12/01/97	3056829	Trinordiol
12/01/97	3058001-4	Triphasil-28
6/18/01	3741376-8	Nordette-21
7/17/04	4412805-1	Nordette-21
2/2/06	4902505-3	Nordette-21
2/28/03	4065974-X	
11/30/99	3416111-3	Triphasil-28
6/30/00	3	
12/29/00	3640160-3	Triphasil-21
1/25/01	3656040-3	Mirena
3/26/01	3700957-8	Levlite
6/18/01	3741376-8	Nordette-21
8/21/01	3781552-1	Mirena
9/20/01	3796431-3	Alesse-28
8/09/02	3961641-9	Levlite-21
8/15/02	3964208-1	Triquilar
2/20/03	4061279-1	Mirena
3/05/03	4071425-1	Microgynon
11/03/03	4226802-2	Tridiol-28
12/02/03	4245542-7	Mirena
5/21/04	4363772-0	Nordette-21
6/17/04	4382494-3	Mirena
9/27/04	4462728-7	Levlen
2/28/05	4596309-1	
4/04/05	4628502-3	Trinordiol
6/03/05	4686111-4	Alesse-28
7/29/05	4734121-0	Seasonale
8/10/05	4743529-9	Levora-28
3/22/06	4954000-3	Mirena
4/10/06	4975478-5	Mirena
7/20/06	5060812-0	Seasonale
8/17/06	5086087-4	Trinodiol
8/30/06	5095100-X	Plan b
7/21/06	5058172-4	Trinovum
11/21/06	5161338-6	Mirena
4/25/07	5314285-0	Seasonale
5/29/07	5337347-0	Mirena
7/23/07	5399025-1	Seasonale
11/12/99	3396782-0	Nordette

Levonorgestrel

(FDA - more cases are being recorded)

10/5/2001	3810911-3	Uterine rupture	Mirena	22
1/7/2002	3849708-7	Uterine rupture	Mirena	26
1/7/2002	3849709-9	Uterine rupture	Mirena	
1/7/2002	3849711-7	Uterine rupture	Mirena	
4/2/2002	3896625-2	Uterine rupture	Mirena	22
4/2/2002	3896630-6	Uterine rupture	Mirena	27
4/2/2002	3896633-1	Uterine rupture	Mirena	37
4/2/2002	3896635-5	Uterine rupture	Mirena	34
7/5/2002	3988713-7	Uterine rupture	Mirena	
10/7/2002	4011784-9	Uterine rupture	Mirena	32
10/7/2002	4011785-0	Uterine rupture	Mirena	35
10/7/2002	4011786-2	Uterine rupture	Mirena	40
10/7/2002	4011789-8	Uterine rupture	Mirena	
10/7/2002	4011790-4	Uterine rupture	Mirena	
10/7/2002	4011792-8	Uterine rupture	Mirena	
10/7/2002	4011845-4	Uterine rupture	Mirena	
10/7/2002	4011846-6	Uterine rupture	Mirena	24
10/7/2002	4114540-6	Uterine rupture	Mirena	
10/7/2002	4011850-8	Uterine rupture	Mirena	
10/7/2002	4011851-X	Uterine rupture	Mirena	
10/7/2002	4011853-3	Uterine rupture	Mirena	
10/7/2002	4011855-7	Uterine rupture	Mirena	
5/20/2003	4114540-6	Uterine rupture	Mirena	25
5/28/2003	4119350-1	Uterine rupture	Mirena	
11/29/1997	3002759-7	Blindness	Trigoa	25
11/26/1997	3002759-7	Renal Artery-Blindness	Trigoa	
2/4/1998	3040177-6	Cerebrovascular-Blind	Nordette-28	29
2/25/1998	3036909-3	Cerebrovascular-Blind	Nordette-28	28
4/21/1998	3065844-X	Blindness	Norplant	18
8/17/2001	378037-2	Blindness	Alesse-28	21
9/9/2002	3974077-1	Blindness	Mirena	40
7/1/2003	4140637-0	Blindness	Microgyno	48
11/3/2003	4226800-9	Blindness	Mirena	22
1/23/2004	4303313-7	Blindness	Mirena	46
3/5/2004	4318867-4	Blindness	Alesse-28	51
4/20/2004	4345337-X	Blindness	Alesse-28	
11/12/2004	4503181-4	Blindness	Nordette-28	17
12/2/2004	4519404-1	Blindness	Levonova	32
12/30/2004	4544258-7	Blindness	Microval	42
2/23/2005	4594822-4	Blindness	Mirena	42
3/21/2005	4616743-0	Blindness	Mirena	
4/7/2005	4631509-3	Blindness		42
6/14/2005	4692274-7	Blindness	Microval	42
5/16/2005	4664826-1	Blindness	Mirena	
6/28/2005	4704285-3	Blindness	Mirena	27
7/8/2005	4711193-0	Blindness	Mirena	27
8/24/2005	47534662-4	Blindness	Trinordiol	37
8/29/2005	4757247-4	Blindness	Trinordiol	37
10/20/2005	4807821-1	Blindness	Trinordiol	35
10/20/2005	4808026-0	Blindness		35
2/3/2006	4905825-1	Blindness	Mirena	

Levonorgestrel

2/28/2006	4930117-4	Blindness	Mirena	40
3/8/2006	4941330-4	Blindness	Mirena	38
3/16/2000	4950874-0	Blindness	Mirena	42
3/29/2006	4961617-9	Renal Artery-Blindness		
4/12/2006	4977413-2	Blindness	Mini-ovral-21	25
4/25/2006	4988256-8	Blindness	Mini-ovral-21	25
6/28/2006	5043057-X	Blindness	Mirena	
10/30/2006	5143233-1	Disability-Blind	Neogentrol	22
11/21/2006	5162086-9	Blindness	Neogentrol	22
7/27/2007	5399461-3	Blindness	Mirena	23

10/5/2001	3810911-3	Uterine rupture	Mirena	22
1/7/2002	3849708-7	Uterine rupture	Mirena	26
1/7/2002	3849709-9	Uterine rupture	Mirena	
1/7/2002	3849711-7	Uterine rupture	Mirena	
4/2/2002	3896625-2	Uterine rupture	Mirena	22
4/2/2002	3896630-6	Uterine rupture	Mirena	27
4/2/2002	3896633-1	Uterine rupture	Mirena	37
4/2/2002	3896635-5	Uterine rupture	Mirena	34
7/5/2002	3988713-7	Uterine rupture	Mirena	
10/7/2002	4011784-9	Uterine rupture	Mirena	32
10/7/2002	4011785-0	Uterine rupture	Mirena	35
10/7/2002	4011786-2	Uterine rupture	Mirena	40
10/7/2002	4011789-8	Uterine rupture	Mirena	
10/7/2002	4011790-4	Uterine rupture	Mirena	
10/7/2002	4011792-8	Uterine rupture	Mirena	
10/7/2002	4011845-4	Uterine rupture	Mirena	
10/7/2002	4011846-6	Uterine rupture	Mirena	24
10/7/2002	4114540-6	Uterine rupture	Mirena	
10/7/2002	4011850-8	Uterine rupture	Mirena	
10/7/2002	4011851-X	Uterine rupture	Mirena	
10/7/2002	4011853-3	Uterine rupture	Mirena	
10/7/2002	4011855-7	Uterine rupture	Mirena	
5/20/2003	4114540-6	Uterine rupture	Mirena	25
5/28/2003	4119350-1	Uterine rupture	Mirena	
11/29/1997	3002759-7	Blindness	Trigoa	25
11/26/1997	3002759-7	Renal Artery-Blindness	Trigoa	
2/4/1998	3040177-6	Cerebrovascular-Blind	Nordette-28	29
2/25/1998	3036909-3	Cerebrovascular-Blind	Nordette-28	28
4/21/1998	3065844-X	Blindness	Norplant	18
8/17/2001	378037-2	Blindness	Alesse-28	21
9/9/2002	3974077-1	Blindness	Mirena	40
7/1/2003	4140637-0	Blindness	Microgyno	48
11/3/2003	4226800-9	Blindness	Mirena	22
1/23/2004	4303313-7	Blindness	Mirena	46
3/5/2004	4318867-4	Blindness	Alesse-28	51
4/20/2004	4345337-X	Blindness	Alesse-28	
11/12/2004	4503181-4	Blindness	Nordette-28	17
12/2/2004	4519404-1	Blindness	Levonova	32
12/30/2004	4544258-7	Blindness	Microval	42
2/23/2005	4594822-4	Blindness	Mirena	42
3/21/2005	4616743-0	Blindness	Mirena	
4/7/2005	4631509-3	Blindness		42
6/14/2005	4692274-7	Blindness	Microval	42
5/16/2005	4664826-1	Blindness	Mirena	
6/28/2005	4704285-3	Blindness	Mirena	27
7/8/2005	4711193-0	Blindness	Mirena	27
8/24/2005	47534662-4	Blindness	Trinordiol	37
8/29/2005	4757247-4	Blindness	Trinordiol	37
10/20/2005	4807821-1	Blindness	Trinordiol	35
10/20/2005	4808026-0	Blindness		35
2/3/2006	4905825-1	Blindness	Mirena	

Levonorgestrel

2/28/2006	4930117-4	Blindness	Mirena	40
3/8/2006	4941330-4	Blindness	Mirena	38
3/16/2000	4950874-0	Blindness	Mirena	42
3/29/2006	4961617-9	Renal Artery-Blindness		
4/12/2006	4977413-2	Blindness	Mini-ovral-21	25
4/25/2006	4988256-8	Blindness	Mini-ovral-21	25
6/28/2006	5043057-X	Blindness	Mirena	
10/30/2006	5143233-1	Disability-Blind	Neogentrol	22
11/21/2006	5162086-9	Blindness	Neogentrol	22
7/27/2007	5399461-3	Blindness	Mirena	23

12/1/1997	3058004-X	Triphasil-28	Pulmonary Embolism	
12/17/1997	3011767-1	Tri Levlen	Pulmonary Embolism	21
1/27/1998	3092371-6	Alesse	Pulmonary Embolism	38
2/6/1998	3110645-7	Norplant	Ectopic	18
2/6/1998	3110645-7	Norplant	Ectopic	26
2/6/1998	3119326-7	Norplant	Ectopic	19
2/6/1998	3119794-0	Norplant	Ectopic	30
2/6/1998	3120219-X	Norplant	Ectopic	34
2/6/1998	3120230-9	Norplant	Ectopic	33
2/6/1998	3122909-1	Norplant	Ectopic	26
2/6/1998	3122913-3	Norplant	Ectopic	21
2/6/1998	3122916-9	Norplant	Ectopic	27
2/6/1998	3122921-2	Norplant	Ectopic	37
2/6/1998	3122920-0	Norplant	Ectopic	27
2/6/1998	3122923-6	Norplant	Ectopic	
2/6/1998	3123983-9	Norplant	Ectopic	34
2/24/1998	3120340-6	Norplant	Ectopic	26
3/6/1998	3043939-4	Norplant	Ectopic	35
6/19/1998	3096813-1	Norplant	Ectopic	
7/3/1998	3112441-3	Norplant	Ectopic	
7/8/1998	3103241-9	Norplant	Ectopic	19
8/12/1998	3116969-1	Norplant	Ectopic	37
8/21/1998	3120149-3	Norplant	Ectopic	37
10/15/1998	3143524-X	Norplant	Ectopic	29
4/23/1999	3245978-7	Norplant	Ectopic	26
4/29/1999	3250006-3	Norplant	Ectopic	19
5/13/1999	3261246-1	Norplant	Ectopic	23
6/8/1999	3278037-8		Ectopic	
6/14/1999	3282670-7	Norplant	Ectopic	19
6/23/1999	3289826-8			23
6/30/1999	3295104-3	Norplant	Ectopic	39
3/19/2003	4078643-7	Mirena	Ectopic	
3/19/2003	4079085-0	Levonell-2	Ectopic	22
3/26/2003	4084226-5		Ectopic	35
4/7/2003	4102614-5	Mirena	Ectopic	22
4/7/2003	4102617-0		Ectopic	23
4/7/2003	4102621-2	Mirena	Ectopic	
4/7/2003	4102637-6	Mirena	Ectopic	
4/18/2003	4098438-8	Levonell-2	Ectopic	39
4/21/2003	4099584-5		Ectopic	35
5/23/2003	4116850-5	Postinor-2	Ectopic	34
5/23/2003	4116880-3	Postinor-2	Ectopic	19
5/23/2003	4116881-5	Postinor-2	Ectopic	34
5/23/2003	4116892-X	Postinor-2	Ectopic	20
5/23/2003	4116893-1	Levonell-2	Ectopic	18
5/29/2003	4120381-6	Levonell-2	Ectopic	15
5/29/2003	4120452-4	Levonell-2	Ectopic	15
7/8/2003	4145069-7	Mirena	Ectopic	31
7/16/2003	4150560-9	Levonell-2	Ectopic	35
8/19/2003	4174717-0	Mirena	Ectopic	38
8/28/2003	4181339-4	similar Plan b	Ectopic	

Levonorgestrel

8/13/2007 5412700-5	Mirena	Ectopic	37
8/14/2007 5414340-0	Mirena	Ectopic	
8/14/2007 5414344-8	Mirena	Ectopic	35
2/2/2002 3873965-4	Mirena	Ectopic	
2/28/2002 3877342-1	Levonell-2	Ectopic	20
4/2/2002 3896625-2	Mirena	Ectopic	
4/2/2002 3896628-8	Mirena	Ectopic	30
4/2/2002 3896630-6	Mirena	Ectopic	27
4/2/2002 3896633-1	Mirena	Ectopic	27
4/2/2002 3896635-5	Mirena	Ectopic	34
4/4/2002 3896143-1	Postinor-2	Ectopic	34
5/2/2002 3911763-3	Mirena	Ectopic	34
8/20/2002 3965210-6	Mirena	Ectopic	32
8/21/2002 3966451-4	Mirena	Ectopic	32
10/7/2002 4011787-4	Mirena	Ectopic	
12/24/2002 4035344-9	Mirena	Ectopic	23
12/24/2002 4035347-4	Mirena	Ectopic	33
5/31/2001 3731599-6	Levonell-2	Ectopic	19
11/27/2001 3831699-6	Levonell-2	Ectopic	19
11/27/2001 3831700-X	Levonell-2	Ectopic	19
11/30/2001 3833289-8	Levonell-2	Ectopic	20
2/28/2001 3877342-1	Levonell-2	Ectopic	20
9/11/2001 3974444-6	Levonell-2	Ectopic	29
9/11/2002 3974465-3	Levonell-2	Ectopic	38
3/7/2003 4072621-X	Levonell-2	Ectopic	28
3/7/2003 4072625-7	Levonell-2	Ectopic	26
3/19/2003 4079085-0	Levonell-2	Ectopic	32
4/8/2003 4098438-8	Levonell-2	Ectopic	39
5/23/2003 4116893-1	Levonell-2	Ectopic-cystectomy	18
5/29/2003 4120452-4	Levonell-2	Ectopic	15
7/6/2003 4150460-9	Levonell-2	Ectopic	35
2/12/2004 4295472-X	Levonell-2	Ectopic	22
11/27/2001 3831699-6	Postinor-2	Ectopic	19
11/29/2001 3844159-3	Postinor-2	Ectopic	34
4/4/2002 3896143-1	Postinor-2	Ectopic	26
9/11/2002 3974488-4	Postinor-2	Ectopic	26
10/9/2002 3991046-6	Postinor-2	Ectopic	26
5/23/2003 4116850-5	Postinor-2	Ectopic	34
5/23/2003 4116881-5	Postinor-2	Ectopic	34
5/23/2003 4116892-X	Postinor-2	Ectopic	20
4/20/2004 4345050-9	Plan b	Ectopic	35
3/2/2001 3688557-X	Plan b	Ectopic	35
4/20/2004 4345056-X	Plan b	Ectopic	26
4/13/2005 4635478-1	Nordette-21	Ectopic	34
7/13/2000 3538271-6	Plan b	Ectopic	
8/4/2000 3542945-0	Plan b	Ectopic	27
1/2/2001 3640939-8	Plan b	Ectopic	34
8/28/2003 4182227-X	similar Plan b	Ectopic	
9/29/2003 4201989-6	similar Plan b	Ectopic	26
4/9/2001 3701868-4	Plan b	Ectopic	
5/31/2001 3731596-0	Plan b	Ectopic	
8/8/2003 4181339-4	similar Plan b	Ectopic	
9/2/2005 4764187-3	Plan b	Ectopic	28
5/10/2006 4999818-6	Plan b	Ectopic	27

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
N. C. VITAL RECORDS

CERTIFICATE OF DEATH

Registration District No. 06045 Local No. 200600 3714

DECEDENT

DECEDENT'S NAME (First, Middle, Last)			SEX	DATE OF DEATH (Month, Day, Year)
1. NIKITA	D	SMOUTHERSON	2. F	3. August 10, 2006

SOCIAL SECURITY NUMBER	AGE—Last Birthday (Years)	UNDER 1 YEAR: Months / Days	UNDER 1 DAY: Hours / Minutes	DATE OF BIRTH (Month, Day, Year)	BIRTHPLACE (City and State or Foreign Country)
4. 581-94-5037	5. 30	5b.	5c.	6. May 24, 1976	7. Washinton DC

WAS DECEDENT EVER IN U.S. ARMED FORCES? (Yes or No)	8a. PLACE OF DEATH (Check only one)
8. No	HOSPITAL: ☐ Inpatient ☒ ER/Outpatient ☐ DOA OTHER: ☐ Nursing Home ☐ Residence ☐ Other (Specify)

FACILITY NAME (If not institution, give street and number)	CITY, TOWN, OR LOCATION OF DEATH	INSIDE CITY LIMITS? (Yes or No)	COUNTY OF DEATH
9b. CMC -UNIVERSITY	9c. Charlotte	9d. Yes	9e. Mecklenburg Co.

MARITAL STATUS—Married, Never Married, Widowed, Divorced (Specify)	SURVIVING SPOUSE (If wife, give maiden name)	DECEDENT'S USUAL OCCUPATION (Give kind of work done during most of working life. Do not use retired.)	KIND OF BUSINESS/INDUSTRY
10. Divorced	11.	12a. Park Entertainer	12b. Amusement Park

RESIDENCE—STATE	COUNTY	CITY, TOWN, OR LOCATION	STREET AND NUMBER
13a. NC	13b. Mecklenburg	13c. Charlotte	13d. 6630 Pinta Court

INSIDE CITY LIMITS? (Yes or No)	ZIP CODE	Was Decedent of Hispanic Origin? (Specify Yes or No. If yes, specify Cuban, Mexican, Puerto Rican, etc.)	RACE—American Indian, Black, White, Etc. (Specify)	DECEDENT'S EDUCATION (Specify only highest grade completed) Elementary/Secondary (0-12) College (13-17+)
13e. Yes	13f. 28227	14. ☐ Yes ☒ No (Specify)	15. Blk	16. 17+

PARENTS

FATHER'S NAME (First, Middle, Last)	MOTHER'S NAME (First, Middle, Maiden Surname)
17. Klevin Stouffer	18. Sheila Moody

INFORMANT

INFORMANT'S NAME (Type/Print)	MAILING ADDRESS (Street or Rural Route Number, City or Town, State, Zip Code)	DATE AMENDED
19a. Sheila Moody	19b. 753 Chris Dr, Mooresville, NC 28082	19c.

CAUSE OF DEATH

Part I. Enter the diseases, injuries, or complications that caused the death. Do not enter the mode of dying, such as cardiac or respiratory arrest, shock or heart failure. If appropriate, enter tobacco, alcohol, or drug use. List only one cause on each line. (PRINT or TYPE)

		Approximate Interval Between Onset and Death
IMMEDIATE CAUSE (Final disease or condition resulting in death)	a. Pulmonary Emboli — DUE TO (OR AS A CONSEQUENCE OF):	
Sequentially list conditions if any, leading to immediate cause. Enter UNDERLYING CAUSE (Disease or injury that initiated events resulting in death) LAST.	b. Oral Contraceptive Use — DUE TO (OR AS A CONSEQUENCE OF):	
20a.	c. — DUE TO (OR AS A CONSEQUENCE OF):	
	d.	

Part II. Other significant conditions contributing to death but not resulting in the underlying cause given in Part I, such as tobacco, alcohol, or drug use; diabetes, etc.

20b.

AUTOPSY? (Yes or No)	If yes, were findings considered in determining cause of death?	Was case referred to Medical Examiner? (Yes or No)	TIME OF DEATH
21a.	21b.	21c.	22. M.

NOTICE: STATE LAW REQUIRES THAT ALL DEATHS DUE TO TRAUMA, ACCIDENT, HOMICIDE, SUICIDE, OR UNDER SUSPICIOUS, UNUSUAL OR UNNATURAL CIRCUMSTANCES BE REPORTED TO, AND CERTIFIED BY A MEDICAL EXAMINER-ON A MEDICAL EXAMINER'S CERTIFICATE OF DEATH. ANY DEATH FALLING INTO THESE CATEGORIES IS WITHIN THE MEDICAL EXAMINER'S JURISDICTION REGARDLESS OF THE LENGTH OF SURVIVAL FOLLOWING THE UNDERLYING INJURY.

CERTIFIER

SIGNATURE AND TITLE OF CERTIFIER	DATE SIGNED (Month, Day, Year)
23a.	23b. 08/28/2006

NAME AND ADDRESS OF PERSON WHO COMPLETED CAUSE OF DEATH (ITEM 20) (Type or Print)

24. C Dutton r.D. P.O. Box 560727 Charlotte, NC 28256

DISPOSITION

METHOD OF DISPOSITION	PLACE OF DISPOSITION (Name of cemetery, crematory, or other place)	LOCATION — City or Town, State, Zip Code
X ☐ Burial ☐ Cremation ☐ Removal 25a. ☐ Donation ☐ Other	25b. Rutherford Park Cemetery	25c. Concord, NC

NAME AND ADDRESS OF FUNERAL HOME	NAME OF FUNERAL DIRECTOR	LICENSE NUMBER
26a. Bryant Lytle Young/Mooresville, NC	26b. W. H. Bryant	26c. 1890

REGISTRAR'S SIGNATURE	DATE FILED (Month, Day, Year)	NAME OF EMBALMER	LICENSE NUMBER
27. Earl Nunez Mabry MD VR	28. AUG 30 2006	29d. W. H. Bryant	29e. 1079

DHHS 1872 (Revised 3/03 Review 3/08) VITAL RECORDS

UNOFFICIAL

over

Contentions Rise over the "Morning after Pill"

KEENE – The Keene Planned Parenthood office was one of seven Northern New England Planned Parenthood facilities in New Hampshire that gave away free Plan B emergency contraception on Wednesday December 6. Three Free EC signs were displayed at the Planned Parenthood office at 8 Middle St. in Keene. Protesters against Planned Parenthood gathered outside the office to demonstrate their concerns regarding the safety the Plan B pill.

Wednesday evening, the Respect Life Committee sponsored a discussion about the dangers of birth control pills and emergency contraception at the Clairvaux Center in downtown Keene. The event was well attended and the audience included students from Keene State College. The discussion featured two guest speakers, Ebony Moody from Washington D.C., and Dr. Jonathan Abel, a board certified family medicine doctor from Massachusetts.

Ms. Moody spoke concerning the August 2006 death of her sister, Niki Moody, from a pulmonary embolism, which was directly attributed to the oral contraceptive Lo Ovral. Niki Moody was a college graduate and a young mother, who had only begun using the oral contraceptive three weeks prior to her death. A FDA Freedom of Information Report Selected for Ethinyl and Lo Ovral details 34,980 adverse cases reported to the FDA since 1997. This FDA report covers only oral contraceptives, such as Lo Ovral, which contain the hormone Ethinyl estradiol.

Following Ms. Moody's heartbreaking story, Dr. Abel gave a talk called, "What Happened to Plan A?" He gave an introduction to oral contraceptives and spoke about the health risks associated with oral contraceptives and the emergency contraception Plan B. Dr. Abel stressed that oral contraceptives are not necessary in family planning, since safe alternatives exist. In addition, Dr. Abel pointed out that emergency contraception can cause a chemical abortion, which many women taking Plan B may not know. Dr. Abel's informative presentation led into an animated question and answer period.

Jack Laurent, a former New Hampshire state representative, presented additional information regarding a parental abortion notification bill, which passed the N.H. state legislature and was signed into law by former Governor Craig Benson. The bill has been challenged by Planned Parenthood as unconstitutional and Mr. Laurent states that the bill will most likely be repealed. Mr. Laurent also discussed an emergency contraception bill, Senate Bill 30, which was passed into state law in June 2005. This law makes New Hampshire a "pharmaceutical collaborative" state (with eight other states) and allows a nurse or pharmacist to dispense emergency contraception with no age restrictions for minors. According to www.GO2EC.org, approximately 200 pharmacists in N.H. have received training to initiate prescriptions for emergency contraception. Emergency contraception is covered by Medicaid, HMOs, and Title X. Title X provides federal money to the state for funding school programs. This state law effectively means that even young children may get emergency contraception over the counter.

WYETH

RECEIVED AT DRUG SAFETY SURVEILLANCE
01-DEC-1997-2084

ME
ICAL PRO

ST. DAVIDS, PA. 19087

Page

Individual Safety Report
3056829-8-00

3/93
03N

FDA Use Only

A. Patient Information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	19 YR / Unknown	[X] female [ ] male	lbs / or / kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [X] death [redacted] (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization - initial or prolonged
- [ ] recovered
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [X] other: serious

3. Date of event (mo/day/yr): 04 / 10 / 97

4. Date of this report (mo/day/yr): 06 / 25 / 97

5. Describe event or problem

The patient, who took Trinordiol (equivalent to Triphasil), experienced diarrhea, vomiting and headache for two days prior to lapsing into a coma. An MRI revealed CEREBRAL THROMBOPHLEBITIS; the patient subsequently died. No autopsy.

8. Relevant tests/laboratory data, including dates

DATE	TEST	RESULT
Unknown	MRI	Cerebral thrombophlebitis

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

None provided

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TRINORDIOL (0.05MG LNG/0.03MG E.E., 0.075 LNG/0.04MG E.E., 0.125MG LNG/0.03MG E.E.)
#2

2. Dose, frequency & route used
#1 1 TABLET ONCE DAILY ORAL
#2

3. Therapy dates (if unknown, give duration)
#1 1 YEAR
#2

4. Diagnosis for use (indication)
#1 Unknown
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
See following page

G. All manufacturers

1. Contact office - name/address (& MFG site for devices)
WYETH-AYERST LABORATORIES
170 RADNOR CHESTER ROAD
ST. DAVIDS, PA. 19087

KAREL F. BERNADY, PH.D.

2. Phone number
(610) 902-3760

3. Report source (check all that apply)
- [X] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [ ] other:

4. Date received by manufacturer (mo/day/yr): 06 / 24 / 97

5. (A)NDA # 19-192
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
- [ ] 5-day
- [ ] 10-day
- [X] initial
- [ ] 15-day
- [X] periodic
- [ ] follow-up #

8. Adverse event term(s)
CEREBRAL THROMBOSIS
VOMITING
DIARRHEA
HEADACHE

9. Mfr. report number
8-97176-003N

E. Initial reporter

1. Name, address & phone #
[redacted]

[redacted]

FRANCE

4

2. Health professional? [X] yes [ ] no

3. Occupation
N/A

4. Initial reporter also sent report to FDA
[ ] yes [X] no [ ] unk

DATE SENT TO FDA: NOV 25 1997
19970380

Submission of a report does not constitute an admission that

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

SPASMINE 3 tablets daily ORAL (02 / 18 / 97 to 04 / 12 / 97)
ZOVIRAX 800 mg QID ORAL (04 / 00 / 96 to 04 / 00 / 97)

WYETH AYERST

MEDWATC

WYETH-AYERST LABORATORIES — THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

170 ST. RECEIVED AT DRUG SAFETY SURVEILLANCE

01-DEC-1997-5265

Individual Safety Report

3058001-4-00

FDA Use Only

A. Patient Information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	23 YR [redacted]	[X] female [ ] male	129 lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [X] death — Unknown (mo/day/yr)
- [ ] life-threatening
- [X] hospitalization - initial or prolonged
- [ ] recovered
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
04 / 14 / 97	04 / 28 / 97

5. Describe event or problem

The patient, with Down's Syndrome, presented to the ER unresponsive with CPR in progress. Her color was dusty-blue, petechia were present on face, skin cool and she had orange-red emesis coming from her mouth. Suctioning and intubation were attempted; intubation was unsuccessful and the patient subsequently died. The provisional autopsy report revealed an ACUTE PULMONARY EMBOLUS.

6. Relevant tests/laboratory data, including dates

(Cont.)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Down's Syndrome; hypothyroidism; used Depo-Provera in the past (q 3 months from [redacted] to [redacted]) with weight gain ~101 lb. [redacted] to 125 lb. [redacted]. No previous history of T. Upjohn has been notified of this adverse event.

DATE SENT TO FDA [illegible] 28

Submission of a report does not constitute an admission that

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TRIPHASIL-28 TABLETS
#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 1 TABLET ONCE DAILY ORAL	#1 08 / 08 / 96 to 04 / 14 / 97
#2	#2

4. Diagnosis for use (indication)
#1 REGULATE MENSES/DYSMENORRHEA
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
See following page

G. All manufacturers

1. Contact office - name/address (& MFG site for devices)

WYETH-AYERST LABORATORIES
170 RADNOR CHESTER ROAD
ST. DAVIDS, PA. 19087

KAREL F. BERNADY, PH.D.

2. Phone number
(610). 902-3760

3. Report source (check all that apply)
- [ ] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [ ] other:

4. Date received by manufacturer (mo/day/yr)
04 / 24 / 97

5. (A) NDA # 19-190
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
- [ ] 5-day
- [ ] 10-day
- [X] initial
- [ ] 15-day
- [X] periodic
- [ ] follow-up #

8. Adverse event term(s)
PULMONARY EMBOLUS

9. Mfr. report number
8-97118-249N

DEC 01 1997

E. Initial reporter

1. Name, address & phone #
[redacted]

00006

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
[X] ... [ ] ...	Pharmacist	[ ] ... [X] ...