THE STATE OF NEW HAMPSHIRE

CHESHIRE, SS. SUPERIOR COURT

Docket # _____

Betty Buzzell
597 Fitzwilliam Road
Richmond, NH 03470

Robert J. Carbone
75 Granite Hill Road
Richmond, NH 03470

and

New Hampshire Right to Life
PO Box 421
Merrimack, NH 03054

v.

New Hampshire Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518

PETITION FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

I. INTRODUCTION

This is a Petition for Declaratory Judgment and Injunctive Relief regarding the New Hampshire Board of Pharmacy's unlawful granting of licenses to Planned Parenthood of Northern New England's [PPNNE] six abortion clinics. PPNNE knowingly violates FDA safety protocols by administering and dispensing the abortion pill past 49 days pregnancy and having its non-physician staff dispense the pills for take home use. The FDA has cataloged thousands of adverse events, including excessive bleeding and hemorrhaging, as well as several deaths from abortionists administering and dispensing the abortion pill contrary to FDA safety protocols. The FDA safety protocols are, pursuant to RSA 318:42(VII), and the Nurse Formulary, a required part of New Hampshire law and the Board of Pharmacy has acted unlawfully in

granting pharmaceutical licenses to abortion clinics in knowing violation of these FDA safety protocols. The Petitioners seek a declaratory judgment and injunction against the Board of Pharmacy to stop the Board of Pharmacy from continuing to grant licenses to abortion clinics that are unlawfully and dangerously administering and dispensing the abortion pill.

II. PARTIES

1. Betty Buzzell is a taxpayer and a resident of the Town of Richmond.

2. Robert Carbone is a taxpayer and a resident of the Town of Richmond.

3. New Hampshire Right to Life [NHRTL] is a non-profit organization with over 10,000 members throughout the State of New Hampshire, including Cheshire County.

4. The New Hampshire Board of Pharmacy [BOP] is an agency of the State of New Hampshire, was formed pursuant to RSA 318:2, and is responsible for enforcing the pharmaceutical statute pursuant to RSA 318:8.

III. JURISDICTION AND VENUE

5. Venue is appropriate in Cheshire County as some of the plaintiffs reside in Cheshire County.

6. This Court has jurisdiction to enter a declaratory judgment pursuant to RSA 491:22 as the recent amendment to RSA 491:22 grants standing to seek declaratory judgments to any taxpayer when it "is alleged that the taxing district or any agency or authority thereof has engaged, or proposes to engage, in conduct that is unlawful or unauthorized," and, other than via RSA 491:22, no one has standing to challenge BOP unlawfully granting licenses.

7. The Petitioners allege that the BOP acted unlawfully in granting certain pharmaceutical licenses to Planned Parenthood of Northern New England [PPNNE] and allege

that the BOP will continue to grant licenses to PPNNE without a declaratory judgment from this Court.

IV. FACTS

8. The BOP is responsible for enforcing the provisions of RSA 318. Pursuant to RSA 318:42, "it shall be unlawful for any person who is not a licensed pharmacist in a pharmacy registered in accordance with the provisions of this chapter to manufacture, compound, dispense, sell, offer for sale or have in possession any prescription drug ..."

9. There are some exceptions to RSA 318:42 including 318:42(VII) which allows for the "dispensing of non-controlled prescription drugs by registered nurses in clinics operated by or under contract with the Department of Health & Human Services, or by such nurses in clinics of non-profit family planning agencies under contract with the Department of Health & Human Services ..."

10. In order to qualify for the exemption found in RSA 318:42(VII), one needs to obtain from the BOP a Limited Retail Drug Distributorship [LRDD] license annually pursuant to RSA 318:51-b.

11. An LRDD license allows one to distribute certain non-controlled prescription drugs by persons who are not licensed pharmacists.

12. PPNNE operates abortion clinics in the State of New Hampshire in Manchester, Derry, West Lebanon, Claremont, Keene and Exeter.

13. The BOP has granted to Planned Parenthood of Northern New England [PPNNE] six LRDD licenses for the period July 1, 2013 through June 30, 2014 to allow PPNNE to distribute prescription drugs without a pharmacist. See Exhibit I.

14. The drugs distributed by Planned Parenthood include the abortion pill, a/k/a RU486.[1]

15. The Petitioners have challenged the Board of Pharmacy's actions, alleging that its conduct is unlawful and contrary to RSA 318:42.

16. In proceedings regarding the Board of Pharmacy's unlawful granting of licenses to Planned Parenthood for the period July 1, 2012 to June 30, 2013, the BOP held that no person had standing to challenge the BOP's granting of licenses as "[n]o individual or group of individuals has standing to appeal when the alleged injury caused by an administrative agency's action affects the public in general."[2]

17. The Petitioners, in letters dated June 17, 2013 and July 3, 2013, advised the BOP that granting LRDD licenses to PPNNE's six abortion clinics would be unlawful. See attached as Exhibits J and K.

18. Nevertheless, the BOP's Executive Secretary issued six LRDD licenses for the period July 1, 2013 to June 30, 2014.

A. BOP Cannot Grant a LRDD License to Entities Not Possessing a Contract With the New Hampshire Department of Health and Human Services

19. RSA 318:42(VII) provides that a LRDD license may only be granted to family planning clinics "operated by or under contract with the department of health and human services."

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[1] The abortion pill is actually two drugs. Mifepristone is taken first, followed by a drug called Misoprostol taken 3 days later.

[2] The action to challenge the 2012 licenses is currently on appeal to the New Hampshire Supreme Court, Docket #2012-0828. The Supreme Court accepted this appeal solely on the issue of standing. The Supreme Court is not considering the merits of the Board of Pharmacy's actions. RSA 491:22 was amended, effective January 1, 2013, to greatly expand standing in declaratory judgment actions to any taxpayer. This present action is being brought under the recently amended RSA 491:22 and relates to the licenses granted for the period July 1, 2013 through June 30, 2014.

20. BOP's application form for a LRDD license makes clear that one needs to be under contract with the NH Department of Health and Human Services for the provision of family planning services. See attached as Exh. A.

21. Planned Parenthood is not currently under contract with the NH Department of Health and Human Services for the provision of family planning services.

22. Planned Parenthood was not under contract with the NH Department of Health and Human Services for the provision of family planning services on July 1, 2013 when the current LRDD licenses were granted.

23. Planned Parenthood has not been under contract with the NH Department of Health and Human Services for the provision of family planning services since June 30, 2011.

24. Planned Parenthood's CEO acknowledged to the *Concord Monitor* that without a family planning contract with the state of New Hampshire, it cannot lawfully distribute prescription drugs until it obtains a state contract. See attached as Exhibit B.

25. The BOP knew that Planned Parenthood did not have a family planning contract with the NH Department of Health and Human Services when it granted LRDD licenses on or about July 1, 2013.

26. The BOP acted unlawfully in granting LRDD licenses to Planned Parenthood.

B. BOP Cannot Grant a LRDD License to Allow Non-Pharmacists to Distribute the Abortion Pill

27. A LRDD license only authorizes one to distribute drugs on the Nurse Formulary. See RSA 318:42(VII)(b).

28. The current Nurse Formulary, approved pursuant to RSA 326-B, is attached as Exhibit C.[3]

29. The Nurse Formulary has not been amended since August of 2007.

30. The Nurse Formulary provides that Mifepristone can only be distributed under the supervision of a physician who meets the federal Prescriber's Agreement. See Exhibit C, p.15.

31. The federal Prescriber's Agreement provides that the abortion pill may only be used through 49 days of pregnancy. See attached as Exhibit D.

32. The federal Prescriber's Agreement incorporates the Patient Agreement which provides that both the 1st pill and the 2nd pill must be taken in the physician's office. See Exhibit E, ¶¶ 5 & 6.

33. The FDA protocols, incorporated into New Hampshire law via the Nurse Formulary and RSA 318:42(VII)(b) clearly prohibit dispensation of the abortion pill for take-home use.

34. The FDA protocols, incorporated into New Hampshire law via the Nurse Formulary and RSA 318:42(VII)(b), clearly prohibit administration or dispensation of the abortion pill past 49 days of pregnancy.

35. Planned Parenthood advertises that the process of abortion can be completed at home with drugs dispensed to the patient for take home use.[4]

36. Planned Parenthood advertises on its website that the abortion pill is available up to 63 days of pregnancy.[5]

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[3] Only the relevant pages are attached as Exhibit C. The current Nurse Formulary, in its entirety, is published on the Board of Pharmacy's website: http://www.nh.gov/pharmacy/documents/arnp-formulary.pdf (last visited October 22, 2013).

[4] See http://www.plannedparenthood.org/ppnne/abortion-pill-40598.htm attached as Exhibit H. See also http://www.youtube.com/watch?feature=player_embedded&v=0U20nhWCzJ0

37. The BOP knew that Planned Parenthood was administering and dispensing the abortion pill past 49 days pregnancy and for take home use when it granted Planned Parenthood 6 LRDD licenses.

38. The requirements in the federal Prescriber and Patient Agreements were imposed by the FDA after several years of study.

39. The FDA specifically rejected the claim that the abortion pill could be safely administered past 49 days pregnancy or distributed for take home use.

40. In addition, the FDA expressly rejected the sponsor's suggestion that patients be allowed to self-administer Misoprostol at home. See United States Government Accountability Office, GAO Report: Approval and Oversight of the drug Mifeprex at 23 attached as Exhibit F.

41. The FDA, and by incorporation New Hampshire law, has specifically restricted the use of Mifepristone to the requirement in the Federal Prescriber's and Patient's Agreements as a requirement of approval under subpart H.

42. Drugs approved with post marketing restrictions under 21 C.F.R. §314.520 are those that "would not have been approved for use without those restrictions because the risk/benefit balance would not justify such approval." 57 Fed. Reg. 58942, 58949.

43. The concern over off label use has proven true. An FDA report in 2011 acknowledged that at least 2,207 cases of severe adverse events, including hemorrhaging, blood loss requiring transfusion, serious infection, and even fourteen deaths have resulted from the off label use. See FDA, Mifepristone US Post Marketing Adverse Event Summary, April 2011 attached as Exhibit G. ("FDA investigated the deaths of 6 US women who developed a fatal infection [as of 2008] following treatment with Mifeprex for medical abortion. FDA has

[5] See http://www.plannedparenthood.org/ppnne/abortion-pill-40598.htm attached as Exhibit H. See also http://www.youtube.com/watch?feature=player_embedded&v=0U20nhWCzJ0

determined that in all 6 of the deaths, the women used a Mifeprex treatment regimen that has not been approved by FDA.")

44. The BOP acted unlawfully in granting LRDDs to PPNNE when it knew or should have known that PPNNE was violating New Hampshire law by distributing the pill for take home use and by administering and dispensing it past 49 days of pregnancy.

C. The BOP Cannot Grant a LRDD Licenses Without First Verifying PPNNE's Protocols Comply With New Hampshire Law

45. Pursuant to RSA 318:42(VII)(a), a LRDD license holder can only dispense pursuant to an approved written protocol.

46. By statute, the written protocol must contain "the name of each registered nurse." See RSA 318:42(VII)(a).

47. The BOP did not require that Planned Parenthood submit a newly updated protocol prior to obtaining a new LRDD license on July 1, 2013.

48. The BOP never reviewed any Planned Parenthood protocol (either new or from September 2012) to determine whether it complies with NH law regarding administering and distributing the abortion pill. See Exhibit A.

49. The BOP acted unlawfully in not verifying that the drugs on Planned Parenthood's protocol were being lawfully administered or dispensed.

D. The BOP Unlawfully Deferred Decision Making Authority to its Executive Secretary

50. Pursuant to RSA 318:51-b, "no person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so ***from the board***."

51. The BOP received Planned Parenthood's applications for new licenses on Wednesday June 26, 2013.

52. The BOP's Executive Secretary Jay Queenan approved new licenses to Planned Parenthood without bringing the matter before the Board of Pharmacy.[6]

53. Pursuant to RSA 318:9, the Executive Secretary "may not perform any discretionary or decision-making functions for which the board is solely responsible."

54. The Board is solely responsible for the granting of LRDD licenses pursuant to RSA 318:51-b.

55. Licenses putatively granted by the Executive Secretary without being brought before the Board are invalid as a matter of law.

56. The BOP acted unlawfully in attempting to delegate the Board's decision making authority to the Executive Secretary.

E. The BOP acted Unlawfully in Approving Administration or Dispensation of the Abortion Pill By or Under the Supervision of ARNPs

57. PPNNE does not have physicians on staff at each of its six New Hampshire abortion clinics.[7]

58. In approving PPNNE's 2012 LRDD licenses, the BOP relied on June 8, 2012 and August 7, 2012 Memoranda from the BOP's Compliance Officer Margaret Clifford who found that although PPNNE does not have MDs at each site, it does have 13 ARNPs, Advanced Registered Nurse Practitioners.

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[6] PPNNE's licenses expired on June 30, 2013. Other applicants had license renewals considered at the BOP's June 19, 2013 meeting. PPNNE should not be able to avoid Board review by waiting until the last minute to submit their application.

[7] The 4 MDs employed by Planned Parenthood are responsible not just for PPNNE's 6 NH abortion clinics but PPNNE's 12 Vermont abortion clinics as well.

59. The BOP unlawfully relied on MDs and ARNP's ability to *administer* drugs to allow PPNNE to *dispense* the abortion pill contrary to FDA protocols.

60. Under NH law, ARNPs can *administer* prescription drugs "to meet the immediate medical needs of their patients." RSA 318:42(II).

61. ARNPs cannot, however, *dispense* drugs for take home use.

62. RSA 318:42 (II) provides that MDs and ARNPs can administer drugs but does not grant them the authority to dispense drugs. RSA 318:1 (I) defines "administer" to be "a single dose ... for immediate consumption or use" while "dispense" is defined by RSA 318:1 (V) "to distribute ... one or more doses of a drug."

63. Therefore, while Planned Parenthood's MDs and ARNPs may administer drugs for a client's immediate use, Planned Parenthood's MDs and ARNPs may NOT dispense drugs for their take home use. Planned Parenthood's practitioners, like any other practitioner, must write prescriptions to be filled at a licensed pharmacy.

64. The BOP acted unlawfully when it granted a LRDD license to PPNNE to dispense the second abortion pill for take home use based on an erroneous presumption that MDs and ARPNs could do so without a license.

65. In addition, pursuant to the federal Prescriber's Agreement, see Exh. D, which is incorporated into New Hampshire law pursuant to Nurse Formulary (Exh. C) , RSA 326-B:10, II, RSA 318:42(VII)(a)& (b), the abortion pill "must be provided by or under the supervision of a ***physician***."[8]

66. An ARNP is not a physician.

[8] See Exhibit D. The FDA further limits the physicians who can safely administer the abortion pill to only those physicians who have the "[a]bility to provide surgical intervention . . . and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation." The BOP knew or should have known that Planned Parenthood's clinics are not able to provide blood transfusions.

67. Therefore, while a physician may administer the first abortion pill to a patient, an APRNs may not administer the first dose of the abortion pill to a patient unless under the supervision of a physician.

68. The BOP acted unlawfully in granting a LRDD to allow nurses to dispense the abortion pills.

F. The BOP acted Unlawfully in Granting Licenses to PPNNE Where PPNNE Either Knowingly Failed to Complete Required Patient Agreements or Fraudulently Completed Patient Agreements

69. New Hampshire law requires that the Patient Agreement (see Exh. E) must be completed by the patient and provider each time a patient receives the abortion pill.

70. Pursuant to the Patient Agreement, the provider (PPNNE) must sign that the patient is no more than 49 days pregnant and that the patient will take the second abortion pill in the provider's office. See Exhibit E, ¶¶ 4 & 6. See also Exhibit D.

71. PPNNE advertises that it will distribute the abortion pill up to 63 days pregnancy and dispenses the second pill for take home use. [9]

72. PPNNE has a nationwide policy of ignoring the FDA safety protocols and distributing the abortion pill to maximize its profits. See Planned Parenthood Southwest Ohio Region v. Dewine, 696 F.2d 490 (6th Cir. 2012) (affirming the State of Ohio's decision to protect patient safety by prohibiting use past 49 days or take home use against challenge by Planned Parenthood that their nationwide policy of ignoring the Federal Prescriber Agreement is just as safe).

73. Pursuant to RSA 318:51-b, (II)(a) no license shall be issued unless the applicant proves to the Board that it "is of good moral character."

[9] See http://www.plannedparenthood.org/ppnne/abortion-pill-40598.htm attached as Exhibit H. See also http://www.youtube.com/watch?feature=player_embedded&v=0U20nhWCzJ0

74. PPNNE's refusal to honestly complete the Patient Agreement indicates poor moral character.

75. PPNNE's knowing violation of the 49 day limitation and the physician presence requirement both risk maternal safety and indicate poor moral character.

76. Pursuant to RSA 318:51-b, II, (a) and RSA 318:51-b, III, the BOP acted unlawfully in granting LRDD licenses to Planned Parenthood.

V. Petitioners Are Entitled to Declaratory Judgment Finding the BOP Acted Unlawfully in Granting LRDD Licenses to Planned Parenthood.

77. Pursuant to RSA 491:22, as amended by 2012 NH Laws 262, any taxpayer "shall be deemed to have an equitable right and interest in the preservation of an orderly and lawful government" and may petition the superior court for a declaratory judgment "when it is alleged that . . . any agency . . . has engaged or proposes to engage in conduct that is unlawful or unauthorized."

78. The BOP has acted unlawfully in granting LRDD licenses to Planned Parenthood's six New Hampshire abortion clinics.

79. The BOP proposes to continue to act unlawfully and renew LRDD licenses to Planned Parenthood to allow distribution of the abortion pill contrary to FDA safety protocols.

80. This Court should issue a Declaratory Judgment that it is unlawful for the BOP to issue LRDD licenses to Planned Parenthood for the following reasons:

a. RSA 318:42(VII) requires applicants to have a family planning contract with the state of New Hampshire. It is unlawful to grant a LRDD license where PPNNE has a federal family planning contract but does not have a family planning contract with the state of New Hampshire.

b. Pursuant to RSA 318:42(VII), an LRDD license only authorizes distribution of drugs on the Nurse Formulary. Planned Parenthood has repeatedly violated the restrictions of the Nurse Formulary and had its practitioners violate the law by administering the abortion pill past 49 days pregnancy and by dispensing the abortion pill for take home use. The BOP cannot lawfully grant a LRDD license to an entity unlawfully administering and dispensing contrary to the Nurse Formulary.

c. The BOP cannot grant LRDD licenses without annually reviewing the written protocols required by RSA 318:42(VII)(a). The BOP acted unlawfully in granting Planned Parenthood six LRDD licenses where the BOP never received 2013 protocols.

d. LRDD licenses granted by the BOP's Executive Secretary without consideration by the Board are void as the Board cannot delegate its license granting authority to the Executive Secretary pursuant to RSA 318:51-b and RSA 318:9.

e. ARNPs cannot administer the abortion pill without supervision and neither ARNPs nor physicians may lawfully dispense the second abortion pill for take home use pursuant to RSA 318:42(II)(limiting administration and distribution to "***immediate*** medical needs of their patients.") The BOP unlawfully granted LRDD licenses to Planned Parenthood to allow RNs to dispense the abortion pill based on an erroneous understanding that physicians and ARNPs could dispense drugs to their patients.

f. Pursuant to RSA 318:51-b, II, (a) and RSA 318:51-b, III, the BOP acted unlawfully in granting LRDD licenses to Planned Parenthood where Planned Parenthood openly flaunted its refusal to comply with FDA safety protocols by administering the abortion pill past 49 days pregnancy and dispensing the second abortion pill for take home use.

WHEREFORE, the Petitioners, Betty Buzzell, Robert Carbone and New Hampshire Right to Life, respectfully request that this Honorable Court:

a. Issue a declaratory judgment that the New Hampshire Board of Pharmacy acted unlawfully in granting six limited retail drug distributorship licenses to Planned Parenthood's abortion clinics where the BOP knew or should have known that PPNNE did not have a Family Planning Contract with the New Hampshire Department of Health & Human Services, that PPNNE was administering and dispensing the abortion pill past 49 days of pregnancy and for take home use contrary to FDA's safety protocols which were required by New Hampshire law pursuant to RSA 318:42(VII), that the BOP cannot grant LRDD licenses without reviewing the written protocols, that the BOP cannot delegate license granting authority to its Executive Secretary, that the BOP cannot authorize ARNPs to administer the abortion pill, nor can it authorize ARNPs nor physicians to dispense the second abortion pill for take home use and that the BOP acted unlawfully in granting LRDD licenses to Planned Parenthood where Planned Parenthood had openly flaunted its refusal to comply with FDA's safety protocols and the required Patient Agreement;

b. Order that the LRDD licenses granted to Planned Parenthood's six abortion clinics, having been unlawfully granted, are hereby void;

c. Enjoin the Board of Pharmacy from granting LRDD licenses to Planned Parenthood in the future; and

d. Such other and further relief as may be just and equitable.

Respectfully submitted,

BETTY BUZZELL, ROBERT CARBONE
AND NEW HAMPSHIRE RIGHT TO LIFE

By its attorneys,

WADLEIGH, STARR & PETERS, PLLC

By: _____
Michael J. Tierney – NHBA# 17173
95 Market Street
Manchester, NH 03101
(603) 669-4140
mtierney@wadleighlaw.com

ALLIANCE DEFENDING FREEDOM

By /S/ Catherine Glenn Foster
Catherine Glenn Foster, Esq.,
(*pro hac vice* motion pending)
VA Bar #82109
801 G Street NW, Ste 509
Washington, DC 20001
202-393-8690
cfoster@alliancedefendingfreedom.org

CERTIFICATE OF SERVICE

I hereby certify that I sent a copy of the foregoing, this day, to Lynmarie Cusack, Esq., Attorney General's Office, 33 Capitol Street, Concord, NH 03301, attorney for the New Hampshire Board of Pharmacy.

_____
Michael J. Tierney

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EXHIBIT INDEX

EXHIBIT A - Board of Pharmacy's application form for an LRDD license

EXHIBIT B - Concord Monitor article

EXHIBIT C - Nurse Formulary

EXHIBIT D - Prescriber's Agreement

EXHIBIT E - Patient Agreement

EXHIBIT F - GAO Report on FDA Approval

EXHIBIT G - FDA, Mifepristone Adverse Event Summary, April 2011

EXHIBIT H - PPNNE Website

EXHIBIT I - LRDD Licenses July 1, 2013 to June 30, 2014

EXHIBIT J - June 17, 2013 letter to BOP

EXHIBIT K - July 3, 2013 letter to BOP

EXHIBIT A

Return Application With Check Payable To:
NH Board of Pharmacy
Renewal Fee: $150

State of New Hampshire
Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518
Tel.: (603) 271-2350 Fax: (603) 271-2856
Website: www.nh.gov/pharmacy/

Board Use Only
RECEIVED
JUN 26 2013
STATE OF NH
BOARD OF PHARMACY

RENEWAL APPLICATION - JULY 1, 2013 TO JUNE 30, 2014 LICENSING PERIOD [redacted]

LIMITED RETAIL DRUG DISTRIBUTOR - *PUBLIC HEALTH CLINIC*

(UNDER CONTRACT WITH THE DIVISION OF PUBLIC HEALTH SERVICES – A COPY OF YOUR CONTRACT WITH NH DHHS MUST BE ATTACHED)

Licensed Location – Name & Location Of Public Health Clinic:

LIC. #: 7060

PLANNED PARENTHOOD OF NORTHERN NE
8 MIDDLE ST
KEENE, NH 03431

Please Verify Information & Correct Any Errors

Telephone:	Fax:	E-Mail Address (If Applicable):
603-352-6898	603-352-0682	N/A

Parent Company (If Applicable): N/A

Clinic Specialty:
☑ Family Planning ☐ STD
☐ Other Please Specify: _____

Security:
Alarm Installed: ☑ Yes ☐ No

Applicant's Proposed Drug Activity: **(To bona fide patients of clinic only)**
☑ Administer (Non-Controlled Drugs) ☑ Dispense (Non-Controlled Drugs)

Licensure does not authorize the receipt, storage or dispensing of controlled substances.

Name Of Owner(s): (Indicate Individual, Partners, Etc. - If Corporation, Show Title Of Officers) Attach Additional Sheet If Necessary

Name	Address	Title
Please see attached		

Since your last renewal, has registration or licensure granted to the applicant by any state or federal agency been suspended or revoked?
☐ Yes * ☑ No * If "yes", attach a detailed description.

Verify the name, title, & mailing address of the person to whom the permit, future renewal applications, and all Board communications should be directed:

Current Contact:

[redacted] SITE
PLANNED PARENTHOOD OF NORTHERN NE
8 MIDDLE ST
KEENE, NH 03431

Corrected Contact (If Different Than At Left):

Tom Lee

APPLICATION CONTINUED ON OTHER SIDE

Hours of Operation					
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
9am - 5pm	11am - 6:30pm	11am - 5pm	11am - 5pm	11am - 5pm	10am - 1pm

Medical Director: John Doe #2

Name	Address	Telephone Number
[redacted]	128 Lakeside Ave, Ste 301 Burlington, VT 05401	802-448-9743

Does the clinic maintain a written copy of a drug dispensing protocol (per NH RSA 318:42, VII) ? ☑ Yes * ☐ No *

(If "yes", enter date the protocol was approved by the Department of Health & Human Services If 'no", attach explanation). 09/14/12

Provide name(s) of person(s) in charge of drug purchasing, dispensing records and security. (Use Reverse Side If Necessary)

Name:	Title:	Name:	Title:
John Doe #1 [redacted]	Site Manager		

Consultant Pharmacist: John Doe #3

Printed Name	Signature (Applications without consultant's signature will be returned)	NH Pharmacist Lic. #
[redacted]	[redacted]	[redacted]

Declaration And Signature By Clinic Representative:

I declare under penalties of perjury that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the permit herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State.

Signature: Heather L. Bushey (Responsible Party) Title: CFO (Indicate whether owner, partner, or officer of corporation) Date: 06/17/13

THE LICENSEE SHALL NOTIFY THE BOARD, IN WRITING, OF ANY CHANGES IN THE INFORMATION CONTAINED IN THIS APPLICATION.

A COPY OF YOUR CURRENT CONTRACT WITH NH DHHS MUST BE ATTACHED TO THIS RENEWAL.

ALL QUESTIONS MUST BE ANSWERED – INCOMPLETE APPLICATIONS OR APPLICATIONS WITHOUT BOTH THE CONSULTANT PHARMACIST'S & THE CLINIC REPRESENTATIVE'S SIGNATURES WILL NOT BE ACCEPTED.

Return Application
With Check Payable To:
NH Board of Pharmacy

Annual Licensing Fee:
$150

State of New Hampshire
Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518
Tel.: (603) 271-2350 Fax: (603) 271-2856
Website: www.nh.gov/pharmacy

Board Use Only (Do Not Write In This Box)

July 1, 2012 – June 30, 2013
Registration Period

LIMITED RETAIL DRUG DISTRIBUTOR
PUBLIC HEALTH CLINIC

UNDER CONTRACT WITH THE NH DHHS DIVISION OF PUBLIC HEALTH SERVICES
A COPY OF YOUR CURRENT CONTRACT WITH NH DHHS MUST BE ATTACHED TO THIS APPLICATION

Clinic Name & Address: *(Actual Licensed Location)*

Clinic Name

Street Address

City *State* *Zip Code*

Telephone: | Fax: | E-Mail Address (If Applicable):

Parent Company (If Applicable):

Clinic Specialty:
☐ Family Planning ☐ STD
☐ Other Please Specify:

Security:
Alarm Installed: ☐ Yes ☐ No

Applicant's Proposed Drug Activity: **(To bona fide patients of clinic only)**
☐ Administer (Non-Controlled Drugs) ☐ Dispense (Non-Controlled Drugs)
Licensure does not authorize the receipt, storage or dispensing of controlled substances.

Name Of Owner(s): (Indicate Individual, Partners, Etc. - If Corporation, Show Title Of Officers) Attach Additional Sheet If Necessary

Name | Address | Title

Name | Address | Title

Has registration or licensure granted to the applicant by any state or federal agency ever been suspended or revoked? ☐ Yes ☐ No
(If "yes", attach a detailed description).

Does the clinic maintain a written copy of a drug dispensing protocol (per NH RSA 318:42, VII) ? ☐ Yes * ☐ No
(If "yes", enter date the protocol was approved by the Department of Health & Human Services?).

Provide the information below for the person responsible for the operation of the clinic: (The permit & future renewals will be directed to this person)

Name: Title: Tel. #:

Business Mailing Address:

Hours of Operation

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Provide name(s) of person(s) in charge of drug purchasing, dispensing records and security. (Use Reverse Side If Necessary)

ALL QUESTIONS MUST BE ANSWERED – INCOMPLETE APPLICATIONS OR APPLICATIONS WITHOUT BOTH THE CONSULTANT PHARMACIST'S & THE CLINIC REPRESENTATIVE'S SIGNATURES WILL NOT BE ACCEPTED.

APPLICATION CONTINUED ON OTHER SIDE ↳

Medical Director of Clinic:		
Name	Address	Telephone Number

Practitioners: (Use Reverse Side If Necessary)			
Name:	Title:	Name:	Title:

Consultant Pharmacist:		
Name	**Signature (Applications without consultant's signature will be returned)**	NH License No.

Declaration And Signature By Clinic Representative:

I declare under penalties of perjury that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the permit herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State.

Signature: _____ Title: _____ Date: _____

(Responsible Party) *(Indicate whether owner, partner, or officer of corporation)*

**** THE LICENSEE SHALL NOTIFY THE BOARD, IN WRITING, OF ANY CHANGES IN THE INFORMATION CONTAINED IN THIS APPLICATION.***

**** A COPY OF YOUR CURRENT CONTRACT WITH NH DEPARTMENT OF HEALTH & HUMAN SERVICES, DIVISION OF PUBLIC HEALTH SERVICES MUST BE ATTACHED TO THIS APPLICATION IN ORDER FOR IT TO BE PROCESSED.***

EXHIBIT B

CONCORD MONITOR

Published on *Concord Monitor* (http://www.concordmonitor.com)

Centers stop dispensing birth control

Planned Parenthood loses contract

By Karen Langley / Monitor staff
July 8, 2011

The six Planned Parenthood centers in New Hampshire stopped dispensing contraception last week after the Executive Council rejected a new contract with the organization.

Planned Parenthood had operated under a limited retail pharmacy license that was contingent on having a state contract, said Steve Trombley, president and CEO of Planned Parenthood of Northern New England. Two weeks ago, the all-Republican Executive Council voted 3-2 against a new contract that would have provided the organization $1.8 million in state and federal money for the two years starting this month.

Executive Councilor Dan St. Hilaire of Concord, who cast one of the three votes in opposition, said the contract should go to an organization that does not perform abortions. The councilors approved 10 other contracts for family planning services.

The Planned Parenthood contract, which accounts for about 20 percent of its annual New Hampshire budget, would have paid for education, distributing contraception, and the testing and treatment of sexually transmitted infections. The organization's abortion practice is paid for by private donations, Trombley said, with audits ensuring no public money is used.

Last year, Planned Parenthood provided contraception for 13,242 patients in New Hampshire, Trombley said. The organization also provided 6,112 breast exams, 5,548 screenings for cervical cancer and 18,858 tests for sexually transmitted infections. If the contract is not renewed, Planned Parenthood will drastically reduce its services, Trombley said. The organization employs 80 people in New Hampshire.

Planned Parenthood treats 52 percent of patients whose care is subsidized by the New Hampshire state family planning program, Trombley said. It provides its services on a sliding scale based on income, with 70 percent of patients paying nothing or near nothing for birth control pills because they earn less than 150 percent of the federal poverty line. The federal poverty guidelines vary with the number of people in a household, with a single person qualifying at $10,890 per year and a family of four qualifying at $22,350 a year.

At the Planned Parenthood center in West Lebanon yesterday, Laura Caravella arrived to pick up her patient file to bring it to a physician. Caravella, a 25-year-old paraprofessional at an elementary school in Vermont, had tried to refill her birth control prescription last Friday and learned she could not.

She said she was concerned about the cost of her prescription without the sliding scale offered by Planned Parenthood.

"Financially it's really stressful," Caravella said. "I'm already living almost paycheck to paycheck as it is."

Stephanie Hiltunen, a 26-year-old who lives in Hanover, said she picked up a monthlong supply of birth control last Thursday, the day before the center stopped dispensing it. But future refills will require an inconvenient trip to Enfield, she said. Hiltunen said she would like to have a child but cannot afford it, and she worries there will be a public cost if contraception is inaccessible to low-income women.

"If they can't afford to have a baby, then we'll be paying for them in the long run," she said.

The center has turned away 20 to 30 patients a day who have arrived to refill their birth control prescriptions, said site manager Amanda Mehegan. She said some women have said they will stop taking birth control because they cannot afford the higher prices charged by pharmacies. Seventy percent of the center's patients lack private health insurance, she said.

Mehegan said she also worries the denied contract will lead to women with breast and cervical cancer going longer without a diagnosis, both because of direct cuts in funding for examinations and because many women are drawn to the center to pick up their birth control and then receive checkups.

"For most of our patients Planned Parenthood may be the only medical visit they have in a year," she said. "I think a lot of patients really rely on that as their yearly checkup."

Anne Hildreth, a practitioner at the West Lebanon center who has worked for Planned Parenthood for 22 years, said her goal is to help prevent unwanted pregnancies. She questioned the rationale of limiting access to contraception in an effort to prevent abortions.

"It's crazy to not give women birth control if you want to stop women from having abortions," Hildreth said.

Yesterday, Planned Parenthood launched an advertising campaign about the Executive Council vote in state newspapers. The advertisement in the Monitor asks St. Hilaire to "put women's health above politics" and shows a photograph of a young woman from Portsmouth who says she cannot afford birth control at pharmacies.

Trombley said the organization is focusing its efforts to pass the contract on St. Hilaire because the Concord councilor voted in favor of each of the family planning contracts except the one with Planned Parenthood. Officials from the organization met with St. Hilaire last week, but he made no commitment about a future vote, Trombley said.

St. Hilaire did not respond to messages seeking comment.

Another executive councilor who opposed the contract, Raymond Wieczorek of Manchester, said he had asked if the contract could exclude the issuance of condoms. Wieczorek said he supports paying to test for sexually transmitted diseases but does not believe the state should subsidize contraception.

"If they want to have a good time, why not let them pay for it?" he said.

(Karen Langley can be reached at 369-3316 or klangley@cmonitor.com.)

EXHIBIT C

New Hampshire Board of Nursing

Preamble to the Formulary

EXCLUSIONARY FORMULARY

PREAMBLE

The following formulary applies to all A.R.N.P.'s licensed in the State of New Hampshire. It is developed and approved by the Joint Health Council. This revision, dated August 2007, replaces all previous formularies.

The following applies to this formulary:

1. It is an exclusionary formulary; i.e., if a drug is NOT listed, it is approved for use within an A.R.N.P.'s scope of practice.

2. There are two columns: the first, a list of drugs alphabetically by generic name; the second, a column marked "Exceptions" which further clarifies any restrictions or requirements.

3. If a drug is listed in the first column and there are no clarifications in the second column, that drug is totally restricted for A.R.N.P. use.

a. Example: apraclonidine ophthalmic. This drug is listed in the first column. Therefore it is restricted for A.R.N.P. use. The second column is blank. Thus, there are no exceptions to that restriction. The restriction is total.

4. If a drug is listed in the first column, it is restricted unless that restriction is modified or clarified in the second column (i.e., an "exception" to that restriction.)

a. Example: alprostadil. This drug is listed in the first column. Therefore it is restricted for A.R.N.P. use. The second column notes: "Permitted with physician consultation." Thus, although this drug is restricted, it is permitted with physician consultation, within the A.R.N.P.'s scope of practice. The restriction is not total, as with the example in (3) above.

5. For combination drugs with more than one active ingredient, if one ingredient is restricted, the entire combination drug is restricted.

6. If a drug is restricted to "renewal of physician initiated prescription," the A.R.N.P. must write the letter "R" on the face of the prescription or the order sheet.

DEFINITIONS

1. CONSULTATION: Consultation is defined as written communication with a practitioner who has expertise in the pharmacologic management of a particular patient condition. The written communication shall appear in the patient's medical

record. Dosage adjustments consistent with appropriate clinical monitoring may be performed by an ARNP once initial consultation communication is in place, as long as specific consultant recommendations regarding dosing and follow up care occur. (Revised 5/21/07).

2. COLLABORATION: Collaboration is defined as a discussion or other mode of communication between the ARNP and another practitioner who has expertise in the pharmacological management of a particular patient condition. This requirement may be satisfied by the use of specific group protocol or established practice parameters. (Revised 11/28/05).

3. PHYSICIAN: A Doctor of Medicine or Doctor of Osteopathy currently licensed in 1 of the 50 United States.

4. INSTITUTION: Institution is defined as a health care facility that provides in-patient care and includes hospitals, nursing homes, extended care facilities, residential care facilities, infirmaries and clinics.

5. PARENTERAL: Parenteral means by injection (intradermal, subcutaneous, intramuscular, intravenous, or per non-enteral catheter.)

6. RENEWAL OF PHYSICIAN INITIATED PRESCRIPTION: Renewal of a physician initiated prescription without change in dose.

GENERIC NAME	EXCEPTION	Last Reviewed
abacavir	Approved for use with an Infectious Disease consultation. Collaboration for ARNPs working in a HIV clinic.	6-5-2006
abacavir/lamivudine/ zidovudine	Approved for use with an Infectious Disease consultation. Collaboration for ARNPs working in a HIV clinic.	6-5-2006
acetazolamide	Collaboration	6-5-2006
acetylcholine chloride ophthalmic	Restricted	
acyclovir injection	Collaborative use in an institutional setting.	
adefovir dipivoxil	Collaboration for ARNPs working in an Infectious Disease or Gastroenterology setting. Other use requires consultation.	6-5-2006
adenosine	Collaborative use for Cardiology and Critical Care ARNP's. No restriction for use in ACLS protocol.	
alatrofloxacin	Restricted	
aldesleukin	Consultation in Heme/Onc setting otherwise restricted.	9/5/2006

mercaptopurine	Consultation in a heme/onc setting and Inflamitory Bowel Disease Clinic otherwise restricted.	9/5/2006
meretek UBT Kit w/pranactin	Restricted	
mesna	Consultation in a heme/onc setting otherwise restricted.	9/5/2006
metaraminol	Consultation required	
methimazole	Restricted	
methocarbamol injection	Collaboration required	
methohexital	Approved for CRNA use only.	
methotrexate	Consultation in heme/onc setting, non heme/onc use requires collaboration.	11/28/2006
methoxamine	Collaboration required.	11/28/2006
methoxyflurane	Approved for CRNA use only.	
methyldopate injection	Collaboration required.	11/28/2006
methylergonovine	Approved for use by CNM only	
methylphenidate	Approved for Psych/ MentalHealth, CRNA's, Family, Adult, and Pediatric use.	
methylprednisolone ophthalmic	Restricted	
methyltestosterone	Consultation in heme/onc setting. Collaboration in all other settings.	11/28/2006
metipranolol ophthalmic	Restricted	
metoclopramide injection	Approved for use in an oncology setting. Approved for CRNA and CNM use, all others require collaboration.	
metocurine	Unrestricted for CRNA's. All others Consultation required.	11/28/2006
metoprolol injection	Approved for CRNA use. All other NPs institutional use only in collaboration.	9/8/03
metronidazole injection	Collaboration required	
mexiletine HCl	Unrestricted in pain clinic setting. Consultation for all other use.	11/28/2006
mibefradil	Restricted	
midazolam injection	Unrestricted use for CRNA's. Collaborative use for Critical Care ARNP's.	3/10/03
midodrine injection	Consultation only.	11/28/2006
mifepristone	Permitted under the supervision of a physician who meets the federal prescriber's agreement.	
mitomycin	Consultation in a heme/onc setting otherwise restricted.	11/28/2006

EXHIBIT D

MIFEPREX®
(Mifepristone) Tablets, 200 mg

PRESCRIBER'S AGREEMENT

We are pleased that you wish to become a provider of Mifeprex* (Mifepristone) Tablets, 200 mg, which is indicated for the medical termination of intrauterine pregnancy through 49 days from the first day of the patient's last menstrual period (see full prescribing information). Prescribing Information, Mifeprex Medication Guides and PATIENT AGREEMENT forms will be provided together with your order of Mifeprex.

Prior to establishing your account and receiving your first order, you must sign and return this letter to the distributor, indicating that you have met the qualifications outlined below and will observe the guidelines outlined below. If you oversee more than one office facility, you will need to list each facility on your order form prior to shipping the first order.

By signing the reverse side, you acknowledge receipt of the PRESCRIBER'S AGREEMENT and agree that you meet these qualifications and that you will follow these guidelines for use. You also understand that if you do not follow these guidelines, the distributor may discontinue distribution of the drug to you.

Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex. The prescribing information is attached to this letter, and is also available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to these qualifications, you must provide Mifeprex in a manner consistent with the following guidelines.

- Under Federal law, each patient must be provided with a Medication Guide. You must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and PATIENT AGREEMENT, give her an opportunity to read and discuss them, obtain her signature on the PATIENT AGREEMENT, and sign it yourself.
- The patient's follow-up visit at approximately 14 days is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications. You must notify Danco Laboratories in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.
- While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.
- Each package of Mifeprex has a serial number. As part of maintaining complete records for each patient, you must record this identification number in each patient's record.

Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

EXHIBIT E

PATIENT AGREEMENT
Mifeprex (mifepristone) Tablets

1. I have read the attached Medication Guide for using Mifeprex and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office.
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will. I have the provider's name, address and phone number.
12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I will do the following:

- return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
- return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well

Patient Signature: _____

Patient Name (print): _____

Date: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the Medication Guide for mifepristone.

Provider's Signature: _____

Name of Provider print: _____

Date: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the Medication Guide to the patient.

9/21/00

EXHIBIT F

United States Government Accountability Office

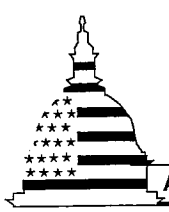
GAO

Report to Congressional Requesters

August 2008

FOOD AND DRUG ADMINISTRATION

Approval and Oversight of the Drug Mifeprex



GAO

Accountability * Integrity * Reliability

GAO-08-751

restrictions requested by FDA. However, in a September 2000 letter to FDA, the sponsor agreed to FDA's requirement that approval be under Subpart H, while noting that it still believed that applying these regulations to Mifeprex was not appropriate.

- Conditions of Use: FDA reviewed data and held multiple meetings with the sponsor regarding the specific conditions of use that should be required for Mifeprex. For example, FDA deliberated about whether it was necessary to require that prescribing physicians possess the ability to perform follow-up surgical interventions in the event that it was necessary to manage complications. The sponsor maintained that such a requirement was inconsistent with the practice of medicine, because management of incomplete miscarriages was routinely handled by referring patients to outside providers with specialized surgical or emergency care training. On this issue, FDA concluded that access to follow-up care could be ensured by requiring adequate information in the labeling and requiring that physicians attest to having made arrangements for their patients to have access to any needed surgical or emergency care. The SGE consultant agreed with FDA's conclusion. FDA disagreed with the sponsor on other suggested conditions of use. For example, the sponsor provided data to support allowing patients to self-administer the misoprostol dose at home, instead of requiring them to return to their prescribing physicians. FDA concluded that the available data did not support the safety of home use of misoprostol and that such use should not be included in the final product label. As a part of its deliberations about the conditions of use, FDA also concluded that approved labeling should include a medication guide to provide patients with information about the risks and benefits of the drug and the approved conditions of use and treatment regimen.[44]

- Postmarketing Study Commitments: In both the September 1996 and February 2000 approvable letters, FDA had reminded the sponsor of its commitment to conduct a series of six postmarket studies to address comments raised in the 1996 advisory committee meeting. FDA reviewed data and met with the sponsor during the final stages of its review to revisit these commitments in light of experience gained with the treatment regimen since the advisory committee meeting, concerns about potential infringement on the privacy of patients, and the potential resources needed to fulfill all six commitments. FDA concluded that the originally proposed commitments could be sufficiently addressed in two redesigned

[44]FDA may require that a drug be distributed with a medication guide that provides patients with information about the safe and effective use of the drug. See 21 C.F.R. pt. 208 (2007).

EXHIBIT G

RCM 2007-525
NDA 20-687
Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011

The following information is from United States post-marketing reports (i.e., not from a clinical trial) received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use and other possible medical or surgical treatments. The estimated number of women who have used mifepristone in the US through the end of April 2011 is approximately 1.52 million women.

Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy	
Cut off date of cumulative reports since approval date in US (September 2000)	04/30/11
Cases with any adverse event	2207
Died [1]	14
Hospitalized, excluding deaths	612
*Ectopic pregnancies [2]	58
*Experienced blood loss requiring transfusions [3]	339
*Infections [4] (Severe infections[5])	256 (48)

* The majority of these women are included in the hospitalized category.

[1] Deaths were associated with sepsis in eight of the 14 reported fatalities (7 cases tested positive for *Clostridium sordellii,* 1 case tested positive for *Clostridium perfringens).* All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome (uterine cultures were positive for *Peptostreptococcus* and fibroid cultures were positive for *Prevotella*), and there were two cases of ruptured ectopic pregnancy. There were five additional deaths in women from foreign countries (non-US) who used mifepristone for termination of pregnancy. These included one death associated with septic shock (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial and four deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, "multivisceral failure" and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, respectively.

[2] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

[3] As stated in the approved Mifeprex (mifepristone) labeling, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

[4] This category includes endometritis (involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as Chlamydia infections and gonorrhea, cystitis and women with toxic shock syndrome not associated with a pelvic infection.

[5] This subset of infections includes cases that were determined to be severe based on medical review of the case details. Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours, total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

EXHIBIT H

Planned Parenthood® of Northern New England

- Home
- Who We Are
- For Parents
- For Patients
  - Abortion Services
    - The Abortion Pill
    - In-Clinic Abortion
  - Birth Control Options
  - Emergency Contraception
  - Sexually Transmitted Infections & Diseases (STIs & STDs)
  - Locations and Hours
  - Request an Appointment
  - Payment Information
  - Give us Feedback!
  - Access Plan
  - BlueMail
  - Green Mountain Care
  - Clinical Mental Health Counseling Services
  - Patient Privacy Notice (HIPAA)
  - Patient Safety Zone
- For Teens
- Get Involved
- Education & Training
- News
- Jobs
- Volunteer
- Contact Us

FOLLOW

- Facebook
- Twitter
- A Naked Notion
- Good Chemistry

SHARE +

The Abortion Pill

The abortion pill is a medicine called mifepristone that ends an early pregnancy.

The Abortion Pill at a Glance

- Take medicines to end an early pregnancy
- Safe and effective
- Available from many Planned Parenthood of Northern New England health centers
- Costs about $300—$800

Thinking about abortion? Call 1-866-476-1321 to make an appointment at the Planned Parenthood of Northern New England health center nearest you.

A woman has many decisions to make when considering abortion. If you're thinking about abortion, your health care provider may talk with you about a few different abortion methods. You may be offered the option to have an **in-clinic abortion procedure**. Or you may be offered the option to have a medication abortion by taking the abortion pill. Medication abortion is the kind of abortion discussed on this page.

Whether you're thinking about having a medication abortion, you're concerned about a woman who may be having one, or you're someone who's just curious about medication abortion, you may have many questions. Here are some of the most common questions we hear women ask about the abortion pill. We hope you find the answers helpful. And if you're thinking of having a medication abortion, we hope they help you decide what is best for you.

If you are under 18, your state may require one or both of your parents to give permission for your abortion or be told of your decision prior to the abortion. However, in most states you can ask a judge to excuse you

from these requirements. Learn more about parental consent for abortion.

What Is the Abortion Pill?

The abortion pill is a medicine that ends an early pregnancy. In general, it can be used up to 63 days — 9 weeks — after the first day of a woman's last period. Women who need an abortion and are more than 9 weeks pregnant can have an **in-clinic abortion.**

The name for "the abortion pill" is **mifepristone**. It was called RU-486 when it was being developed.

How Effective Is the Abortion Pill?

What Happens During a Medication Abortion?

It's common for women to be nervous about having a medication abortion — or any other medical procedure. But many of us feel better if we know what to expect. Your health care provider will talk with you and answer your questions. Here's a general idea of how it works and what to expect.

Before taking the abortion pill, you will need to

- discuss your options
- talk about your medical history
- have laboratory tests
- have a physical exam. This usually includes an ultrasound.
- read and sign papers

You will also be given a medication guide, instructions, and other information to take home with you, including a 24-hours-a-day, seven-days-a-week telephone number you can call if you have any questions or concerns.

Medication abortion is a process that begins immediately after taking the abortion pill.

There are three steps:

STEP ONE — THE ABORTION PILL

Your health care provider will give you the abortion pill at the clinic. You will also be given some antibiotics to start taking after the abortion pill.

The abortion pill works by blocking the hormone progesterone. Without progesterone, the lining of the uterus breaks down, and pregnancy cannot continue.

STEP TWO — MISOPROSTOL

You will take a second medicine — misoprostol. It causes the uterus to empty.

You and your health care provider will plan the timing and place for the second step. You'll take the second medicine up to three days after taking the abortion pill. Your health care provider will give you instructions on how and when to take the second medicine.

The second medicine — misoprostol — will cause you to have cramps and bleed heavily. Some women may begin bleeding before taking the second medicine. But for most, the bleeding and cramping begin after taking it. It usually lasts a few hours. You may see large blood clots or tissue at the time of the abortion.

More than half of women abort within four or five hours after taking the second medicine. For others, it takes longer. But most women abort within a few days.

It's normal to have some bleeding or spotting for up to four weeks after the abortion. You may use sanitary pads or tampons. But using pads makes it easier to keep track of your bleeding.

How Does Medication Abortion Feel?

For most women, medication abortion is like an early miscarriage. It is normal for you to have bleeding and cramping. You might also

- feel dizzy
- feel strong cramps
- feel nauseous or vomit
- have diarrhea
- feel temporary abdominal pain
- have temporary mild fever or chills

Acetaminophen (like Tylenol) or ibuprofen (like Advil) can reduce most of these symptoms. Do not take aspirin.

You may feel more at ease if you have a trusted loved one with you during the abortion.

STEP THREE — FOLLOW-UP

You will need to follow up within two weeks. Follow-up is important to make sure your abortion is complete and that you are well. You will need an ultrasound or blood test.

In the unlikely event that you are still pregnant, your health care provider will discuss your options with you. It's likely you will need to have an aspiration abortion if the medication abortion did not end the pregnancy.

How Safe Is the Abortion Pill?

Why Do Women Choose the Abortion Pill?

- It can be done early — women can begin treatment as soon as they know they are pregnant.
- It's private — women may complete the process of abortion at home.
- There's usually no anesthesia.
- Many women feel it's more "natural" — they feel it is more like miscarriage.
- Women may feel more in control — many feel it is less invasive.

Nearly all women who have used the abortion pill would recommend the method to a friend.

What Can I Expect After Using the Abortion Pill?

Where Can I Get a Medication Abortion? How Much Does Medication Abortion Cost?

EXHIBIT I

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7060

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 8 MIDDLE ST *City/Town of* KEENE

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

-THE BOARD MUST BE NOTIFIED OF ANY CHANGES OF PHYSICAL LOCATION OR MAILING ADDRESS WITHIN 15 DAYS OF CHANGE. CHANGES OF OWNERSHIP REQUIRE A NEW APPLICATION / FEE BE SUBMITTED.

-NOTICE OF ADDRESS CHANGES CAN BE SENT BY E-MAIL TO: pharmacy.board@nh.gov

FAX: (603) 271-2856

OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7058

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 24 PENNACOOK ST *City/Town of* MANCHESTER

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

-THE BOARD MUST BE NOTIFIED OF ANY CHANGES OF PHYSICAL LOCATION OR MAILING ADDRESS WITHIN 15 DAYS OF CHANGE. CHANGES OF OWNERSHIP REQUIRE A NEW APPLICATION / FEE BE SUBMITTED.

-NOTICE OF ADDRESS CHANGES CAN BE SENT BY E-MAIL TO: pharmacy.board@nh.gov

FAX: (603) 271-2856

OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7053

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 4 BIRCH ST *City/Town of* DERRY

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

-THE BOARD MUST BE NOTIFIED OF ANY CHANGES OF PHYSICAL LOCATION OR MAILING ADDRESS WITHIN 15 DAYS OF CHANGE. CHANGES OF OWNERSHIP REQUIRE A NEW APPLICATION / FEE BE SUBMITTED.

-NOTICE OF ADDRESS CHANGES CAN BE SENT BY E-MAIL TO: pharmacy.board@nh.gov

FAX: (603) 271-2856

OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7052

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 108 HIGH ST *City/Town of* EXETER

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

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OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7048

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 136 PLEASANT ST *City/Town of* CLAREMONT

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

-THE BOARD MUST BE NOTIFIED OF ANY CHANGES OF PHYSICAL LOCATION OR MAILING ADDRESS WITHIN 15 DAYS OF CHANGE. CHANGES OF OWNERSHIP REQUIRE A NEW APPLICATION / FEE BE SUBMITTED.

-NOTICE OF ADDRESS CHANGES CAN BE SENT BY E-MAIL TO: pharmacy.board@nh.gov

FAX: (603) 271-2856

OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

State of New Hampshire

BOARD OF PHARMACY

2013 2014

LIMITED RETAIL DRUG DISTRIBUTOR

PUBLIC HEALTH CLINIC

No. 7047

This is to Certify *that* PLANNED PARENTHOOD OF NORTHERN NE

located at 89 S MAIN ST *City/Town of* WEST LEBANON

is duly licensed under the provisions of chapter 318 and 318-B, New Hampshire Revised Statutes Annotated.

THIS PERMIT EXPIRES ON JUNE 30, 2014

Executive Secretary

*PLEASE NOTE: THE ABOVE PERMIT EXPIRES ON JUNE 30, 2014. A RENEWAL APPLICATION WILL BE SENT TO THE CONTACT ADDRESS LISTED ON THE APPPLICATION FOR PERMIT APPROXIMATELY 60 DAYS PRIOR TO THE EXPIRATION DATE.

-THE BOARD MUST BE NOTIFIED OF ANY CHANGES OF PHYSICAL LOCATION OR MAILING ADDRESS WITHIN 15 DAYS OF CHANGE. CHANGES OF OWNERSHIP REQUIRE A NEW APPLICATION / FEE BE SUBMITTED.

-NOTICE OF ADDRESS CHANGES CAN BE SENT BY E-MAIL TO: pharmacy.board@nh.gov

FAX: (603) 271-2856

OR BY U.S. MAIL TO:

STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY
57 REGIONAL DR
CONCORD NH 03301-8518

EXHIBIT J

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Direct Dial: (603) 206-7239
mtierney@wadleighlaw.com

June 17, 2013

New Hampshire Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518
Via regular mail and e-mail: pharmacy.board@nh.gov

Re: Planned Parenthood's applications for a limited retail drug distributorship license for 2013 to 2014

Dear Board of Pharmacy:

I am writing on behalf of my client, New Hampshire Right to Life, in objection to the granting of licenses to Planned Parenthood for its six locations for the 2013-2014 limited drug distributorship license year, should they apply for licenses this year. In addition, we are requesting that the BOP take all appropriate action to stop the dispensation of the abortion pill for take home use and in excess of 49 days pregnancy in violation of FDA protocols and New Hampshire law.

As you are aware, a limited retail drug distributorship license may only be granted to an entity possessing a contract with the New Hampshire Department of Health and Human Services for family planning services. Planned Parenthood does not possess a contract with the New Hampshire Department of Health and Human Services and has not possessed a contract with the New Hampshire Department of Health and Human Services since June 30, 2011. Although Planned Parenthood had previously argued that their federal Title X contract should be accepted in lieu of a State contract, their federal contract expired on December 30, 2012. Upon information and belief, Planned Parenthood has continued to dispense prescription drugs for the past six months even though it never had a State or a federal contract as required by RSA 318:42, VII. Whereas Planned Parenthood still does not possess the statutorily required contract, the Board cannot lawfully grant a limited retail drug distributorship license to Planned Parenthood pursuant to RSA 318:42 (VII).[1]

[1] The Board is also reminded that neither the Board nor its Executive Director may "ministerially grant" a temporary permit on the expectation that Planned Parenthood will obtain a contract in the future. RSA 541-A:30

In addition, it has previously been argued that because Planned Parenthood has physicians or APRNs who can ***administer*** prescription drugs to their patients, that others working for Planned Parenthood should be allowed to ***dispense*** prescription drugs for patients to take home with them. This argument ignores the legal difference between administering and dispensing drugs. RSA 318:42 (II) provides that MDs and APRNs can administer drugs but does not grant them the authority to dispense drugs. RSA 318:1 (I) defines "administer" to be "a single dose ... for immediate consumption or use" while "dispense" is defined by RSA 318:1 (V) "to distribute ... one or more doses of a drug." Therefore, while Planned Parenthood's MDs and APRNs may administer drugs for their clients' immediate use, Planned Parenthood's MDs and APRNs may **NOT** dispense drugs for their take home use. Planned Parenthood's practitioners, like any other practitioner, must write prescriptions to be filled at a licensed pharmacy.

It is particularly problematic that Planned Parenthood announced it has a nationwide policy of distributing the abortion pill (otherwise known as RU 486) for ***take home use*** instead of being personally administered by a surgeon capable of performing a surgical procedure in case of complications. Planned Parenthood Southwest Ohio Region v. Dewine, 696 F.2d 490, 495 (6th Cir. October 2, 2012). In particular, the FDA protocols require that "Mifepristone requires three office visits by the patient." Cordray v. Planned Parenthood Cincinnati Region, 911 N.E.2d 871, 877 (Ohio 2009). In addition, the FDA protocol prohibits the use of Mifepristone to induce abortion past 49 days of pregnancy. Id. RSA 318:42 (VII)(A) prohibits dispensation contrary to the nurses' formulary and the formulary provides that Mifepristone is only permitted under the supervision of a physician who meets the federal prescriber's agreement. Therefore, the Board of Pharmacy cannot lawfully grant a license to an entity wishing to dispense Mifepristone for take home use, nor an entity that wishes to induce abortion by Mifepristone past 49 days of pregnancy. Nevertheless, in a video on its website, [2]Planned Parenthood of Northern New England advertises that the abortion pill is available up to 63 days of pregnancy and that the process of abortion can be completed at home with drugs dispensed to them. The Board of Pharmacy cannot grant Planned Parenthood a license to distribute the abortion pill contrary to the formulary and FDA protocol. Furthermore, regardless of whether PPNNE applies for LRDD licenses, the Board of Pharmacy cannot allow distribution of the abortion pill past 49 days pregnancy and for take home use.

Finally, whereas NHRTL possesses information that may assist the Board of Pharmacy in performing its regulatory duties and NHRTL would be harmed by the Board of Pharmacy misapplying the law with regard to regulated entities, NHRTL respectfully requests that the

---

provides for ministerial renewal only in such cases where there has been a "timely and ***sufficient*** application" and the existing license "does not automatically expire by law." First, RSA 318:51-B (I) provides that limited retail drug distributorship licenses "shall expire annually on June 30." Second, a family planning contract is a necessary part of any application and whereas Planned Parenthood has not obtained a contract, their application should be deemed insufficient.

[2] See http://www.plannedparenthood.org/ppnne/abortion-pill-40598.htm See also http://www.youtube.com/watch?feature=player_embedded&v=0U20nhWCzJ0

Board of Pharmacy allow it to intervene as a party to consideration of Planned Parenthood's applications for limited retail drug distributorship licenses for the time period July 1, 2013 through June 30, 2014 pursuant to New Hampshire Administrative Rule PH 204.07 (B)(1-3). Should PPNNE not apply for licenses, NHRTL respectfully requests that the Board of Pharmacy allow intervention for whatever action the BOP takes to stop PPNNE from dispensing the abortion pill past 49 days of pregnancy and for take home use in violation of FDA protocols and New Hampshire law.

Very truly yours,

Michael J. Tierney

MJT/pad
cc: Kurt Wuelper, President, NH Right to Life via e-mail
Lynn Cusack, Attorney for Board of Pharmacy via e-mail
Mary Ann Dempsey, Esq., AG's office, via e-mail

EXHIBIT K

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mtierney@wadleighlaw.com

July 3, 2013

New Hampshire Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518
Via regular mail and e-mail: pharmacy.board@nh.gov

Re: Planned Parenthood's Applications for a Limited Retail Drug Distributorship License for July 1, 2013 – June 30, 2014

Dear Board of Pharmacy:

I am writing on behalf of my clients, Betty Buzzell. Robert Carbone and Kurt Wuelper, taxpayers from Richmond and Strafford, New Hampshire as well as New Hampshire Right to Life, a non-profit organization whose members reside in all parts of New Hampshire. We respectfully object to the Board of Pharmacy granting any limited retail drug distributorship licenses to Planned Parenthood of Northern New England as Planned Parenthood does not (1) possess a family planning contract from the State of New Hampshire as required by RSA 318:42 (VII); (2) PPNNE advertises that it distributes the abortion drug for take home use and past 49 days of pregnancy contrary to the requirement of RSA 318:42 (VII)(a); and (3) Planned Parenthood has knowingly participated in having its patients and providers sign the FDA and New Hampshire State required patient agreement providing that the abortion pill will not be taken past 49 days of pregnancy and will only be taken in the surgeon's office while simultaneously advertising that the abortion pill regimen can be taken at home and up to 63 days pregnancy. Use of the abortion pill, contrary to FDA protocols, has resulted in 2,207 adverse events and 14 maternal deaths which is why the FDA and the State of New Hampshire imposed these restrictions.

First, RSA 318:42 (VII) requires that Planned Parenthood obtain a contract with the Department of Health & Human Services for the State of New Hampshire for family planning services. Planned Parenthood does not currently possess a contract with the New Hampshire Department of Health & Human Services and has not possessed a contract with the New Hampshire Department of Health & Human Services since June 30, 2011. Planned Parenthood's expectations that it will obtain a license in the future is insufficient for obtaining a limited retail

drug distributorship license. RSA 318:51-B (I) clearly provides that a full application must be submitted "annually on or before July 1" and that any previous license "shall expire annually on June 30." Should Planned Parenthood obtain a contract subsequent to today, and they were to meet all of the other requirements, they would be able to apply for a license effective July 1, 2014.

Second, a limited retail drug distributorship license only permits the dispensing of drugs from the nurse formulary. RSA 318:42 (VII)(B). I have attached a copy of the relevant page of the formulary as Exhibit A to this letter. The formulary clearly provides that Mifepristone is only permitted pursuant to the Federal Prescriber's Agreement. A copy of the Federal Prescriber's Agreement is attached as Exhibit B. As you can see, Mifepristone is not to be used for termination of pregnancy past 49 days and specifically requires the signing of a patient agreement by both the patient and the provider. A copy of the required patient agreement is attached as Exhibit C. The patient agreement makes clear, in Paragraphs 5 and 6, that providers must administer Mifeprex (Mifepristone) in the provider's office on Day 1 and then administer[1] Misoprostol in the provider's office on Day 3.

While the requirements under New Hampshire law to have the two doses of the abortion pill personally administered in a physician's office, as well as the prohibition against using the abortion pill past 49 days of pregnancy are abundantly clear, Planned Parenthood of Northern New England advertises on its website that the abortion pill is available up to 63 days of pregnancy and that the process of abortion can be completed at home with drugs dispensed to the patient for take home use.[2] The Board of Pharmacy cannot grant a license to Planned Parenthood to allow distribution of the abortion pill past 49 days of pregnancy and for take home use contrary to New Hampshire law.

Third, the Board of Pharmacy cannot grant licenses to an organization that refuses to sign the lawfully required patient agreement and/or causing its providers and patients to fraudulently sign such patient agreement when the agreement clearly provides that the pill cannot be taken past 49 days of pregnancy, nor can it be taken for at home use. Regardless, such lack of candor is an independent reason to deny the granting of licenses pursuant to RSA 318:51-B.

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[1] It has previously been argued that because Planned Parenthood has physicians or APRNs who can ***administer*** prescription drugs to their patients, that others working for Planned Parenthood should be allowed to ***dispense*** prescription drugs for patients to take home with them. This argument ignores the legal difference between administering and dispensing drugs. RSA 318:42 (II) provides that MDs and APRNs can administer drugs but does not grant them the authority to dispense drugs. RSA 318:1 (I) defines "administer" to be "a single dose ... for immediate consumption or use" while "dispense" is defined by RSA 318:1 (V) "to distribute ... one or more doses of a drug." Therefore, while Planned Parenthood's MDs and APRNs may administer drugs for their clients' immediate use, Planned Parenthood's MDs and APRNs may **NOT** dispense drugs for their take home use. Planned Parenthood's practitioners, like any other practitioner, must write prescriptions to be filled at a licensed pharmacy.

[2] See http://www.plannedparenthood.org/ppnne/abortion-pill-40598.htm See also http://www.youtube.com/watch?feature=player_embedded&v=0U20nhWCzJ0

Finally, the FDA has required such restrictions on the use of Mifepristone due to the inherent dangers of using Mifepristone past 49 days of pregnancy and self administering the second dose at home. In fact, the FDA expressly rejected the sponsor's suggestion that patients be allowed to self administer Misoprostol at home. See United States Government Accountability Office, GAO Report: Approval and Oversight of the drug Mifeprex at 23.[3] The FDA, and by incorporation New Hampshire law, has specifically restricted the use of Mifepristone to the requirement in the Federal Prescriber's and Patient's Agreements as a requirement under its approval under subpart H. Drugs approved with post marketing restrictions under 21 C.F.R. §314.520 are those that "would not have been approved for use without those restrictions because the risk/benefit balance would not justify such approval." 57 Fed. Reg. 58942, 58949. The concern over off label use have proven true. An FDA report in 2011 acknowledged that at least 2,207 cases of severe adverse events, including hemorrhaging, blood loss requiring transfusion, serious infection and even 14 deaths have resulted from the off label use. (FDA, Mifepristone US Post Marketing Adverse Event Summary, April 2011)[4] ("FDA investigated the deaths of 6 US women who developed a fatal infection [as of 2008] following treatment with Mifeprex for medical abortion. FDA has determined that in all 6 of the deaths, the women used a Mifeprex treatment regimen that has not been approved by FDA.")

As a matter of patient safety, the State of New Hampshire has lawfully prohibited the distribution of Mifepristone contrary to the Federal Provider Agreement and the Patient Agreement. See RSA 318:42 (VII)(b) and Exhibits B and C. Nevertheless, Planned Parenthood has, in New Hampshire, as they have done in other states, refused to follow the lawful prohibitions against distributing the abortion pill for take home use and/or administering the abortion pill past 49 days of pregnancy. See Planned Parenthood Southwest Ohio Region v. Dewine, 696 F.2d 490 (6th Cir. October 2, 2012) (affirming the State of Ohio's decision to protect patient safety by prohibiting use past 49 days or take home use against challenge by Planned Parenthood that their nationwide policy of ignoring the Federal Prescriber Agreement is just as safe).

The Board of Pharmacy must follow New Hampshire law and deny Planned Parenthood limited retail drug distributorship licenses for their willful failure to follow the required Federal Prescriber's Agreement.

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[3] Available at www.gao.gov/new.items/d08751.pdf (last visited July 1, 2013). "FDA concluded that the available data did not support the safety of home use of Misoprostol."

[4] Available at www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm263353.pdf (last visited July 1, 2013) See also GAO Report at 7, referenced in footnote 3.

Very truly yours,

Michael J. Tierney

MJT/pad
Enclosures
cc: Elizabeth Buzzell
Robert Carbone
Kurt Wuelper, President, NH Right to Life
Mary Ann Dempsey, Esq.
Lyn Cusack, Esq.

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EXHIBIT A

New Hampshire Board of Nursing

Preamble to the Formulary

EXCLUSIONARY FORMULARY

PREAMBLE

The following formulary applies to all A.R.N.P.'s licensed in the State of New Hampshire. It is developed and approved by the Joint Health Council. This revision, dated August 2007, replaces all previous formularies.

The following applies to this formulary:

1. It is an exclusionary formulary; i.e., if a drug is NOT listed, it is approved for use within an A.R.N.P.'s scope of practice.

2. There are two columns: the first, a list of drugs alphabetically by generic name; the second, a column marked "Exceptions" which further clarifies any restrictions or requirements.

3. If a drug is listed in the first column and there are no clarifications in the second column, that drug is totally restricted for A.R.N.P. use.

a. Example: apraclonidine ophthalmic. This drug is listed in the first column. Therefore it is restricted for A.R.N.P. use. The second column is blank. Thus, there are no exceptions to that restriction. The restriction is total.

4. If a drug is listed in the first column, it is restricted unless that restriction is modified or clarified in the second column (i.e., an "exception" to that restriction.)

a. Example: alprostadil. This drug is listed in the first column. Therefore it is restricted for A.R.N.P. use. The second column notes: "Permitted with physician consultation." Thus, although this drug is restricted, it is permitted with physician consultation, within the A.R.N.P.'s scope of practice. The restriction is not total, as with the example in (3) above.

5. For combination drugs with more than one active ingredient, if one ingredient is restricted, the entire combination drug is restricted.

6. If a drug is restricted to "renewal of physician initiated prescription," the A.R.N.P. must write the letter "R" on the face of the prescription or the order sheet.

DEFINITIONS

1. CONSULTATION: Consultation is defined as written communication with a practitioner who has expertise in the pharmacologic management of a particular patient condition. The written communication shall appear in the patient's medical

mercaptopurine	Consultation in a heme/onc setting and Inflamitory Bowel Disease Clinic otherwise restricted.	9/5/2006
meretek UBT Kit w/pranactin	Restricted	
mesna	Consultation in a heme/onc setting otherwise restricted.	9/5/2006
metaraminol	Consultation required	
methimazole	Restricted	
methocarbamol injection	Collaboration required	
methohexital	Approved for CRNA use only.	
methotrexate	Consultation in heme/onc setting, non heme/onc use requires collaboration.	11/28/2006
methoxamine	Collaboration required.	11/28/2006
methoxyflurane	Approved for CRNA use only.	
methyldopate injection	Collaboration required.	11/28/2006
methylergonovine	Approved for use by CNM only	
methylphenidate	Approved for Psych/ MentalHealth, CRNA's, Family, Adult, and Pediatric use.	
methylprednisolone ophthalmic	Restricted	
methyltestosterone	Consultation in heme/onc setting. Collaboration in all other settings.	11/28/2006
metipranolol ophthalmic	Restricted	
metoclopramide injection	Approved for use in an oncology setting. Approved for CRNA and CNM use, all others require collaboration.	
metocurine	Unrestricted for CRNA's. All others Consultation required.	11/28/2006
metoprolol injection	Approved for CRNA use. All other NPs institutional use only in collaboration.	9/8/03
metronidazole injection	Collaboration required	
mexiletine HCl	Unrestricted in pain clinic setting. Consultation for all other use.	11/28/2006
mibefradil	Restricted	
midazolam injection	Unrestricted use for CRNA's. Collaborative use for Critical Care ARNP's.	3/10/03
midodrine injection	Consultation only.	11/28/2006
mifepristone	Permitted under the supervision of a physician who meets the federal prescriber's agreement.	
mitomycin	Consultation in a heme/onc setting otherwise restricted.	11/28/2006

EXHIBIT B

MIFEPREX™
(Mifepristone) Tablets, 200 mg

PRESCRIBER'S AGREEMENT

We are pleased that you wish to become a provider of Mifeprex* (Mifepristone) Tablets, 200 mg, which is indicated for the medical termination of intrauterine pregnancy through 49 days from the first day of the patient's last menstrual period (see full prescribing information). Prescribing Information, Mifeprex Medication Guides and PATIENT AGREEMENT forms will be provided together with your order of Mifeprex.

Prior to establishing your account and receiving your first order, you must sign and return this letter to the distributor, indicating that you have met the qualifications outlined below and will observe the guidelines outlined below. If you oversee more than one office facility, you will need to list each facility on your order form prior to shipping the first order.

By signing the reverse side, you acknowledge receipt of the PRESCRIBER'S AGREEMENT and agree that you meet these qualifications and that you will follow these guidelines for use. You also understand that if you do not follow these guidelines, the distributor may discontinue distribution of the drug to you.

Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex. The prescribing information is attached to this letter, and is also available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to these qualifications, you must provide Mifeprex in a manner consistent with the following guidelines.

- Under Federal law, each patient must be provided with a Medication Guide. You must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and PATIENT AGREEMENT, give her an opportunity to read and discuss them, obtain her signature on the PATIENT AGREEMENT, and sign it yourself.
- The patient's follow-up visit at approximately 14 days is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications. You must notify Danco Laboratories in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the

event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.

- While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.
- Each package of Mifeprex has a serial number. As part of maintaining complete records for each patient, you must record this serial number in each patient's record.

Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

EXHIBIT C

PATIENT AGREEMENT
Mifeprex® (mifepristone) Tablets

1. I have read the attached MEDICATION GUIDE for using Mifeprex* and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office (Day 1).
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will. I have that provider's name, address and phone number.
12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I will do the following:
    - contact my provider right away if in the days after treatment I have a fever of 100.4°F or higher that lasts for more than 4 hours or severe abdominal pain.
    - contact my provider right away if I have heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours).
    - contact my provider right away if I have abdominal pain or discomfort, or I am "feeling sick", including weakness, nausea, vomiting or diarrhea, more than 24 hours after taking misoprostol.
    - take the MEDICATION GUIDE with me when I visit an emergency room or a provider who did not give me Mifeprex, so that they will understand that I am having a medical abortion with Mifeprex.
    - return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
    - return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well.

Patient Signature: _____

Patient Name (print): _____

Date: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____

Name of Provider (print): _____

Date: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the MEDICATION GUIDE to the patient.

Rev 2: 7/19/05

MIFEPREX®

(Mifepristone) Tablets, 200 mg

MEDICATION GUIDE

MEDICATION GUIDE

MIFEPREX® (Mifepristone) Tablets, 200 mg
For Oral Administration Only

Contact Information

Danco Laboratories
P.O. Box 4816
New York, NY 10185

1.877.4 EARLY OPTION
(1.877.432.7596)
www.earlyoptionpill.com

MEDICATION GUIDE

MIFEPREX® (MIF-eh-prex)
(mifepristone)

Read this information carefully before taking Mifeprex* and misoprostol. It will help you understand how the treatment works. This MEDICATION GUIDE does not take the place of talking with your health care provider (provider).

What is Mifeprex?

Mifeprex is used to end an early pregnancy. It blocks a hormone needed for your pregnancy to continue. It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (7 weeks) or less since your last menstrual period began. When you use Mifeprex (Day 1), you also need to take another medicine, misoprostol, 2 days after you take Mifeprex (Day 3) to end your pregnancy. But about 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances. Serious infection has resulted in death in a very small number of cases; in most of these cases misoprostol was used in the vagina. There is no information that use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your provider. Your provider's telephone number is _____.

* Mifeprex is a registered trademark of Danco Laboratories, LLC.

Be sure to contact your provider promptly if you have any of the following:

Heavy Bleeding. Contact your provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical abortion/D&C) to stop it.

Abdominal Pain or "Feeling Sick". If you have abdominal pain or discomfort, or you are "feeling sick", including weakness, nausea, vomiting or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

Fever. In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your provider right away. Fever may be a symptom of a serious infection or another problem (including an ectopic pregnancy).

Take this MEDICATION GUIDE with you. When you visit an emergency room or a provider who did not give you your Mifeprex, you should give them your MEDICATION GUIDE so that they understand that you are having a medical abortion with Mifeprex.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

Talk with your provider. Before you take Mifeprex, you should read this MEDICATION GUIDE and sign a statement (PATIENT AGREEMENT). You and your provider should discuss the benefits and risks of your using Mifeprex.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take it if:

- It has been more than 49 days (7 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your provider has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next 2 visits.
- You cannot easily get emergency medical help in the 2 weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Tell your provider about all your medical conditions to find out if you can take Mifeprex. Also, tell your provider if you smoke at least 10 cigarettes a day.

How should I take Mifeprex?

Day 1 at your provider's office:

- Read this MEDICATION GUIDE.
- Discuss the benefits and risks of using Mifeprex to end your pregnancy.
- If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
- After getting a physical exam, swallow 3 tablets of Mifeprex.

Day 3 at your provider's office:

- If you are still pregnant, take 2 misoprostol tablets.
- Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your provider may send you home with medicines for these symptoms.

About Day 14 at your provider's office:

- This follow-up visit is very important. You must return to the provider about 14 days after you have taken Mifeprex to be sure you are well and that you are not pregnant.
- Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your provider about them because they may interfere with the treatment. Ask your provider about what medicines you can take for pain.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your provider if you should stop breastfeeding for a few days.

What are the possible and reasonably likely side effects of Mifeprex?

Cramping and bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must return to your provider on Day 3 and about Day 14. See "How should I take Mifeprex?" for more information on when to return to your provider. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9–16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of ending the pregnancy.

Other common symptoms of treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. Your provider will tell you how to manage any pain or other side effects.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

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Medicines are sometimes prescribed for purposes other than those listed in a MEDICATION GUIDE. For more information, ask your provider for the information about Mifeprex that is written for health care professionals. Ask your provider if you have any questions.

This MEDICATION GUIDE has been approved by the U.S. Food and Drug Administration.

Rev 3: 4/22/09

PATIENT AGREEMENT

Mifeprex® (mifepristone) Tablets

1. I have read the attached Medication Guide for using Mifeprex and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office (Day 1).
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will. I have that provider's name, address and phone number.
12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.

14. I will do the following:

- contact my provider right away if in the days after treatment I have a fever of 100.4°F or higher that lasts for more than 4 hours or severe abdominal pain.
- contact my provider right away if I have heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours).
- contact my provider right away if I have abdominal pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol.
- take the MEDICATION GUIDE with me when I visit an emergency room or a provider who did not give me Mifeprex, so that they will understand that I am having a medical abortion with Mifeprex.
- return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
- return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well.

Patient Signature: _____

Patient Name (print): _____

Date: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____

Name of Provider (print): _____

Date: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the MEDICATION GUIDE to the patient.

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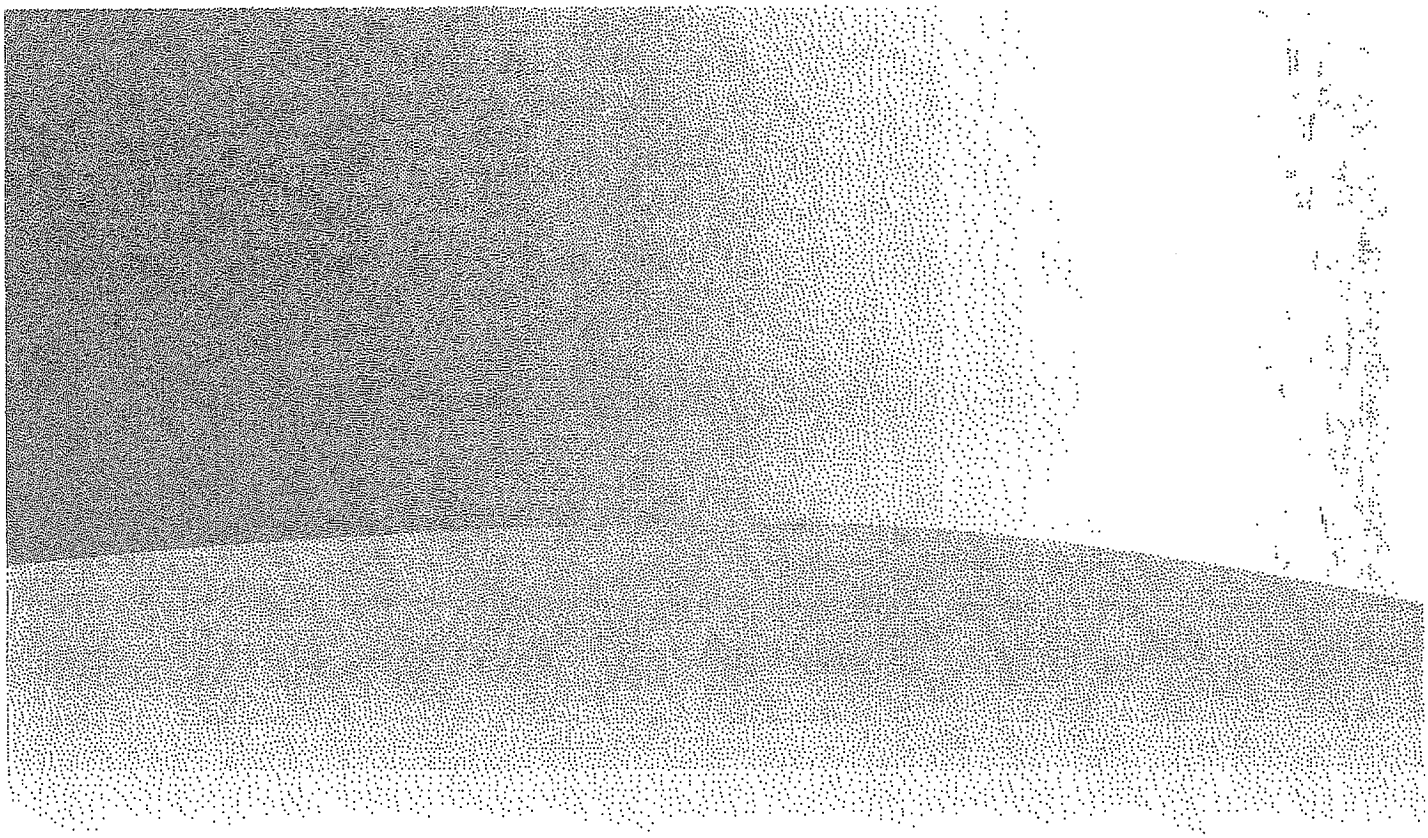

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