement is to permit emergency contraception drug therapy and to ensure that the patient receives appropriate information from the licensed pharmacist regarding the drug therapy;

4. The procedures to be followed by the licensed pharmacist when the patient requests drug therapy, including any applicable referrals;

5. Any limitation agreed upon by both the licensed pharmacist and the authorized prescriber including, but not limited to, approved drugs that may not be prescribed to the patient;

6. A statement that the label placed on the drug therapy product shall contain the names of both the pharmacist and the authorized prescriber of this agreement;

7. An informed consent to be used by the licensed pharmacist to inform the patient about the emergency contraception drug therapy. The informed consent shall be signed by both the licensed pharmacist and the patient on form Ph EC-2, which may be obtained from the office of the board identified in Ph 103.03;

8. A patient assessment for each patient obtaining emergency contraception drug therapy shall be completed and signed by the licensed pharmacist on form Ph EC-3, which may be obtained from the office of the board identified in Ph 103.03; and

9. The following completed forms shall be maintained for 4 years at the dispensing pharmacy where emergency contraception drug therapy was provided:

a. Collaborative Agreement (Ph EC-1) in effect during the time emergency contraception drug therapy was delivered to specific patients at that location (a copy is acceptable);

b. Informed Consent (Ph EC-2), patient specific forms; and

c. Patient Assessment (Ph EC-3) forms for each patient.

Ph 1001.04 Provision of Standardized Fact Sheet Required.

(a) For each emergency contraception drug therapy initiated pursuant to this chapter, the pharmacist shall provide the recipient of the emergency contraceptive drug with a standardized fact sheet developed by the board that includes, but is not limited to:

1. The indications for use of the drug;
2. The appropriate method for using the drug;
3. The need for medical follow-up and referral information; and
4. Information on sexual assault and referral information.

(b) A copy of the standardized fact sheet Ph EC-4 may be obtained from the office of the board identified in Ph 103.03.

Ph 1001.05 Confidentiality. Nothing in this chapter affects the provisions of law relating to maintaining the confidentiality of medical records.

Emergency Contraception: Instructions for Use

- Swallow the first dose of EC pills as soon as possible – within 120 hours – after unprotected sexual intercourse. EC works better the sooner you use it.

- If you have been told to take a second dose, swallow the second dose of EC pills **12 hours after taking the first dose.**

- For some types of EC, nausea and vomiting are possible, but not likely. If you vomit **after** 2 hours of taking your dose, do not worry. The medication is already in your system.

- If you vomit **before** 2 hours of taking your dose, the EC may not be effective. Call your pharmacist – you may need to take a repeat dose.

- If you are prescribed or advised to use a medication for possible nausea, take that medication **1 hour before** you take the first dose of EC.

- Some women may feel tired or dizzy, or may have headaches or tender breasts. These side effects should go away within a day or two. Non-prescription pain relievers (such as ibuprofen or acetaminophen) can be used for headache or breast tenderness. You may also have some menstrual spotting (small amounts of bleeding – less than a period) after taking EC. This should go away in a day or two.

- EC is not 100% effective. If you do not get your period within 3 weeks after taking EC, you may be pregnancy and need to see your health care provider or use a home pregnancy test.

- EC will not protect you from pregnancy during the remainder of your menstrual cycle. You will need to use an effective form of birth control if you have sexual intercourse again.

- Remember, EC is not as effective as other forms of birth control, and does not protect against sexually transmitted infections (STIs)or HIB. See your health care provider for a regular methof of birth control and STI testing and prevention. If you do not have a regular provider, ask the pharmacist of assistance in finding one.

You have been given: ❑ Plan B™ for emergency contraception.

❑ Oral Contraceptive Pills: (_____)

Take: ❑ 2 pills ASAP

❑ 1 pill ASAP & 1 pill in 12 hours

❑ Take ___ pill(s) ASAP and take ___ pill(s) in 12 hours

You have been given/advised to take:_____ to prevent nausea.
Take this medication 30-60 minutes before your first EC dose (as advised).

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

PHARMACIST/PRESCRIBER EC COLLABORATIVE PRACTICE PROTOCOL

As a licensed health care provider authorized to prescriber medications in the State of New Hampshire, I authorize _____, R.Ph. to initiate emergency contraceptive drug therapy according to the protocol that follows. The protocol provides written guidelines for initiating drug therapy in accordance with the laws and regulations of the State of New Hampshire.

Purpose: Provide access to emergency contraception within the required time frame and to ensure the patient receives adequate information to successfully complete therapy.

Procedure: When the patient requests emergency contraception pills (ECP's), the pharmacist will assess the need for drug therapy and/or referral for contraceptive care. The pharmacist will determine the following:

- The date of the patient's last menstrual period to rule out established pregnancy.
- That the elapsed time since unprotected intercourse is less than 72 hours (or as agreed upon by collaborators).
- Whether the victim has been a victim of sexual assault.

Referrals: If EC drug therapy services are not available at the pharmacy, the patient will, if possible, be referred to another ECP provider or to the NH Planned Parenthood website for additional ECP provider information. The pharmacist should refer the patient to a health care provider or family planning office if established pregnancy cannot be ruled out.

If there is a concern that the patient may have contracted a sexually transmitted infection through unprotected sex and/or if the patient indicates that she has been sexually assaulted, the pharmacist will provide appropriate referral information while providing ECP's.

While ECP's can be used repeatedly without serious health risks, patients who request ECP's repeatedly will be referred to a health care provider or family planning office for follow-up.

Prophylactic Provision: The pharmacist may also dispense a course of ECP's to a patient in advance of the need for emergency contraception. In addition, the pharmacist will counsel the patient on available options for regular contraceptive methods or offer to refer the patient to a health care provider for additional contraceptive services.

ECP Product Selection: The pharmacist will only dispense medication from a list of products approved for emergency contraception and agreed upon as part of this agreement. The pharmacist should seek to provide the most effective ECP product to patients. The list will contain ECP's and adjunct medications for nausea and vomiting associated with EC drug therapy. The list will be maintained at the pharmacy and shared by all participants in the agreement. Along with the medications, patients will be provided with information concerning dosing, potential adverse effects, and follow-up contraceptive care.

Documentation and Quality Assurance: Each prescription initiated by the pharmacist will be documented in a patient profile as required by law and maintained at the pharmacy. EC therapy prescriptions and other patient information shall be provided the same confidentiality as all other patient records maintained at/by the pharmacy.

The pharmacist may, at the request of the patient, communicate information to the patient's primary care provider or for purposes of being referred to a practitioner as a new patient regarding her care relevant to emergency contraception drug therapy.

On a quarterly basis, the authorizing prescriber and the pharmacist will perform a quality assurance review of the decisions made according to mutually acceptable criteria.

The pharmacist named below has completed a specified training program approved by the New Hampshire Board of Pharmacy covering procedures listed above, the management of the sensitive communications often encountered in emergency contraception and the appropriate use of referral sources.

Authorized Prescriber's Signature: _____ Date: _____

Authorized Prescriber's Printed Name: _____ NH Medical Lic. #: _____
Type or Print Full Name

Authorized Prescriber's Office Address: _____
Street Address

_____
City State Zip Code

Phone # : _____ Fax # : _____

Licensed Pharmacist's Signature: _____ Date: _____

Licensed Pharmacist's Printed Name: _____ NH Pharmacist Lic. #: _____
Type or Print Full Name

Pharmacy Address: _____
Street Address

_____
City State Zip Code

Phone # : _____ Fax # : _____

INFORMED CONSENT FOR EMERGENCY CONTRACEPTION

Name: _____ Date of Birth: ____/____/____

Before giving your consent, be sure that you understand both the pros and cons of Emergency Contraception (EC). If you have any questions, we will be happy to discuss them with you. Do not sign your name at the end of this form until you have read and understood each statement. This information is confidential.

I understand that:

- Emergency contraceptive pills contain the same medication as regular birth control pills and can help prevent pregnancy. These pills are taken after having unprotected sex (if my regular birth control fails or I have sex without birth control).
- EC is for emergency use only. It should not take the place of regular birth control methods, such as the "pill", condoms, the birth control patch or shot, etc.
- EC can work by stopping the release of an egg from the ovary (ovulation), or it may prevent the union of sperm and egg (fertilization), or it may prevent a fertilized egg from attaching to the womb (implantation). EC will not work after implantation of a fertilized egg. EC will not disrupt an established pregnancy.
- It is best to use EC within 3 days of having unprotected sex. New information shows that EC may sometimes prevent pregnancy up to five days after sex, but EC works better the sooner you use it.
- EC is not 100 percent effective.
- Reactions to the pills may include nausea, vomiting, headache, stomach pain, dizziness, breast tenderness, early or late menstrual period.
- I should see a physician if my period has not started within 3 weeks after treatment.
- I should use a regular method of birth control to prevent pregnancy if I have sex before my next period.
- EC will not protect me from or treat sexually transmitted diseases, including HIV/AIDS.

I have read and understand all of the above information. ☐ **Yes** ☐ **No**

Patient's Signature: _____ Date: _____

Pharmacist's Signature: _____ Date: _____

EC PATIENT ASSESSMENT

Name: _____ Phone #: _____

Address: _____ City: _____ State: _____ Zip: _____

Date of Birth (Month / Day / Year): _____ /_____ /_____

Please answer the following questions:

1. When was the first day of your last menstrual period? Date *(Month / Day / Year)*:

   _____ /_____ /_____

2. Did your period come on time? ☐ Yes ☐ No

3. Was it the usual number of days and the usual amount of bleeding? ☐ Yes ☐ No

4. Why do you need emergency contraception?
   - ☐ Recent unprotected sex or birth control failure
   - ☐ Future need *(If only for future need, skip to question #6)*

5. Have you had unprotected sex during the last 5 days? ☐ Yes ☐ No
   If yes, when? Date *(Month / Day / Year)*: _____ /_____ /_____

6. Are you allergic to any medications or drugs? ☐ Yes ☐ No
   If yes, please list: _____

The following advice to the patient is optional:

- EC is for emergency use only. For regular, long-term use other methods of birth control are better and more effective. You should consult your health care provider for further information.
- If you have any of the following you may have a sexually transmitted infection (STI) and should see a doctor: burning when urinating, vaginal discharge/itch, pelvic pain, partner has a STI, abnormal vaginal bleeding, or pain during sex. You should consult your health care provider or your local public health clinic as soon as possible.

FOR PHARMACIST USE ONLY:

Client provided with:	*Referral Made for?*	Additional pharmacist notes/comments:
☐ Key Facts Sheet	☐ *Contraception*	_____
☐ Consent Sheet	☐ *STI / HIV*	
☐ EC Product	☐ *Pregnancy*	_____
☐ Plan B	☐ *Primary Care*	
☐ Other _____	☐ *Sexual Assault / CPS*	_____

Date: _____ / _____ / _____ Time: _____ : _____ AM / PM (Circle One) _____, *R.Ph.*
Pharmacist's Signature

Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception if:

- You didn't use a contraceptive during sex: or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills (ECP's) contain the same medication as regular birth control pills, and help to prevent pregnancy. There are two basic types of Emergency Contraceptive pills:

- Plan B™ progestin-only pills.
- High doses of regular oral contraceptive pills.

Don't wait! Take ECP's as soon as possible.

- It is best to take ECP's within three days of unprotected sex.
- The sooner you take ECP's, the more effective they are.
- For more information talk to your pharmacist or doctor.

ECP's are safe and effective.

- Progestin-only pills reduce the risk of pregnancy by 89 percent.*
- Combined estrogen/progestin pills reduce the risk of pregnancy by 75 percent.*
- For regular, long-term use, other contraceptive methods are more effective than EC.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

** Pregnancy risk reduction based on one-time use.*

ECP's won't cause an abortion.

- Emergency Contraceptive pills are **not** the same as RU-486 (*the abortion pill*).
- Emergency Contraceptive pills are not effective after pregnancy has occurred and cannot interrupt it.

ECP's won't harm a developing fetus.

- If Emergency Contraceptive pills are taken mistakenly during pregnancy, they will not harm the developing fetus.
- Using Emergency Contraceptive pills will not effect a woman's ability to become pregnant in the future.

Women can keep pills at home in case of an emergency.

- Many women find it convenient to have Emergency Contraceptive pills on hand in case of an emergency.
- Medical providers or your pharmacist can provide Emergency Contraceptive pills before they are needed.

Medical follow-up after taking Emergency Contraceptive pills.

- If you don't experience a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic if you need a regular birth control method or information about preventing sexually transmitted infections, such as HIV/AIDS.

Referral Sources

- To find the nearest Planned Parenthood clinic, call 1-800-230-PLAN (7526)
- For domestic violence support, call 1-866-644-3574
- For sexual assault support, call 1-800-277-5570

b

New Hampshire State Profile

EC PHARMACY UPDATE

Since Governor John Lynch signed EC pharmacy access bill (**SB 30**) into law in June 2005, approximately 200 pharmacists have received training to initiate prescriptions for EC.On June 16, 2005 Governor John Lynch signed EC pharmacy access bill, **SB 30** The bill, introduced by Senator Lou D'Allesandro (D), allows pharmacists to initiate emergency contraception drug therapy under procedures approved by the State Board of Pharmacy and a physician or other prescriber. Efforts to add an amendment with an age restriction were unsuccessful. The bill went into effect on August 16, 2005, and planning for implementation has begun. On September 22, 2005, **LSR 2169** was posted by Representative Michael A Balboni (R) as it relates to parental notification of a parent or legal guardian of a child who has been provided with emergency contraception by a pharmacist.

In January 2006, Representative Balboni introduced **HB 1682** of which the companion bill, LSR 2169, was introduced last year. Also in January 2006, a similar bill **SB 343** that requires parents or legal guardians to give consent before pharmacists may dispense EC to minors, was introduced by Senator Robert Letourneau (R).

This bill was introduced in 2004 as well, passing both the Senate and the House despite unfavorable committee reports. On June 4, 2004, Governor Craig Benson vetoed SB 484, citing concern about irresponsible sexual behavior and the lack of parental notification. A veto override was unsuccessful. Click to view the **response (DOC-36K)** from Planned Parenthood Northern New England (PPNNE).

Groups testifying on behalf of the bill included PPNNE, NARAL Pro-Choice New Hampshire, the NH Reproductive Health Association, the NH Civil Liberties Union, the Board of Pharmacy, and the NH Coalition Against Domestic and Sexual Violence. NARAL Pro-Choice New Hampshire also crafted sign-on letters for pharmacists and prescribers to show support in the state. Outreach was done to gain the support of the NH Pharmacists Association representing independent pharmacists, as well as the association for chain drugstores. There was also outreach to the NH Medical Society, which has not yet taken a position on the legislation.

Jennifer Frizzell, public affairs director for Planned Parenthood of Northern New England appeared in a news radio program debating the pharmacy access bill in June 2004. To listen to the radio interview, **click here**. PPNNE also ran a radio ad (available at **www.ppnne.org**) to respond to the Governor's veto of the EC bill.

PPNNE and NARAL Pro-Choice New Hampshire worked on a number of grassroots activities to support their legislative work. Both groups encouraged their supporters to call their senators in support of SB 484. PPNNE conducted a mailing to activists, sending them postcards to send to their senators. These postcards were placed in health center waiting rooms as well. Information about the legislation was on both organizations' websites. In addition, the group encouraged editorial boards to write positive editorials about the legislation. The Reproductive Health Association planned a major educational push for providers Spring 2004, with a one-day symposium scheduled as well as other training opportunities and resources available.

In September 2004, the New Hampshire Pharmacists Association held a one-hour EC training led by Trish Jacobsen, a retired pharmacist and current women's health advocate.

The Association will be publishing a position statement on pharmacist refusal, noting that pharmacists should be able to refuse to provide a service, but that they should refer the patient to another pharmacist who can help.

A bill to permit pharmacists to initiate EC, **HB 1276**, was also introduced in the 2001 session. The bill was reported out of committee and died in 2002. HB 1276 was not reintroduced in the 2003 session because of state elections. Advocates understood from the legislature that it might have passed if it had the support of a broader coalition. The New Hampshire Pharmacists Association had not been brought into design of the legislation and was put in the position of reacting to the bill. Pharmacists expressed interest in a broader collaborative practice act that would have enabled them to offer EC as one of many products. The Pharmacists Association was uncomfortable aligning itself politically with the narrow EC issue, however some individual pharmacists were willing to move forward with collaborative practice for EC alone.

After the 2001 legislation was defeated NARAL-NH began a proactive grassroots EC Campaign to build support for EC

access. Parenthood of Northern New England (PPNNE) and NARAL-NH attended a five-state summit on pharmacy access to EC. They built bridges with pharmacists and physician groups and involved the newly reconstituted Reproductive Health Association, which has a broad membership of reproductive health professionals. PPNNE and NARAL-NH has identified pharmacists and physician groups interested in working with local legislators to support EC. PPNNE has also educated the press so they will not confuse EC with RU-486.

In the summer of 2002, pharmacists were interviewed about EC access and were asked whether they stocked EC and what concerns they had about EC collaborative practice agreements. NARAL-NH wrote follow-up letters thanking the pharmacists.

EC is offered in state-funded family planning clinics. One of the performance measures for state clinics is the percentage of women visiting clinics for specific reasons (including pregnancy tests and barrier or hormonal methods of birth control) who receive a prescription for EC. Clinics however, do not disseminate educational materials about EC.

For press coverage in this state, **click here**.

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USEFUL LINKS

New Hampshire Board of Pharmacy
www.state.nh.us/pharmacy/index.html

New Hampshire Pharmacists Association
www.state.nh.us/pharmacy/nhpamnu.htm

New Hampshire General Court

gencourt.state.nh.us/ic

New Hampshire Department of Health and Human Services
www.dhhs.state.nh.us/DHHS/MCH/fpp.htm

Planned Parenthood of Northern New England
www.ppnne.org/site/PageServer

NARAL Pro-Choice New Hampshire
www.prochoicenewhampshire.org

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PROTOCOL ENVIRONMENT

Unfriendly Environment: *New Authority Required*

In this state, no authority exists for collaborative practice agreements. Any initiative to provide direct pharmacy access to EC would require significant advocacy activity to secure statutory and/or regulatory authority.

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The state comparison information above was adapted from a study conducted by the **American Pharmacists Association** and commissioned by the **Pharmacy Access Partnership**.

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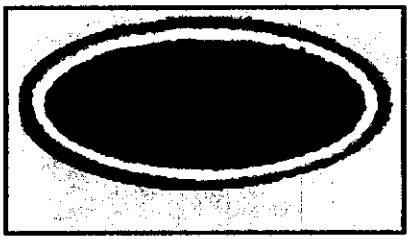
C

Plan B



- **Despite their *promise* to announce a decision on whether or not to approve Barr Laboratories application to make Plan B (a type of Emergency Contraception) over the counter (OTC) for age 16 and over by September 1, 2005, the FDA recently announced it would indefinitely delay its decision again. Read Planned Parenthood's Press Release. On August 26, 2005, the FDA acknowledged the scientific integrity of OTC status for Plan B but called for public comment regarding the implementation of OTC access with (a new) required age barrier.**

You may recall:

- **Barr's initial application in 2003 was rejected because the FDA stated they needed more information on EC use among women under 16. Thus, in 2004 Barr resubmitted their application seeking for OTC status for Plan B for users aged 16 and over. The recent announcement shows the FDA changing their tune: now they are calling for information on EC and use among people under age 17, as well as a yet-to-be scheduled public comment period, despite the fact that the FDA has already had a public comment period on the application and has logged over 17,400 letters from advocacy groups and private citizens!**

Read Related Articles

What's next:

- **Barr Laboratories will need to make some decisions as to their 'next steps'. They could choose to resubmit a slightly altered application, or they could choose to conduct more studies.**
- **At PPNNE, we will work to expand knowledge of, and access to, emergency contraception. Last year, in NH, Governor Lynch signed legislation which will expand access to EC through collaborative practice agreements. Women who need EC will soon be able to access EC through participating and trained pharmacists. See related Concord Monitor article.**
- **Remember, EC is currently available by prescription within 5 days of method failure, unprotected sex, or sexual assault. The sooner it's taken, the more effective it is in preventing pregnancy.**

2006 NH Legislation

Another January, another legislative session in NH. There are a number of bills we will actively support or oppose and some we will track to make sure they do not adversely affect our health centers or women's health and safety. Our primary focus bills involve attacks on the EC bill that was passed just last year as well as attempts to give personhood status and rights to the fetus. In addition, we are monitioring

bills that would affect Temporary Assistance for Families in Need (TANF), Medicaid, and services for minorities and immigrants.

In the very near future we will need your help! If you would be interested in attending a hearing, contacting your legislators, writing a letter to the editor, calling other PPNNE activists or sending us clippings from your local newspapers, please contact our grassroots organizer, Judy Nute, today! Please include contact information and how you would like to help.

Information on the primary focus bills we are opposing

Emergency Contraception

HB 1492 - Granting immunity from liability to any pharmacist who refuses to dispense the "morning after" pill without a prescription. **House Judiciary Committee public hearing: Feb. 14 at 10:30 in Room 208 of the Legislative Office Building (LOB).**

HB 1682 - Relative to parental notification of a parent or legal guardian of a child who has been provided with emergency contraception by a pharmacist. **House Judiciary Committee public hearing: Feb. 14 at 1:00 pm in Room 208 of the LOB.**

SB 343 - Requires parental consent before phamacists may dispense emergency contraceptives to minors; and establishes a conscience clause with immunity for refusing to fill EC prescriptions. **Senate Health and Human Services Committee public hearing: Feb. 14 at 10:45 in Room 101 of the LOB.**

Defining Life

HB 1649 - Including "unborn child" in the definition of another for the purpose of first and second degree murder, manslaughter, and negligent homicide. **House Criminal Justice public hearing was held Jan. 5.** A subcommitte will conduct further analysis of the bill and possible amendments.

HB 1665 - Creating an offense for the death of another resulting in miscarriage or stillbirth. **House Criminal Justice public hearing was held Jan. 5.** A subcommitte will conduct further analysis of the bill and make recommendations to the full committee.

HB 1719 - Defining human life as beginning at the moment of fertilization. **House Judiciary Committee public hearing: Feb. 9 at 1:00 pm in Room 208 of the LOB.**

Family Planning

HB 1710 - relative to appropriations to the department of health and human services for health care providers. This bill would restore $300,000 to family planning. **House Finance Committee public hearing was held Jan. 10.** A subcommitte will conduct further analysis of the bill and make recommendations to the full committee.

241 Elm Street
CLAREMONT, NH 03743
603.542.4568

HOURS:
Monday 9:00 - 4:00
Wednesday 12:00-6:30
Thursday 9:30 - 6:30
(Teen Walk-in Hours 2:30 - 6:30)
Friday 1:00 - 4:00

Click here for a map

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18 Low Avenue
CONCORD, NH 03301
603.225.2925

Administrative / External Affairs Office

Click here for a map

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4 Birch Street
DERRY, NH 03038
603.434.1354

HOURS:
Monday 10:00 - 6:30
Tuesday 10:00 - 6:30
Wednesday 10:00 - 6:30
(Teen Walk-in Hours 2:30 - 5:30)
Thursday 8:30 - 4:00
Friday 8:30 - 4:00
Saturday 9:00 - 12:30

Click here for a map

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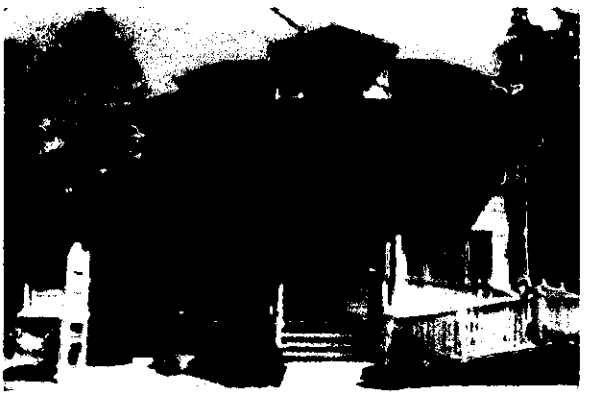
108 High Street
EXETER, NH 03833
603.772.9315

HOURS:
Monday 8:30 - 4:00
Tuesday 11:00 - 6:30
(Teen Walk-in Hours 2:00 - 5:30)
Thursday 11:00 - 6:30
One Saturday a month, by appointment only



Click here for a map

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8 Middle Street
KEENE, NH 03431
603.352.6898

HOURS:
Monday 8:00 - 5:00
Tuesday 11:00 - 6:00
Wednesday 11:00 - 6:00
Thursday 11:00 - 6:00
Friday 8:00 - 5:00

Click here for a map

8 Middle Street
KEENE, NH 03431
603.352.6898

NEW HAMPSHIRE H

HOURS:
Monday 8:00 - 5:00
Tuesday 11:00 - 6:00
Wednesday 11:00 - 6:00
Thursday 11:00 - 6:00
Friday 8:00 - 5:00
Saturday 9:00 - 1:00

Walk-in Hours:
Wednesdays 3:00 - 6:00 & Fridays 2:00 - 4:00

Click here for a map

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24 Pennacook Street
MANCHESTER, NH 03104
603.669.7321

HOURS:
Monday 8:30 - 4:30
Tuesday 8:30 - 7:00
Wednesday 8:30 - 7:00
Thursday 8:30 - 6:30
(Teen Walk-in Hours 2:30 - 6:30)
Friday 8:30 - 4:30
Saturday 8:30 - 12:00

Click here for a map

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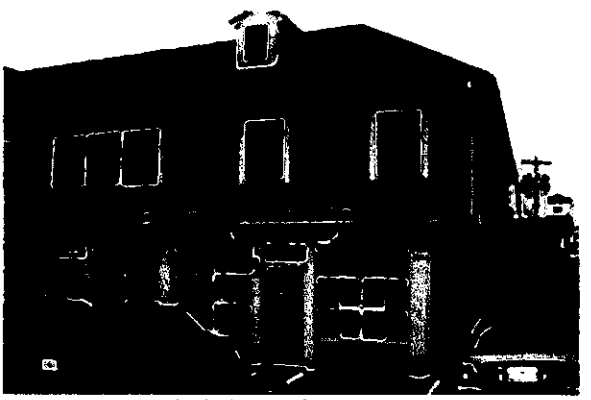
167 High Street
PORTSMOUTH, NH 03801
603.431.6803



HOURS:
Tuesday 11:00 - 6:30
Wednesday 11:00 - 6:30
(Walk-in Hours 2:00 - 5:00)
Friday 8:30 - 4:30
One Saturday a month, call for appointment

Click here for a map

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89 South Main Street
WEST LEBANON, NH 03784
603.298.7766

HOURS:
Monday 8:30 - 4:30
Tuesday 11:00 - 6:30
Wednesday 11:00 - 6:30
(Teen Walk-in Hours 2:00 - 6:00)
Thursday 8:30 - 4:30
Friday 8:30 - 4:30
Saturday 9:00 - 12:30

Click here for a map

D

I AM SUBMITTING THIS STATEMENT IN REGARD TO SB 343.

I AM OPPOSED TO THIS BILL AS INTRODUCED. MY OPION OF THE ENTIRE BILL IS NOT VERY FAVORABLE HOWEVER MY REAL CONCERN IS WITH PARAGRAPH 2 SEC. VII (LINES 25 THU 30) I FEEL THAT ANY PHARMACIST WHO IS UNWILLING TO PROFORM ALL FUCTIONS OF HIS JOB SHOULD SEEK A NEW JOB. NO PERSONS HEALTH SHOULD BE ENDANGERED DUE TO THE PERSONAL FEELINGS OF ANY PHARMACIST. THE ONLY TWO EXCEPTIONS TO THIS IS (A) IF ANOUTHER PHARMACIST IN ON DUTY AT THE SAME TIME AND LOCATION WHO WILL FILL THE PER-CRIPTION OR (B) IF THE PHARMACIST KNOWS THAT THE MEDICATION WILL REACT DANGEROUSLY WITH ANOTHER MEDICATION THE PERSON IS TAKEING. IF THIS SECTION IS TAKEN OUT OF THE BILL I WILL TAKE NO PERSITION ON THE BILL, OTHERWISE I OPOSE IT.

THANK YOU

SAM LANGLEY 27 PUSTON DR.
BOSCAWEN PHONE 796617

Voting Sheets

Senate Health and Human Services Committee

EXECUTIVE SESSION

Bill # SB 343

Hearing date: February 14, 2006 **Room:** LOB 101
Executive session date: March 7, 2006
Motion of: ITL **VOTE:** 3-3

Made by Senator:			***Seconded by Senator:***		
	Martel	☐		Martel	☐
	Kenney	☐		Kenney	☐
	Gallus	☑		Gallus	☐
	Bragdon	☐		Bragdon	☐
	Estabrook	☐		Estabrook	☑
	Fuller Clark	☐		Fuller Clark	☐

Committee Member	***Present***	***Vote***	***Reported out by***
Senator Martel, Chairman	☑	N	✓
Senator Kenney	☑	N	
Senator Gallus	☑	Y	
Senator Bragdon	☑	N	
Senator Estabrook	☑	Y	
Senator Fuller Clark	☑	Y	

***Amendments:**

NOTES:

Committee Report

STATE OF NEW HAMPSHIRE

SENATE

REPORT OF THE COMMITTEE

Date: March 7, 2006

THE COMMITTEE ON Health and Human Services

to which was referred Senate Bill 343

AN ACT relative to emergency contraception.

Having considered the same, the committee recommends that the Bill:

IS INEXPEDIENT TO LEGISLATE

BY A VOTE OF: 3-3

AMENDMENT # {Type 4-digits here}s

Senator Andre A. Martel
For the Committee

Pamela Manocchi 271-3207

SB343 Docket

Next|Prev|Results List|Main|Bill Status

Bill Title: relative to emergency contraception.

Date	Body	Description
1/4/2006	S	Introduced and Referred to Health and Human Services; SJ 1, Pg.12
1/4/2006	S	Hearing; February 14, 2006, Room 101, LOB, 10:45 a.m.; SC1
2/9/2006	S	Hearing; === ROOM CHANGE === February 14, 2006, Room 100, State House, 10:45 a.m.; SC6
3/8/2006	S	Committee Report; Inexpedient to Legislate [03/16/06]; SC10
3/16/2006	S	Inexpedient to Legislate, RC 14Y-10N, MA === BILL KILLED ===; SJ 8, Pg.191

Next|Prev|Results List|Main|Bill Status

Docket Abbreviations

Other Referrals

COMMITTEE REPORT FILE INVENTORY

SB343 ORIGINAL REFERRAL _____ RE-REFERRAL

1. THIS INVENTORY IS TO BE SIGNED BY THE COMMITTEE SECRETARY AND PLACED INSIDE THE FOLDER AS THE FIRST ITEM IN THE COMMITTEE FILE.
2. PLACE ALL DOCUMENTS IN THE FOLDER FOLLOWING THE INVENTORY IN THE ORDER LISTED.
3. THE DOCUMENTS WHICH HAVE AN "X" BESIDE THEM ARE CONFIRMED AS BEING IN THE FOLDER.
4. THE COMMITTEE SECRETARY WILL CONFIRM ALL ENTRIES CHECKED AND SIGN THIS INVENTORY.
5. THE COMPLETED FILE IS THEN DELIVERED TO THE CALENDAR CLERK.

✓ **DOCKET (Submit only the latest docket found in Bill Status)**

✓ **COMMITTEE REPORT (For calendar and floor)**

✓ **HEARING REPORT (Written summary of hearing testimony, if produced)**

✓ **HEARING TRANSCRIPT (Verbatim transcript of hearing)**
List attachments (testimony and submissions which are part of the transcript) by number [1 thru 4 or 1, 2, 3, 4] here: 1-15

✓ **SIGN-UP SHEET**

ALL AMENDMENTS (passed or not) CONSIDERED BY COMMITTEE:

____ - AMENDMENT # _____ ____ - AMENDMENT # _____
____ - AMENDMENT # _____ ____ - AMENDMENT # _____

ALL AVAILABLE VERSIONS OF THE BILL:

✓ AS INTRODUCED ____ AS AMENDED BY THE HOUSE
____ FINAL VERSION ____ AS AMENDED BY THE SENATE

✓ **PREPARED TESTIMONY AND OTHER SUBMISSIONS (Which are not part of the transcript)**
List by letter [a thru g or a, b, c, d] here: A - D

✓ **EXECUTIVE SESSION REPORT**

____ **OTHER (Anything else deemed important but not listed above):**

IF YOU HAVE A RE-REFERRED BILL, YOU ARE GOING TO MAKE UP A NEW FILE FOLDER WITH THE CHAIRMAN'S COPY OF THE BILL AND THE LATEST DOCKET AND KEEP THOSE FILES IN YOUR OFFICE. PLEASE KEEP YOUR MASTER SHEET CURRENT AS YOU CLOSE OUT YOUR FILES AND PROVIDE THE SECRETARIAL SUPERVISOR WITH A COPY WHEN COMPLETED.

DATE DELIVERED TO SENATE CLERK 6-23-06 Pamela Marcuk
COMMITTEE SECRETARY

SENCLK 09/04 (REV 5)