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125 Broad Street, 17th Fl.
New York, NY 10004
212.344.3005
212.344.3318
www.nyclu.org

Elisabeth Ryden Benjamin, M.S.P.H., J.D., Director
Galen Sherwin, J.D., Staff Attorney
Reproductive Rights Project

August 15, 2006

Mr. Richard Trumbull, Supervisor
Investigations Unit
Office of the Professions
New York State Department of Education
80 Wolff Road
Albany, NY 12205

*Re: Complaints by Dr. Marc Heller, M.D., Claudina Ashelman-Owen, R.N., and
Colleen Shaw, P.A. against Matt Weaver, Andrea Barcomb, & Lisa McGuiness*

Dear Mr. Trumbull:

We write on behalf of our clients, Dr. Marc Heller, Ms. Claudina Ashelman-Owen, and Ms. Colleen Shaw (“Complainants”) to set forth arguments in support of their Complaints, filed today before the New York State Department of Education, Office of the Professions, against Respondent pharmacists, Mr. Matt Weaver, Ms. Andrea Barcomb, and Ms. Lisa McGuiness (“Respondents”).

The Complainants respectfully request that the Office of the Professions discipline the Respondent pharmacists for professional misconduct for their failure to dispense prescriptions for Plan B Emergency Contraception (“EC”) as written. Respondents’ conduct violated the New York State pharmacy laws and regulations, professional guidelines, and New York State Human Rights Law.

In both cases described in the attached Complaints, the pharmacists filled the initial prescription for EC, but refused to recognize the refills that the treating medical professional had ordered. Because the effectiveness of EC in preventing pregnancy decreases as time passes, writing prescriptions for EC with refills is the standard of care, and is necessary so that women have access to EC as soon as they need it. The pharmacists offered judgmental—not medical—objections in support of their refusals.

The Respondents’ refusal to honor the prescribed refills interfered with the prescribers’ practice of medicine and harmed their patients by interfering with their ability to provide the standard of care, interfering with the practitioner-patient relationship, taking up the practitioner’s time, and harming the practitioner’s reputation in the community. In addition, Respondents’

actions interfered with the patients' ability to receive the standard of care and denied them equal access to the public accommodations provided by the pharmacy.

These harms were the direct result of the Pharmacists' factually and medically unwarranted assumptions about the patient's sexual practices and history, their moralistic judgments about women's normative sexuality, and their medical ignorance regarding the safety and standard of care for EC.

Complainants therefore respectfully request that the Office of the Professions discipline Respondents on the grounds that their actions: (1) lacked medical justification and therefore exceeded pharmacists' scope of authority; (2) violated New York State pharmacy laws, regulations and guidelines prohibiting the abandonment or neglect of a patient; (3) breached the pharmacist's duty of care to the patient, and (4) violated state laws prohibiting sex discrimination in public accommodations.

Complainants further request that the Board of Pharmacy issue a clarification of its Guidance specifying: (1) that the proscription against abandoning or neglecting a patient includes a duty to log and dispense refills for all duly written prescriptions; and (2) that refusals to provide professional services to patients on the basis of sex violates New York State law prohibiting discrimination in public accommodations.

PARTIES

Complainants:

Planned Parenthood of Mohawk/Hudson ("PPMH") is a health care organization that operates 12 sites in central/eastern New York serving 13 counties, including Essex, Fulton, Hamilton, Herkimer, Madison, Montgomery, Oneida, Saratoga, Schenectady, Schoharie, Warren, and Washington. Its facilities offer numerous services including: health information; community education for youth and parent groups; mid-life services; male and female sterilization counseling and referral; pregnancy testing, counseling and referral; sexually transmitted disease testing and counseling for females and males; routine gynecological examinations; pre-natal care; and contraception information and prescriptions, including prescriptions for Plan B Emergency Contraception.

Complainant Marc Heller, a duly licensed physician and board certified obstetrician and gynecologist, is the Medical Director of PPMH. *See* accompanying Complaint of Dr. Marc Heller, at ¶ 1 ("Heller Compl."). Complainant Claudina Ashelman-Owen is a duly licensed family nurse practitioner working at Planned Parenthood of Saratoga Springs, New York, a member of PPMH. *See* accompanying Complaint of Ms. Claudina Ashelman-Owen, R.N, at ¶ 1 ("Ashelman-Owen Compl."). Complainant Colleen Shaw is a physician Assistant working at Planned Parenthood of Gloversville, New York, a member of PPMH. *See* accompanying Complaint of Colleen Shaw, P.A., at ¶ 1 ("Shaw Compl."). Complainants Heller, Shaw and Ashelman-Owen have authority pursuant to New York law to write prescriptions for Plan B Emergency Contraception. *See* Heller Compl. at ¶ 2; Ashelman-Owen Compl. at ¶ 2; Shaw

Compl. at ¶ 2 (citing N.Y. Educ. Law §§ 6520 *et seq.*, 6542, 6902 (McKinney 2006); 10 N.Y.C.R.R. § 94.2 (2006)).

Subjects of Complaint:

Respondent Matt Weaver is a pharmacist licensed to fill prescriptions under title VIII of the New York Education Law, and is subject to the provisions of New York Education Law § 6509 (McKinney 2006) and 8 N.Y.C.R.R. §§ 29.1, 29.2, 29.7, 63.1 *et seq.* (2006). On November 30, 2005, Mr. Weaver was employed at CVS Store # 0731, located at 34 Congress Street, Saratoga, New York 12866. Ashelman-Owen Compl. ¶ 3; Heller Compl. ¶ 6.

Respondent Andrea Barcomb is a pharmacist licensed to fill prescriptions under title VIII of the New York Education Law, and is subject to the provisions of New York Education Law § 6509 and 8 N.Y.C.R.R. §§ 29.1, 29.2, 29.7, 63.1 *et seq.* Ms. Barcomb is supervisor to Matt Weaver. On November 30, 2005, Ms. Barcomb was employed at CVS store # 0731, located at 34 Congress Street, Saratoga Springs, New York 12866. Ashelman-Owen Compl. ¶ 4; Heller Compl. ¶ 7.

Respondent Lisa McGuinness is a pharmacist licensed to fill prescriptions under title VIII of the New York Education Law, and is subject to the provisions of New York Education Law § 6509 and 8 N.Y.C.R.R. §§ 29.1, 29.2, 29.7, 63.1 *et seq.* On February 3, 2006, Ms. McGuinness was employed at RiteAid pharmacy, located at 169 North Main Street, Gloversville, New York, 12087. Shaw Compl. ¶ 3; Heller Compl. ¶ 8.

FACTUAL ALLEGATIONS

Emergency Contraception:

EC, also known as postcoital contraception, “Plan B,” or “the morning after pill,” is a drug that can prevent a pregnancy from occurring if taken following an act of intercourse where the contraceptive method used failed or where no contraceptive was used. EC consists of the same hormones found in ordinary birth control pills, but is taken in a concentrated dose. Heller Compl. ¶ 15.¹ The form of EC that is approved for prescription use in the United States by the Food and Drug Administration is known as Plan B, which consists of the contraceptive drug Levonorgestrel in tablet form. *Id.* ¶ 16.² EC does not interfere with an established pregnancy. *Id.* ¶ 17.³

¹ Citing David A. Grimes & Elizabeth G. Raymond, *Emergency Contraception*, 137 *Annals of Internal Med.* E-180, E-183 (2002); David Weismiller, *Emergency Contraception*, 70 *Am. Fam. Physician* 707, 709 (2004).

² Citing Carton Text, Plan B, <http://www.fda.gov/cder/foi/label/1999/210451bl.pdf> (package label).

³ See Kristina Gemzell-Danielsson & L. Marions, *Mechanisms of Action of Mifepristone and Levonorgestrel When Used for Emergency Contraception*, 10 *Human Reproduction Update* 341 (2004); H.B. Croxatto et al., *Pituitary–Ovarian Function Following the Standard Levonorgestrel Emergency Contraceptive Dose or a Single 0.75-mg Dose Given on the Days Preceding Ovulation*, 70 *Contraception* 442 (2004); Weismiller, *supra* note 1, at 709.

When taken within 72 hours of unprotected intercourse, EC reduces the risk of pregnancy by approximately 89%. *Id.* ¶ 18.⁴ Although EC can be effective in preventing pregnancy when used up to 120 hours after intercourse, it is most effective if taken within 12-24 hours of unprotected sex. *Id.* As the interval between intercourse and the start of treatment increases, EC's effectiveness declines, and the risk of pregnancy increases significantly. *Id.*

Studies have found that EC is safe and effective, and that it has no known medical contraindications aside from a confirmed pregnancy. *Id.* ¶ 19.⁵ Although EC is not as effective in preventing pregnancy as some other methods of birth control, like hormonal contraception, repeated use of EC poses no health risks. *Id.* ¶¶ 19-20.⁶

The circumstances giving rise to a need for EC include sexual intercourse in which a contraceptive method was used but failed, unplanned sexual intercourse, sexual assault, and/or intercourse in which no birth control method was used. *Id.* ¶ 21.⁷ Contraceptive failure is a common reason for needing EC. For example, condoms, a commonly-used method of contraception, have been found to have breakage or slippage rates ranging between 3.9% and 14.6%. *Id.* ¶ 22.⁸ The need for EC frequently arises at times, such as vacations, weekends, or holidays, when regular doctors offices, including those of PPMH, are closed or inaccessible. *Id.* ¶ 23.⁹

Giving women advance access to EC, before an emergency need for it arises, can prevent delays in obtaining the drug, and help ensure that women who need it are able to take it as soon as possible after unprotected intercourse or contraceptive failure, increasing the chances of preventing an unwanted pregnancy. Numerous scholarly articles and studies support the provision of advance prescriptions for EC, for this very reason. *Id.* ¶ 24.¹⁰

⁴ Citing Carton Text, Plan B., *supra* note 2; Weismiller, *supra* note 1, at 709; Grimes, *supra* note 1, at E-183; Helena von Hertzen et al., *Low Dose Mifepristone and Two Regimens of Levonorgestrel for Emergency Contraception: a WHO Multicentre Randomised Trial*, 360 *The Lancet* 1803 (2002).

⁵ Citing World Health Organization, *Emergency Contraception: A Guide for Service Delivery*, 22-23 (1998).

⁶ Citing *id.* at 21, 24; Katrina Abuabara et al., *As Often as Needed: Appropriate Use of Emergency Contraceptive Pills*, 69 *Contraception* 339 (2004).

⁷ Citing Weismiller, *supra* note 1, at 707.

⁸ Citing James Trussell et al., *Condom Slippage and Breakage Rates*, 24 *Fam. Planning Perspectives* 20, 22 (1992); William R. Grady & Koray Tanfer, *Condom Breakage and Slippage Among Men in the United States*, 26 *Fam. Planning Perspectives* 107, 110 (1994); Richard A. Crosby, *Condom Use Errors and Problems Among College Men*, 29 *Sexually Transmitted Diseases* 552, 554 (2002); Rachel K. Jones et al., *Contraceptive Use among U.S. Women Having Abortions, 2000-2001*, 34 *Perspectives on Sexual and Reproductive Health* 294, 299 (2002).

⁹ Citing Alan Guttmacher Institute, *Emergency Contraception: Improving Access*, 3 *Issues in Brief* 1 (2003).

¹⁰ Citing *id.* at 1-3; Weismiller, *supra* note 1, at 711-12; Tina R. Raine et al., *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs*, 293 *J. Am. Med.*

Moreover, studies have found that prescribing EC in advance of need increases the likelihood that women will take it when needed, but does not increase the likelihood that women will engage in unprotected sex. *Id.* ¶ 25.¹¹

For these reasons, it is the standard of care for all providers of medical care at PPMH to provide advance prescriptions to patients of EC. *Id.* ¶ 26; Ashelman-Owen Compl. ¶ 9; Shaw Compl. ¶ 7. Under this standard of care, providers at PPMH offer a prescription for EC to all sexually active female patients, regardless of the reason for their visit, and to include three to five refills. Practitioners write prescriptions for EC with three to five refills so that women have advance access to EC before an emergency need for it arises, and in the event such an emergency occurs when the PPHM offices are closed for business. Heller Compl. ¶ 26; Ashelman-Owen Compl. ¶ 9; Shaw Compl. ¶ 7.

Providing advance access to EC is also the standard of care on a national level. For example, the American College of Obstetricians and Gynecologists (“ACOG”) has launched a campaign to encourage physicians to offer advance prescriptions for EC during routine gynecological visits. Similarly, the American Medical Women’s Association has recommended that doctors provide preprinted prescriptions and instructions for use of EC, and the American Academy of Pediatrics recommends that pediatricians consider offering advance EC prescriptions for teens and young adults. Heller Compl. ¶¶ 27-28.¹² In fact, no reputable professional medical association has disapproved of this practice. *Id.* ¶ 28.

Complaint Against Mr. Matt Weaver and Ms. Andrea Barcomb:¹³

Around November 30, 2005, Complainant Ashelman-Owen, a duly licensed nurse practitioner at Planned Parenthood of Saratoga Springs, wrote a patient a prescription for EC with three refills. The patient attempted to fill the prescription at CVS Store # 0731 at 34 Congress Street, Saratoga, New York, 12866.

Ass’n 54, 59-62 (2005); Jacqueline S. Gardner et al., *Increasing Access to Emergency Contraception Through Community Pharmacies: Lessons from Washington State*, 33 Fam. Planning Perspectives 172, 174-75 (2001).

¹¹ Citing Weismiller, *supra* note 1, at 711; Raine, *supra* note 10, at 59-62; Rebecca A. Jackson et al., *Advance Supply of Emergency Contraception: Effect on Use and Usual Contraception*, 102 *Obstetrics & Gynecology* 8, 12-15 (2003); Tina Raine et al., *Emergency Contraception: Advance Provision in a Young, High-Risk Clinic Population*, 96 *Obstetrics & Gynecology* 1, 6-7 (2000).

¹² Citing Am. Coll. Obstetricians & Gynecologists, *Emergency Contraception*, ACOG Practice Bulletin, Dec. 2005, at 1, 6-7; ACOG News Release, *New ACOG Leader Promotes Widespread Advance Prescriptions for Emergency Contraception* (April 30, 2001), http://www.acog.org/from_home/publications/press_releases/nr04-30-01-1.cfm; Am. Med. Women’s Ass’n, *Position Statement on Emergency Contraception* (adopted Nov. 1996), <http://www.amwa-doc.org/index.cfm?objectid=0EF88909-D567-0B25-531927EE4CC23EFB>; American Academy of Pediatrics, Committee on Adolescence, *Policy Statement, Emergency Contraception*, 116 *Pediatrics* 1038, 1044 (2005); Guttmacher Institute, *Emergency Contraception*, *supra* note 9, at 1-3.

¹³ The facts described in the following section are drawn from the accompanying Complaint of Ms. Claudina Ashelman-Owen, except where otherwise noted.

According to the patient, the pharmacist on duty, Mr. Matt Weaver, took the prescription but informed her that he would fill the prescription without any refills. Mr. Weaver altered the legally valid prescription by logging it with zero refills. He then filled it for one time only and gave the medication to the patient.

Mr. Weaver called the office of PPMH in Saratoga and left a message with the receptionist that he was “not happy about dispensing [EC] with refills,” and that he would fill the prescription but would not log in the refills. When Ms. Ashelman-Owen returned his call, Mr. Weaver explained that it was his “preference” not to include refills for prescriptions of EC.

Ms. Ashelman-Owen then spoke with Mr. Weaver’s supervisor, Ms. Andrea Barcomb, to complain of Mr. Weaver’s actions. Ms. Barcomb expressed the following objection about EC: she stated her opinion that EC is intended only for emergency situations and that women who needed EC were “being irresponsible,” and that if they used more than one type of birth control, they would not need EC. She further stated her opinion that a patient should have to go to her doctor every time she needs EC because obtaining EC “should be inconvenient” for both women and their doctors. Ms. Barcomb defended Mr. Weaver’s actions, stating that he was completely within his right to refuse to honor the prescription as written simply because he thought refills for EC were a “bad idea.” She did not believe that he needed a medical or safety justification for the refusal. Ms. Ashelman-Owen was unable to convince Ms. Barcomb either to change her position or to instruct Mr. Weaver to fill the prescription as written.

Ms. Ashelman-Owen subsequently informed Dr. Heller, the physician with whom she practices, of what had occurred. Dr. Heller and Ms. Ashelman-Owen then contacted Ms. Barcomb to attempt to persuade her to change her position and require her pharmacists to fill EC prescriptions as written. Ms. Barcomb restated her objections to Dr. Heller, and further stated that women who needed EC were “irresponsible and should bear the consequences of their actions.” Heller Compl. ¶ 30. Dr. Heller was equally unsuccessful in persuading her to fill the prescription as written.

Dr. Heller and Ms. Ashelman-Owen then contacted Ms. Jaqueline Payne, the Assistant Director of Government Relations to the Planned Parenthood Federation of America, PPMH’s parent organization, and requested her assistance. On December 5, 2005, Ms. Payne sent a letter via electronic mail to Ms. Eileen Dunn, Mr. Jon Roberts, and Mr. Todd Andrews of CVS corporate management reporting the incident.

Approximately one week later, on December 12, 2006, Mr. Weaver contacted Ms. Ashelman-Owen to inform her that he would log the refills.

Despite Mr. Weaver’s eventual agreement to log the patient’s refills, his initial refusal to fill the prescription as written and Ms. Barcomb’s support thereof harmed PPMH’s patient and interfered with the practice of medicine in PPMH’s facility in the following ways: (a) it prevented Ms. Ashelman-Owen and PPMH from providing the best standard of care in a timely fashion; (b) it prevented PPMH’s patient from receiving the best standard of care in a timely fashion; (c) it interfered with the relationship of trust and confidence between Ms. Ashelman-

Owen and her patient by undermining the patient's trust in her own healthcare provider; (d) it diminished Ms. Ashelman-Owen's and PPMH's reputation in the patient community for being able to provide proper prescriptions; (e) it reduced available time Ms. Ashelman-Owen had for her other patients; and (f) it denied PPMH's patient equal access to the public accommodations provided by the pharmacy. Heller Compl. ¶ 33; Ashelman-Owen Compl. ¶ 18.

These harms were the direct result of the Pharmacists' factually and medically unwarranted assumptions about the patient's sexual practices and history, their moralistic judgments about women's normative sexuality, and their ignorance regarding the standard of care for EC. Heller Compl. ¶ 34; Ashelman-Owen Compl. ¶ 19.

Complaint Against Ms. Lisa McGuinness:¹⁴

On December 5, 2005, Complainant Shaw, a duly licensed physician Assistant at Planned Parenthood of Gloversville, New York, wrote a patient a prescription for one pack of EC with five refills. On February 3, 2006, the patient presented her prescription at the RiteAid pharmacy in Gloversville, New York, located at 169 North Main Street, Gloversville, New York, 12087.

Ms. Lisa McGuinness, the pharmacist on duty, refused to dispense the prescription as written. Ms. McGuinness called Ms. Shaw and informed her that she was questioning the prescription for two reasons: (1) that it was written in December; and (2) that it had refills. Ms. McGuinness told Ms. Shaw that she did not "believe" that EC should be treated as birth control. Ms. McGuinness then indicated that she would not fill the prescription with refills.

When Ms. Shaw questioned Ms. McGuinness, Ms. McGuinness indicated the patient was lucky that she was willing to fill the prescription at all, because some pharmacists are refusing to do so. She did not reiterate her objection based on the date of the prescription. Ms. Shaw believed that Ms. McGuinness was making a judgmental assumption that the EC was improperly and irresponsibly being used as birth control.

Ms. Shaw told Ms. McGuinness that she did not think of EC as birth control, but that having easy access to EC when needed was vitally important to patient care and good medical practice.

Ms. McGuinness and Ms. Shaw then forged a compromise under which Ms. McGuinness would provide one pack of EC to the patient and return the prescription with the refills to the patient so that she could take it to another pharmacy.

Despite Ms. McGuinness's eventual agreement to return the prescription to the patient, her initial refusal to fill the prescription as written harmed our patient and interfered with the practice of medicine in our facility in the following ways: (a) it prevented Ms. Shaw and PPMH from providing the best standard of care in a timely fashion; (b) it prevented PPMH's patient from receiving the best standard of care in a timely fashion; (c) it interfered with the relationship of

¹⁴ The facts described in the following section are drawn from the accompanying Complaint of Ms. Colleen Shaw, except where otherwise noted.

trust and confidence between Ms. Shaw and her patient by undermining the patient's trust in her own healthcare provider; (d) it diminished Ms. Shaw's and PPMH's reputation in the patient community for being able to provide proper prescriptions; (e) it reduced available time Ms. Shaw had for her other patients; and (f) it denied PPMH's patient equal access to the public accommodations provided by the pharmacy. Heller Compl. ¶ 38; Shaw Compl. ¶ 14.

These harms were the direct result of the Pharmacist's factually and medically unwarranted assumptions about the patient's sexual practices and history, her moralistic judgments about women's normative sexuality, and her ignorance regarding the standard of care for EC. Heller Compl. ¶ 39; Shaw Compl. ¶ 15.

ARGUMENT

I. Refusal to Honor EC Refills Is Unsupported by Medical Science, Is Unauthorized by Law, and Exceeds the Pharmacist's Scope of Authority.

Pharmacists have no legal authority to alter prescriptions absent a justification based on the health of the patient. The law governing prescription drugs provides that "upon a prescription written by a person legally authorized to issue such prescription [the specified drug] shall be compounded or dispensed by a licensed pharmacist." N.Y. Educ. Law § 6810 (McKinney 2006). New York regulations governing the practice of pharmacy recognizes a pharmacist's authority to refuse to dispense prescriptions based on a professional judgment that adverse effects, interactions, or therapeutic complications could harm a patient's health. *See* 8 N.Y.C.R.R. §§ 63.6(b)(8)(i)(e), 63.6(b)(8)(ii)(d)(5). In addition, the professional misconduct statute and regulations prohibit a pharmacist from practicing "beyond [the profession's] authorized scope." N.Y. Educ. Law § 6509(2); *see also* 8 N.Y.C.R.R. § 29.1(b)(9) (prohibiting practicing pharmacy "beyond the scope permitted by law").

In reflection of this rule, a guideline recently issued by the Department of the Professions warns that a pharmacists with personal objections to filling certain prescriptions "should refrain from engaging in non-health related judgmental or confrontational activities with the patient." *See Policy Guideline Concerning Matters of Conscience* (Memorandum from Lawrence H. Mokhiber to Supervising Pharmacists) (November 18, 2005) ("Guideline"), <http://www.op.nysed.gov/pharmconscienceguideline.htm>.

The Respondent pharmacists' actions violated New York Education Law and the Guideline for three reasons: (1) they exceeded the scope of the pharmacists' authority to alter prescriptions for health-related reasons; (2) they substituted the judgment of the pharmacist for that of the provider who is familiar with the patient's sexual practices and medical history, therefore exceeding the pharmacists' authorized scope of practice; and (3) they violated the Guideline's prohibition against engaging in non-health related judgmental activities with the patient.

In each of the cases described above, the stated reason given by the pharmacist for the refusals was that women should not use EC "as birth control." This indicates a belief that women who need EC should not be able to access it easily, and further, that there should be

barriers to access. For example, Ms. Barcomb explicitly stated that access to EC “should be inconvenient,” and that women who needed EC were “being irresponsible and should suffer the consequences.” Ashelman-Owen Compl. at ¶ 14; Heller Compl. ¶ 30. These statements are not based on any medically valid concern for the patient’s health.¹⁵ On the contrary, they constitute poor medical practice, are inconsistent with the standard of care, and are contrary to sound public health policy. *See Factual Allegations, supra*, at 3-5; Heller Compl. ¶¶ 24-28.

Prescribing refills for EC is an integral part of the standard of care. Heller Compl. ¶¶ 26-28; Shaw Compl. ¶ 7; Ashelman-Owen Compl. ¶ 9. Because the need for EC is frequently due to unavoidable contraceptive failure, it is by nature unexpected. *See Factual Allegations, supra*, at 3-5; Heller Compl. ¶¶ 21-23. The treatment must be taken quickly to be effective, and it is often quite difficult to obtain and fill a prescription within the necessary window. *See Factual Allegations, supra*; Heller Compl. ¶¶ 18,21-23. Moreover, studies have shown that the availability of EC does not increase incidence of sexual activity in general, or unprotected sex in particular. *See Factual Allegations, supra*, at 5; Heller Compl. ¶¶ 25. In the reasonable professional medical judgment of most providers, providing refills is crucial for pregnancy prevention purposes, and is the standard of care. *See Factual Allegations, supra*, at 5; Heller Compl. ¶¶ 24-28; Ashelman-Owen Compl. ¶ 9; Shaw Compl. ¶ 7.

As discussed above and in the declaration of Dr. Heller, “repeated use [of EC] poses no health risks and should never be cited as a reason for denying women access to treatment.” *See Heller Compl. ¶ 20* (quoting World Health Organization, *Emergency Contraception: A Guide for Service Delivery* 22-23 (1998)). Because providing advance access to EC is the standard of care, there is no medical or health-related justification for depriving women of access to refills on the ground that women should not be using EC as birth control. Alteration of the prescription for these reasons is therefore unauthorized by New York law.

Second, the pharmacists’ statements that EC should be “inconvenient” and should not be used “as birth control,” presume both that the patients were not using birth control at the time the incident occurred and that the patients did not intend to use any other form of birth control in the future. These assumptions are based on unjustified and unsupported judgments about the women’s sexual behavior. In neither of these cases did the pharmacists have any evidence that the patients were *not* using contraception when the sexual intercourse occurred. In fact, contrary to this assumption, one of the most common reasons for needing EC is that the form of contraception used has failed. *See supra* at 4; Heller Compl. ¶¶ 21-22. Nor did the pharmacists here have any basis to assume that the patients did not intend to use another form of birth control in the future. Indeed, no prescriber would advise a patient to use EC as their only birth control method, precisely because it is less effective than many other methods of contraception. The presumption that having advance access to EC will cause women to engage in more acts of unprotected sex is simply scientifically inaccurate. *See Heller Compl. ¶ 25.*¹⁶

¹⁵ The pharmacists’ refusals to recognize refills in these cases were not grounded in religion. In each case, the pharmacist *filled the initial prescription*, demonstrating that the refusal was not motivated by any firmly held religious belief that could not be set aside.

¹⁶ *See also* sources cited *supra* note 11.

Ms. Barcomb's statement to Dr. Heller that women who need EC are "being irresponsible and should suffer the consequences" implies the view that women who need EC deserve to get pregnant. This judgmental attitude about a patient's sexual behavior is not a proper basis for obstructing access to medical care. On this logic, a pharmacist could refuse to fill a prescription for a drug used to treat high cholesterol for an obese patient on the assumption that the person was "greedy," or for drugs used to treat the symptoms of lung cancer on the assumption that the person was a smoker. Such conduct is impermissible.

To permit pharmacists to alter written prescriptions based on such unsupported assumptions would authorize them to impose their own moralistic—not medical—judgments over the sound medical judgments of the patients' treating healthcare provider. Absent specific and legitimate medical justification, pharmacists should not second-guess the considered judgment of the treating provider, who is actually familiar with the patient's current needs and medical history. Assumptions regarding women's sexual behavior fall outside of the scope of the pharmacists' authorized scope of practice, and therefore violate New York's professional misconduct statute and regulations prohibiting practicing beyond the scope authorized by law.

Finally, refusing to fill prescriptions based on the view that access to EC should be "inconvenient" and that women should "suffer the consequences" of their actions violates the Guideline's prohibition on "engag[ing] in non-health related judgmental . . . activities with the patient." As established above, the pharmacists' refusals were not based in legitimate concern for the patients' health. In fact they obstructed the patient from receiving the standard of care. Moreover, the pharmacists' behaviors were motivated by judgmental assumptions about the patients' sexual behavior. Because these actions were both judgmental and non-health-related, they violate the express terms of the Guideline.

Because there is no medical justification for denying women access to refills for EC, the alteration of prescriptions is unauthorized by law. In addition, altering providers' prescription decisions based on assumptions and judgments about women's sexual practices is beyond the scope of the pharmacists' practice, and violates the Guideline's prohibition against engaging in non-health related judgmental activities with the patient.¹⁷ Accordingly, Complainants respectfully request the Board to discipline Mr. Weaver, Ms. Barcomb, and Ms. McGuinness for professional misconduct.

II. Refusal to Honor EC Refills Without Ensuring the Patient's Access to the Medication Constitutes Professional Misconduct in Violation of the Regulatory Prohibition Against Abandoning or Neglecting a Patient.

The Board of Regents specifies that "abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care" constitutes misconduct by professionals, including pharmacists. 8

¹⁷ Pharmacists are further required by law to fill prescriptions with a label that accurately reflects what is written on the prescription. The laws and regulations governing the labeling of drugs prohibits placing an "untrue" label on a container for a drug. *See* N.Y. Educ. Law § 6816. Filling a prescription with a label that does not accurately reflect the number of refills written on the prescription violates this requirement as well.

N.Y.C.R.R. § 29.2(1); *see also* N.Y. Educ. Law § 6509(9). The Guideline specifically clarifies that a pharmacist's refusal to fill prescriptions without providing for a prompt referral violates this regulation. Guideline at 1. The Guideline provides:

Pharmacists have a professional responsibility to ensure that their patients obtain properly ordered and therapeutically appropriate medications in a timely manner with appropriate counseling from a pharmacist. This is true because licensees have a responsibility to practice competently and to protect against abandoning or neglecting a patient in need of immediate care without making adequate arrangements. . . . When a pharmacist recognizes that his/her religious, moral or ethical belief, or any other factor, will result in the refusal to fill a prescription that is otherwise available in a pharmacy, the pharmacist has a professional obligation to take appropriate steps to avoid the possibility of abandoning or neglecting a patient.

Id.

The Guideline recognizes the pharmacy's obligation to devise "accommodations that will respect the pharmacist's choice while assuring delivery of services to patients in need." *Id.* In this way, the Guideline strikes a balance between respecting the religious beliefs of individual pharmacists and preventing detrimental health consequences for others who may not share those beliefs.

The Respondent pharmacists' refusal to recognize the refills on the patients' prescriptions without enabling the patient to get her prescription filled by another means without delay constitutes abandonment and neglect of the patients. Even assuming that the Respondent pharmacists had a legitimate basis for refusing to honor refills for EC—which, as established above, *see* Section I., *supra*, they did not—the appropriate course would have been to refer the prescription to another pharmacist on duty to fill the prescription for the patient on premises. Neither pharmacist did so. In both cases, the patients suffered needless delays and inconvenience in obtaining the fulfillment of valid prescriptions, and were only able to resolve these difficulties through extensive provider advocacy.

The Respondents' refusal to honor the patients' refills without presenting them with another means to get them filled without delay put the patients at risk that they would not be able to access the drug within the necessary time-frame, if and when the need for it should arise in the future. The pharmacists thus put the patients at increased risk of an unwanted pregnancy. Thus, in refusing to permit the patients to access their refills without delay, they failed to "take appropriate steps to avoid the possibility of abandoning and neglecting the patient."

Indeed, the California Board of pharmacy recently disciplined and fined a pharmacist who had refused to fill or transfer a patient's prescription for EC under a similar provision of California law, which prohibited "obstruct[ing] a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient." *In re Becker-Ellison*, Citation No. CI 2005 31291 (Cal. Bd. of Pharmacy, Dep't of Consumer Affairs, June 30, 2006) (citation and fine) (attached as Exhibit A).

Similarly, because the Respondents here failed to ensure that the patients could access their refills without delay, their actions violate New York Education law and the professional Guideline prohibiting abandoning or neglecting a patient. Mr. Weaver, Ms. Barcomb, and Ms. McGuinness should be disciplined accordingly.

III. Refusal to Honor EC Refills Without Ensuring the Patient's Access to the Medication Breaches the Pharmacist's Duty of Care to the Patient.

Like other professionals, pharmacists owe a duty of care to their patients. *Hand v. Krakowski*, 89 A.D.2d 650, 651, 453 N.Y.S.2d 121 (App. Div. 3d Dep't 1982); *Fagan v. Amerisourcebergen Corp.*, 356 F. Supp. 2d 198 (S.D.N.Y. 2004); *see also France v. State*, 132 Misc. 2d 1031, 1032 (N.Y. Ct. Cl. 1986) (holding in the prison context that refusal to fill a prescription constituted negligence). The relationship between the pharmacist and his or her patient has been characterized as a fiduciary relationship, in which "one party repose[s] trust and confidence in another who exercises discretionary functions for the party's benefit or possesses superior expertise on which the party relie[s]." *Anon. v. CVS*, 188 Misc. 2d 616, 620 (N.Y. Sup. Ct. 2001). Thus, in fulfilling the duty owed to the patient, pharmacists are required to exercise "the highest practicable degree of prudence, thoughtfulness and vigilance commensurate with the dangers involved and the consequences which may attend inattention." *Hand* 89 A.D.2d at 651; *see also Fagan*, 356 F. Supp. 2d at 212; *France*, 132 Misc. 2d at 1032.

The duty of care in the profession of pharmacy is set forth in the American Pharmaceutical Association ("APhA") Principles of Practice, which establish the professional obligations of pharmacists to ensure patients' access to treatment:

[T]he pharmacist holds the patient's welfare paramount, maintains an appropriate attitude of caring for the patient's welfare, and uses all his/her professional knowledge and skills on the patient's behalf. In exchange, the patient agrees to supply personal information and preferences, and participate in the therapeutic plan. *The pharmacist develops mechanisms to assure the patient has access to pharmaceutical care at all times.*

APhA Principles of Practice for Pharmaceutical Care, <http://www.aphanet.org/pharmcare/prinprac.html> (emphasis added) (attached as Exhibit B). The principles further specify that "[t]he pharmacist providing Pharmaceutical Care must assume ultimate responsibility for assuring that his/her patient has been able to obtain, and is appropriately using, any drugs and related products or equipment called for in the [patient's] drug therapy plan." *Id.*

A court in Wisconsin recently upheld a ruling by the Wisconsin Board of Pharmacy disciplining a pharmacist for refusing to transfer a woman's prescription for oral contraceptives to another pharmacy, after he had refused to fill the prescription for religious reasons. *Noesen v. Wisconsin Dep't of Regulation and Licensing Pharmacy Examining Bd.*, No. 05-Cv 212, slip op. at 9-12, 16 (Wisc. Cir. Ct. Feb. 3, 2006) (attached as Exhibit C), *appeal docketed*, No. 2006AP001110 (Wis. Ct. App. May 8, 2006). The court concluded that "substantial evidence suggests that the ordinary standard of care requires a physician asserting a conscientious objection to ensure that an alternative mechanism exists whereby the patient can receive her

medication.” *Id.*, slip op. at 16. Under the circumstances, the court held, the refusal to transfer the subscription “represented a substantial departure from [the] standard of care” in the practice of pharmacy. *Id.*

By refusing the Complainants’ patients access to duly authorized refills for EC and failing to ensure that they could get prompt access to the medication through another pharmacist on the premises, Respondents obstructed the patients’ access to EC should the need for it arise in the future, therefore subjecting them to risk of an unwanted pregnancy. The consequences for the patients’ health were serious, given the emotional consequences and physical risks of an unwanted pregnancy. The pharmacists therefore failed to exercise sufficient “prudence, thoughtfulness, and vigilance commensurate with the dangers [and] the consequences” involved. *See Hand*, 89 A.D.2d at 651. Mr. Weaver, Ms. Barcomb, and Ms. McGuiness breached their duty of care, and should be disciplined accordingly.

IV. Refusal to Honor EC Refills Violates New York State Anti-Discrimination Laws.

The pharmacists should also be disciplined for violating New York State public accommodations law. In addition, the Pharmacy Board should amend its guidelines to reflect the prohibition against gender discrimination in New York’s Human Rights Law and the requirement that prescriptions must be filled as written absent a sound medical reason to do otherwise.

The New York Human Rights Law prohibits sex discrimination in any place of public accommodation. *See* N.Y. Exec. Law § 296(2)(a) (McKinney 2006). Public accommodation is defined to include “wholesale and retail stores and establishments dealing with goods or services of any kind,” N.Y. Exec. Law § 292(9), and has been interpreted broadly to include the vast majority of public facilities, including, for example, a dentist’s office. *See Cahill v. Rosa*, 89 N.Y.2d 14 (1996).

Refusal to honor refills of prescriptions for EC violates New York State laws against sex discrimination in public accommodations because only women use EC. In the employment context, numerous courts have recognized that refusal to provide coverage for contraception constitutes unlawful employment discrimination under Title VII of the 1964 Civil Rights Act, 42 U.S.C. § 2000 *et seq.*, which prohibits discrimination in employment based on sex or pregnancy.¹⁸ *See, e.g.*, EEOC Decision (Dec. 14, 2000), <http://www.eeoc.gov/policy/docs/decision-contraception.html>; *Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266 (W.D. Wash. 2001); *EEOC v. United Parcel Serv., Inc.*, 141 F. Supp. 2d 1216 (D. Minn. 2001); *Cooley v. Daimlerchrysler Corp.*, 281 F. Supp. 2d 979 (E.D. Mo. 2003); *In re*

¹⁸ Both New York State law and federal law recognize that discrimination based on pregnancy and related conditions is a form of sex discrimination. *See Elaine W. v. Joint Diseases North General Hosp., Inc.*, 81 N.Y.2d 211 (1993); *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 682 (1983); *Int’l Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW v. Johnson Controls*, 499 U.S. 187, 199-200 (1991).

Union Pacific RR Employment Practices Litig., 378 F. Supp. 2d 1139 (D. Minn. 2005).¹⁹ These courts have held that providing full insurance coverage to men but excluding prescription coverage of drugs used only by women violates Title VII because it results in less comprehensive benefits for women than for men. See Sylvia Law, *Sex Discrimination and Insurance for Contraception*, 73 Wash. L. Rev. 363 (1998). Because they treat female employees in a manner that would be different if not for their sex and their ability to become pregnant, these policies amount to explicit sex discrimination prohibited by Title VII.

Similarly, refusal to honor refills for EC violates New York's law against sex discrimination in public accommodation. Like an employer's refusal to offer insurance coverage for contraception, a pharmacy's failure to fill or refill prescriptions for EC results in less comprehensive benefits being offered to women than those offered to men. Because only women use EC, only women are refused prescriptions or refills based on pharmacists' non-health related judgments regarding their sexual practices. Meanwhile, men have unimpeded access to the full range of prescription drugs—without judgment, and regardless of the drug's indications.

New York Courts interpret the State's Human Rights Law as analogous to Title VII. See, e.g., *Aurecchione v. New York State Div. of Human Rights*, 98 N.Y.2d 21, 25 (2002) (“We have acknowledged the similarities and attempted to resolve federal and state employment discrimination claims consistently . . . [b]ecause both the Human Rights Law and title VII address the same type of discrimination, afford victims similar forms of redress, are textually similar and ultimately employ the same standards of recovery”) (citations omitted). Refusal to provide access to contraceptives, including EC, constitutes sex discrimination under Title VII. Therefore, refusal to provide access to EC, either upon presentation of the initial prescription or upon request for a properly written refill order, constitutes sex discrimination under New York's Human Rights Law. Mr. Weaver, Ms. Barcomb, and Ms. McGuiness should therefore be disciplined for violating New York State law against discrimination in public accommodations.

Moreover, the Guideline should be amended to reflect that New York law prohibits discrimination in public accommodation based on the patient's sex. The Guideline currently recognizes that “it is professional misconduct to be found to have refused to provide professional services based upon a person's race discrimination based on race, creed, color or national origin.” Guideline at 1. The Guideline should be amended to specify that it is also professional misconduct to refuse to provide professional services based on a person's sex, and to clarify that refusal to fill or refill prescriptions for EC constitute prohibited sex discrimination. Furthermore, in light of the difficulty Complainants have encountered in having their prescriptions filled as

¹⁹ Several state attorneys general have also formally decided that the failure to provide insurance coverage for contraception is sex discrimination. See *Opinion No. 16, Office of the Attorney General, State of Montana*, 2006 WL 842284 (Mont. A.G. March 28, 2006) (excluding coverage for contraception and related medical services violates Montana's unisex insurance law and the Montana Human Rights Act); *Opinion 1-04, Office of the Attorney General, State of Wisconsin*, 2004 WL 3078999, at *1 (Wis. A.G. Aug. 16, 2004) (excluding coverage for contraception from an employer or college or university sponsored benefits program violates Wisconsin law prohibiting sex discrimination in employment and in higher education); *Opinion No. 5, Office of the Attorney General, State of Washington*, 2002 WL 31936085, at *7 (Wash. A.G. Aug. 8, 2002) (excluding coverage for prescription contraceptives is an unfair trade practice under Washington law).

written, the Guideline should be clarified to specify that in the absence of a reasonable belief that there is a health-related justification, the proscription against abandoning or neglecting a patient includes a duty to log and dispense refills for all duly written prescriptions.

CONCLUSION

For the reasons stated above, Complainants request the following relief from this Body:

1. That Mr. Weaver, Ms. Barcomb, and Ms. McGuiness be disciplined for professional misconduct in violation of the Guideline, New York State pharmacy laws and regulations, and the New York State Human Rights Law.
2. That the Pharmacy Board issue a clarification of its Guidance specifying that:
 - a. In the absence of a reasonable belief that there is a health-related justification, the proscription against abandoning or neglecting a patient includes a duty to log and dispense refills for all duly written prescriptions.
 - b. Refusal to provide professional services to patients on the basis of *sex* violates New York State law prohibiting discrimination in public accommodations, and therefore constitutes professional misconduct.

Sincerely,

Galen Leigh Sherwin, Staff Attorney
Reproductive Rights Project,
New York Civil Liberties Union

Elisabeth Ryden Benjamin, Director
Reproductive Rights Project,
New York Civil Liberties Union

Attorneys for Complainants Marc Heller, Claudina Ashelman-Owen, and Colleen Shaw

Cc: Lawrence H. Mokhiber, Executive Secretary
New York State Board of Pharmacy